SYMPOSIUM

The Products Liability Restatement: Was It a Success?

INTRODUCTION

On November 13-14, 2008, the Brooklyn Law Review sponsored a symposium to address a not-so-simple question: Was the Restatement (Third) of Torts: Products Liability a success? The two-day event attracted the leading scholars in products liability. An ensemble of panelists, impressive both for their contributions to the field and for the diversity of their opinions, participated in the symposium in six separate panels.

All panelists addressed a current hot-button topic in products liability, covering such highly debated subjects as design defects, liability for defective drugs, defenses to liability, and liability for failure to warn. The first panel addressed the Restatement provisions on design defects. A second panel examined the proper evidentiary standards for use in determining drug defects, debating whether judges have the capacity to properly assess the science involved. Other panelists focused their discussion on federal preemption in products liability litigation, the only panel topic not given black letter in the Restatement. Another panel discussed the extent to which lawyers and judges should push the failure to warn doctrine after the Restatement (Third). The two-day event ended with a look to the future in products liability. Panelists laid the groundwork for the issues that will unfold in the years ahead, each sharing their own perspective on the direction of products liability over the next decade.

Numerous panelists drafted papers in response to this symposium and the 10th Anniversary of the Restatement (Third). The results of the invigorating symposium appear in this issue of the Brooklyn Law Review.
Product Liability’s Parallel Universe

FAULT-BASED LIABILITY THEORIES AND MODERN PRODUCTS LIABILITY LAW

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I. INTRODUCTION

Strict liability has always been the heart and soul of American products liability law. As early as 1963, Justice Roger Traynor in Greenman v. Yuba Power Products, Inc.1 stated that “[a] manufacturer is strictly liable in tort when an article he places on the market, knowing that it will be used without inspection for defects, proves to have a defect that causes injury to a human being.”2 Shortly thereafter, the drafters of section 402A of the Restatement (Second) of Torts made it clear that the exercise of due care would not shield sellers from liability when their products caused injury.3 The new Products Liability Restatement continues to adhere to the concept of strict liability, at least in theory.4 Nevertheless, plaintiffs now commonly supplement or even replace strict liability with claims that rely on fault-based liability theories. These theories are attractive because they allow plaintiffs to avoid the Restatement’s defect requirement and enable them to focus on a product seller’s behavior instead of the condition of its product.

Part II examines some of these theories, including fraudulent misrepresentation, fraudulent concealment, civil conspiracy, negligent entrustment, negligent marketing, and negligence per se. Part III identifies some of the reasons why plaintiffs prefer fault-based liability theories instead of strict liability: these theories enable them to avoid the product defect requirement, to circumvent the preemptive effect of federal law on certain failure to warn claims, and to focus the jury’s attention on the defendant’s culpable misconduct. In addition, these theories allow plaintiffs to side-step risk-utility analysis in design defect cases and relieve them of the need to prove the existence of a reasonable alternative design. Theories such as fraud and negligent marketing may

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1 377 P.2d 897 (Cal. 1963).
2 Id. at 900.
3 See Restatement (Second) of Torts § 402A (2)(a) (1965).
prove useful in obvious hazard situations. Fault-based liability theories are also useful in suits against drug companies because they help plaintiffs to avoid the Restatement’s special rules, which limit conventional design defect and failure to warn claims against manufacturers of prescription drugs and medical devices.\(^5\)

Part IV concludes by predicting that strict liability will continue to lose ground in products liability law, except in manufacturing defect cases, because of the advantages that plaintiffs see in fault-based liability theories. While this trend may be beneficial because it helps to reorient products liability law toward a conduct-based liability regime, it also encourages litigants to expand existing liability doctrines beyond their traditional boundaries. Hence, courts must be wary of embracing extreme versions of these theories.

II. FAULT-BASED LIABILITY THEORIES

Injured consumers who are unlikely to be successful under traditional strict liability now rely on a variety of other liability theories to improve their chances of recovering. These theories include fraudulent misrepresentation and fraudulent concealment, civil conspiracy, negligent entrustment, negligent marketing, and negligence per se. Although some of these theories, such as misrepresentation and civil conspiracy, are subject to onerous requirements, and others, such as negligent entrustment and negligent marketing, have not completely gained judicial acceptance, it nevertheless appears that plaintiffs continue to invoke them in products liability litigation.

A. Fraudulent Misrepresentation and Fraudulent Concealment

Courts commonly classify fraud as either fraudulent misrepresentation or fraudulent concealment. “Fraudulent misrepresentation is defined as the false statement of a material fact made to induce another party to act in reliance thereon and resulting in damage to the party who so relies.”\(^6\) In order to establish a cause of action for fraudulent misrepresentation, the plaintiff must prove: (1) that the defendant made a false representation of a material fact; (2) that the defendant was aware that the statement was false; (3) that the defendant intended to induce the plaintiff to rely on this false statement; and (4) that the plaintiff suffered harm as a result of his or her justifiable reliance on the defendant’s false statement.\(^7\) In addition, the elements of a fraud claim must be pleaded with particularity.\(^8\)

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5 See id. § 6.
7 See, e.g., Dallas Aerospace, Inc. v. CIS Air Corp., 352 F.3d 775, 784 (2d Cir. 2003) (listing requirements); Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 549 (E.D. Pa. 2006) (same), aff’d, 521 F.3d 253, 276 (3d Cir. 2008), vacated, No. 08-437, 2009 WL 578682 (U.S. Mar. 9, 2009);
These requirements are often difficult for plaintiffs to meet. For example, to satisfy the false statement requirement, the plaintiff must prove that the defendant made a false representation of material fact, as opposed to merely expressing an opinion or engaging in “sales talk.” This caused the court to dismiss the plaintiffs’ fraudulent misrepresentation claim in Boumelhem v. Bic Corp. The plaintiffs were two young children who were injured when the older boy used a disposable lighter manufactured by the defendant to start a fire. The plaintiffs argued that various marketing techniques, such as the slogan “Flick My Bic,” the schoolboy logo on the lighter’s packaging, or the pastel colors of the lighters amounted to a representation that these products were safe for children. Affirming the lower court’s ruling in favor of the defendant, a Michigan intermediate appellate court concluded that the defendant had made no assurances that its lighters could not be used by children to start fires.

The estate of a deceased smoker fared somewhat better in Estate of Schwarz v. Philip Morris, Inc. In that case, the decedent’s personal representative alleged that the defendant made a number of false representations about the health effects of smoking, namely that no causal link between smoking and lung cancer had been established, that cigarettes were not addictive, and that “low tar” cigarettes were safer than regular cigarettes. On appeal, an Oregon court observed that a defendant who made a promise knowing that it would not be performed was guilty of fraudulent misrepresentation. The court found that the plaintiff had presented sufficient evidence at trial for the jury to find that the defendant knew during this period that tobacco smoke was carcinogenic, that nicotine was addictive, and that nicotine addiction was


1. Id. at 576.

12. Id. at 579.

13. Id.


15. Id. at 416.

16. Id. at 422.
the principal reason that smokers continued to smoke. Instead of making this research public, as it had pledged to do, the “defendant publicly denied” that there was any link between smoking and cancer and “suppressed the results of its [own] research.” From this evidence, the court concluded that the defendant promised to conduct research on the health effects of smoking and to promptly and fully disclose the results of this research to the public, but, in fact, had no intention of carrying these promises out. Consequently, the court upheld the deceased smoker’s fraud claim.

Reliance is another essential element of any fraudulent misrepresentation claim. This element is often difficult for a plaintiff to prove. However, as Roney v. Gencorp illustrates, proving reliance is not an insurmountable burden. In Roney, the plaintiff died from liver cancer as the result of exposure at his workplace to vapor, steam, and fumes containing vinyl chloride monomer (VCM). Roney’s personal representative brought suit against various manufacturers and suppliers of VCM, alleging that they fraudulently misrepresented and concealed the dangers of exposure to this chemical. According to the plaintiff, the defendants supplied the decedent’s employer with a publication, DS-56, that contained the fraudulent statements. The plaintiff in Roney had specifically alleged that the fraudulent misrepresentations contained in DS-56 were communicated to the decedent by his employer. In fact, the plaintiffs claimed that the decedent’s employer gave him a copy of DS-56 and that the decedent relied upon the information contained in that document. For this reason, the court in Roney refused to dismiss the plaintiff’s fraudulent misrepresentation claim on grounds of lack of reliance.

17 Id. at 418.
18 Id.
19 Id. at 423.
20 Id.
23 431 F. Supp. 2d at 626-27.
24 Id. at 634.
25 Id. at 636.
26 Id.
27 Id.
28 Id. at 637.
Fraudulent concealment involves the concealment of material facts by one who has knowledge of these facts and a duty to disclose when the purpose of this concealment is to mislead or defraud the plaintiff. Most fraudulent concealment cases involve either a duty to disclose or the reliance requirement. When fraudulent concealment merely involves a failure to disclose information, as opposed to active concealment, the plaintiff must prove that the defendant had a duty to disclose the facts in question. For example, in *Estate of White ex rel. White v. R.J. Reynolds Tobacco Co.*, the court declared that fraudulent concealment required the existence of “a separate duty of disclosure to plaintiff by defendant.” According to the court, this duty to disclose would arise when the parties were in a fiduciary or confidential relationship with each other or when one party made a partial or incomplete statement of fact. The court concluded that “the arms-length relationship between [the] defendant cigarette manufacturers” and the decedent smoker was not the sort of “special relationship” that would create a duty on the part of the defendants to divulge information to consumers about the dangers of smoking.

On the other hand, in the *Roney* case, the court refused to dismiss the plaintiff’s fraudulent concealment claim against the defendant chemical supplier. As noted, the plaintiff in that case alleged, inter alia, that the defendant had concealed information about the danger of workplace exposure to its product, VCM. The court held that the manufacturer had a common law duty to warn and its breach of that duty was sufficient to support a claim for fraudulent concealment. A court employed similar reasoning in *Falk v. General Motors Corp.* In *Falk*, the plaintiffs claimed that General Motors placed defective speedometers in some of its trucks and sports utility vehicles and failed to disclose this information to consumers once it became aware of it. The court concluded that the plaintiffs stated a claim for fraudulent concealment by alleging sufficient facts to establish that General Motors had a duty to warn purchasers of its products about the defective speedometers, a

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32 Id. at 430 (internal citations omitted).
33 Id. at 431.
34 Id.
36 Id. at 637.
37 Id.
38 496 F. Supp. 2d 1088 (N.D. Cal. 2007).
39 Id. at 1092-93.
potential safety hazard, and instead withheld this information from them.\textsuperscript{40} The false representation and reliance requirements sometimes prevent plaintiffs from recovering in fraudulent misrepresentation cases.\textsuperscript{41} However, others, particularly injured smokers, have been successful in bringing fraudulent misrepresentation claims against product manufacturers.\textsuperscript{42} Likewise, the reliance requirement and the duty to disclose requirement have thwarted a number of fraudulent concealment claims, but some plaintiffs have overcome and prevailed, at least in the early stages of litigation.

B. Civil Conspiracy

A civil conspiracy exists when two or more persons engage in concerted action to achieve some unlawful objective (or to achieve a lawful objective by unlawful means).\textsuperscript{43} Thus, the plaintiff in a civil conspiracy case must prove: (1) the existence of an agreement to commit an unlawful act or to commit a lawful act by unlawful means; (2) the commission of an overt act or independent tort for the purpose of furthering the objectives of the conspiracy; and (3) damage to another caused by the conspiracy.\textsuperscript{44} These can be formidable requirements for plaintiffs in products liability cases.

For there to be a civil conspiracy, two or more persons must agree to commit a wrongful act.\textsuperscript{45} Thus, a person who is merely aware that others are engaged in a conspiracy\textsuperscript{46} or becomes involved in one inadvertently, accidentally, or even negligently\textsuperscript{47} will not be subject to liability for civil conspiracy. Furthermore, as illustrated by \textit{Cousineau v.}

\textsuperscript{40} Id. at 1099.
\textsuperscript{42} See, e.g., supra notes 14-20 and accompanying text.
\textsuperscript{46} See \textit{RESTATEMENT (SECOND) OF TORTS § 876 (1965)} (requiring that the actor provide assistance or encouragement to the conspirators).
\textsuperscript{47} See \textit{Jones v. City of Chicago}, 856 F.2d 985, 993 (7th Cir. 1988); \textit{In re Methyl Tertiary Butyl Ether}, 175 F. Supp. 2d at 634.
the agreement between the conspirators must involve an objective that is tortious or unlawful.\textsuperscript{49} In \textit{Cousineau}, the plaintiff’s son was killed when a multi-rim truck wheel flew apart as he was removing it to repair the tire on his employer’s truck.\textsuperscript{50} Because the plaintiff was unable to identify the manufacturer of the truck wheel in question, she sued all of the manufacturers of multi-rim truck wheels, alleging that they conspired to make product identification more difficult.\textsuperscript{51} However, a Michigan appeals court held that the plaintiff’s claim failed because she was unable to prove that the alleged industry-wide agreement was unlawful.\textsuperscript{52}

On the other hand, the plaintiffs in \textit{In re Methyl Tertiary Butyl Ether (MTBE) Products Liability Litigation} successfully demonstrated that the agreement in question was unlawful.\textsuperscript{53} In that class action suit, the plaintiffs alleged that the manufacturers of MTBE, a gasoline additive, formed a number of joint task forces and committees for the express purpose of suppressing information about MTBE’s environmental and health hazards.\textsuperscript{54} The plaintiffs also accused the defendant manufacturers of conspiring to deceive government regulators and the public about these hazards.\textsuperscript{55} The court held that these charges, if proven, would support the plaintiffs’ assertion that the defendants had entered into an unlawful agreement.\textsuperscript{56}

The plaintiff must also show that the defendants have actually committed an “overt act” or “independent tort.”\textsuperscript{57} Although this requirement potentially includes a wide range of wrongful conduct, the overt acts alleged against the defendants in products liability cases have usually been either fraudulent misrepresentation\textsuperscript{58} or fraudulent concealment.\textsuperscript{59} In cases where the overt act alleged is fraudulent misrepresentation, plaintiffs have sometimes had difficulty satisfying the

\textsuperscript{49} \textit{Id.} at 730-31.
\textsuperscript{50} \textit{Id.} at 725.
\textsuperscript{51} \textit{Id.} at 731.
\textsuperscript{52} \textit{Id.}
\textsuperscript{53} 175 F. Supp. 2d 593 (S.D.N.Y. 2001).
\textsuperscript{54} \textit{Id.} at 634.
\textsuperscript{55} \textit{Id.}
\textsuperscript{56} \textit{Id.} at 635.
reliance requirement. Plaintiffs have also relied on fraudulent concealment to satisfy the overt act in civil conspiracy cases. Thus, a court allowed the plaintiffs in *Nicolet, Inc. v. Nutt* to show that the defendant participated in a conspiracy to conceal information about the health risks of exposure to asbestos. The court concluded that a defendant who “actively conceal[ed] a material fact” would be guilty of fraudulent concealment regardless of whether there was a duty to speak. Consequently, the court held that the plaintiffs could recover under a theory of civil conspiracy if they could prove that the defendant was involved in a conspiracy whose participants actively concealed information about the risks of asbestos.

Despite its burdensome requirements, civil conspiracy is a useful theory for plaintiffs because it allows them to sue multiple parties and also enables them to show that an entire industry has acted wrongfully. The imposition of large punitive damage awards in such cases suggests that juries have responded with outrage when plaintiffs presented evidence of concerted action by asbestos and tobacco companies to withhold information from consumers about the health risks associated with their products.

C. Negligent Entrustment

The doctrine of negligent entrustment ordinarily imposes liability on the owners of dangerous chattels, such as motor vehicles or firearms, when they knowingly place these objects in the hands of incompetent persons who harm themselves or others. The defendant’s duty of care arises from the fact that he or she has the ability to determine who may use the chattel. Consequently, the negligent entrustment doctrine is not usually applicable to negligent acts that occur...

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61 525 A.2d 146 (Del. 1987).
62 Id. at 150.
63 Id. at 149.
64 Id. at 150.
65 See *Formosa Plastics Corp. USA v. Presidio Eng’rs & Contractors, Inc.*, 960 S.W.2d 41, 47 (Tex. 1998).
66 See, e.g., Garza v. Asbestos Corp., 74 Cal. Rptr. 3d 359 ( Ct. App. 2008) ($10 million punitive damage award); Boeken v. Philip Morris, Inc., 26 Cal. Rptr. 3d 638 ( Ct. App. 2005) ($3 billion award reduced to $50 million on appeal); Owens-Corning Fiberglas Corp. v. Malone, 972 S.W.2d 35 (Tex. 1998) ($3.7 million punitive damage award upheld); see also DAVID G. OWEN, PRODUCTS LIABILITY § 18.2 at 1184 (2d ed. 2008).
after possession or control has passed to the transferee.69 However, some courts have expanded the doctrine of negligent entrustment and applied it to cases where a defendant who has never had legal possession or control over the chattel assisted or enabled an unsuitable person to acquire possession or control over it.70 For example, a number of courts have applied the negligent entrustment doctrine to impose liability on parents who donated or purchased automobiles for the use of their reckless or incompetent children.71

Recently, plaintiffs have tried to expand the concept of negligent entrustment even further by seeking to impose liability on manufacturers who sell or facilitate the sale of dangerous products to minors and other unsuitable persons.72 So far, these efforts have largely failed.73 A leading example of this is Kyte v. Philip Morris, Inc.,74 where the plaintiffs tried to apply the concept of negligent entrustment to a cigarette manufacturer. The plaintiffs in that case were teenagers who suffered various injuries, including nicotine addiction, as the result of smoking cigarettes manufactured by the defendant, Philip Morris.75 They alleged that they purchased cigarettes at various convenience stores in the area despite the fact that state law prohibited the sale of tobacco products to minors.76 According to the plaintiffs, Philip Morris was guilty of negligent entrustment because it introduced cigarettes into the stream of commerce, knowing that retailers routinely sold cigarettes to minors in violation of the law.77 The lower court denied the manufacturer’s motion for summary judgment.78

On appeal, the Supreme Judicial Court acknowledged that Massachusetts recognized the validity of the negligent entrustment doctrine in its traditional form, but the court refused to extend liability to a manufacturer solely because its products might be dangerous when purchased by certain individuals.79 Furthermore, the court ruled that since the defendant did not sell cigarettes directly to minors, it could only be held liable for their injuries if there were some sort of agreement between

75  Id. at 1026.
76  Id.
77  Id.
78  Id. at 1027.
79  Id. at 1029.
it and its retailers to engage in such sales. In the absence of such an agreement, the fact that retailers engaged in a pattern of selling cigarettes to minors was not enough to hold the manufacturer liable under a theory of negligent entrustment.

A New York intermediate appellate court also refused to apply the doctrine of negligent entrustment to a product manufacturer. In Earsing v. Nelson, a teenaged boy who was hit by a BB pellet from a gun sued the manufacturer of the gun and the retail seller, alleging, inter alia, negligent entrustment. The retailer had sold the BB gun to a thirteen-year-old who gave it to a seventeen-year-old friend for safekeeping. The friend accidentally shot the plaintiff, not knowing that the gun was loaded at the time of the accident. The trial court allowed the negligent entrustment claim against the retailer to stand but dismissed the claim against the manufacturer. On appeal, the higher court noted that “[t]he tort of negligent entrustment is based on the degree of knowledge the supplier of a chattel had or should have concerning the entrustee’s propensity to use the chattel in an improper or dangerous fashion.” Unlike the retail seller, the BB gun manufacturer had no direct involvement in the sale and could not have known that the purchaser of the gun in question was only thirteen years old. Accordingly, the court upheld the trial court’s decision.

Obviously, it would be a huge boon to injured consumers if courts were to recognize the expanded version of negligent entrustment proposed by the plaintiffs in Kyte and Earsing. This form of negligent entrustment would be especially effective against manufacturers of inherently dangerous products such as handguns and cigarettes. Although courts have so far refused to extend negligent entrustment beyond its traditional boundaries, plaintiffs will no doubt continue to push for a change in the law.

D. Negligent Marketing

The theory of negligent marketing requires sellers to market their products in a manner that will not increase the products’ inherent risks to consumers or third parties. There are three categories of negligent

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80 Id.
81 Id.
83 Id. at 564.
84 Id.
85 Id.
86 Id.
87 Id. at 565.
88 Id. at 564.
89 Id. at 565.
marketing claims: “(1) product designs that make the product more attractive to criminals; (2) advertising and promotional activities that target inappropriate users; and (3) product distribution practices that [encourage or] facilitate retail sales of dangerous products to vulnerable or unsuitable users.”

Merrill v. Navegar, Inc. provides a good example of a negligent marketing claim based on product design. Navegar, the defendant, manufactured two types of semiautomatic assault weapons, the TEC-9 and the TEC-DC9. A man named Gian Ferri used several of the defendant’s products to kill eight persons and wound six others before killing himself. Although Ferri purchased the weapons from licensed gun dealers in a nearby state, the plaintiffs argued that the manufacturer should be held civilly liable because the weapons were designed to appeal to those who were likely to use them to commit criminal acts. For example, the TEC-9 and TEC-DC9 were designed to accept large-capacity fifty-round magazines and were equipped with “barrel shroud[s],” which allowed the user to spray his fire. In addition, the barrels were threaded to enable the user to attach a silencer or flash suppressor to the weapon. Furthermore, the weapons were fitted with a sling device that allowed them to be fired rapidly from the hip. Finally, the TEC-DC9s were compact and capable of being broken down for easy concealment, and they were compatible with a “Hell Fire” trigger mechanism, which enabled them to be fired at a faster rate than a normal semiautomatic weapon. A TEC-DC9 so equipped could be easily modified to fire like a fully automatic submachine gun. In spite of this, the trial court granted the defendant’s motion for summary judgment on the plaintiffs’ negligence claims, finding that they had failed to establish that Navegar had any duty to protect them against the criminal actions of Mr. Ferri.

On appeal, a California intermediate appellate court focused on duty and causation. In its analysis of the duty issue, the court acknowledged that the manufacturer of a non-defective product is not liable for merely placing it in the market. However, the court declared

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92 89 Cal. Rptr. 2d 146 (Ct. App. 1999), rev’d, 28 P.3d 116 (Cal. 2001).
93 Id. at 152.
94 Id.
95 Id. at 152, 159-60.
96 Id. at 154.
97 Id.
98 Id.
99 Id.
100 Id. at 157.
101 See id. at 152.
102 Id. at 161.
103 Id. at 163.
that the defendant could be liable if it increased the risk of an activity beyond its inherent risks.\textsuperscript{104} The court then considered a number of factors that might give rise to a duty to refrain from affirmatively increasing the risk of marketing firearms. These factors included the foreseeability of harm to the plaintiff, the public interest in preventing future harm, and the burden that imposing a duty would have on the defendant and the community.\textsuperscript{105}

Addressing the foreseeability issue, the court in \textit{Merrill} stated that criminal acts, such as those committed by Ferri, were foreseeable, in part because many of the TEC-DC9’s features were designed to appeal to criminal users.\textsuperscript{106} Turning to the public interest issue, the court observed that gunshot-related crimes imposed substantial social costs on the community and that public policy, as expressed by courts and legislatures, provided strong support for reducing these costs by imposing a duty on handgun manufacturers to market their products more responsibly.\textsuperscript{107} Finally, the court declared that the imposition of a duty to exercise due care in the marketing of its products would not be unduly burdensome for the defendant and that the costs to society of imposing such a duty would be slight since this type of weapon had such low social utility.\textsuperscript{108} Therefore, the court concluded it should impose a duty on Navegar to avoid marketing the TEC-DC9 “in such a way as to increase the inherent risks posed by such a weapon.”\textsuperscript{109} Unfortunately for the plaintiffs, the California Supreme Court reversed the intermediate appellate court, holding that the negligent marketing claim was actually a product category claim prohibited by state law.\textsuperscript{110} In addition, the court concluded that the defendant’s marketing choices did not actually cause the plaintiffs’ injuries.\textsuperscript{111}

Another form of negligent marketing involves sales campaigns that are directed at consumers who are likely to harm themselves or others.\textsuperscript{112} \textit{Pelman ex rel. Pelman v. McDonald’s Corp.}\textsuperscript{113} is illustrative. In \textit{Pelman}, the plaintiffs alleged that McDonald’s was guilty of targeting much of its fast food advertising at young children.\textsuperscript{114} One promotion

\begin{thebibliography}{114}
\bibitem{104} Id. at 163-64.
\bibitem{105} Id. at 163-65.
\bibitem{106} Id. at 166-67.
\bibitem{107} Id. at 169-71.
\bibitem{108} Id. at 171-72.
\bibitem{109} Id. at 172.
\bibitem{111} Id. at 131.
\bibitem{113} 237 F. Supp. 2d 512 (S.D.N.Y. 2003).
\bibitem{114} Id. at 530.
\end{thebibliography}
featured “a plastic beef steak figure named ‘Slugger’” who was accompanied by a pamphlet that assured customers that eating two servings a day from the meat group would help them “climb higher and ride [their] bike[s] farther.” The second promotion featured the “Mighty Kids Meal,” a beefed-up version of the “Happy Meal.” The plaintiffs contended that the phrase “Mightier Kids Meal” suggested to children that they would become “mightier” or more grown up if they consumed large quantities of this product.

McDonald’s moved to dismiss the complaint and the trial court agreed but granted the plaintiffs leave to file an amended complaint. The court refused to consider the “Slugger” claim because it had not been mentioned in the original complaint. However, the court declared that if the plaintiffs cited the “Slugger” example in their amended complaint, they would have to show that the pamphlet was deceptive and that they suffered injury as a consequence of this deceptive language. The court also rejected the argument that the “Mightier Kids Meal” promotion constituted improper targeting, concluding instead that it was merely an example of sales talk or “puffery.” The plaintiffs subsequently filed an amended complaint that dropped the targeting claim and focused on alleged violations of New York’s Consumer Protection Act. The trial court also dismissed this complaint, but portions of it were reinstated on appeal.

Plaintiffs have also brought negligent marketing claims against manufacturers who targeted unsuitable consumers. For example, the court in Merrill also found that Navegar directed its advertising and promotional activities toward a criminal clientele. According to the court, the defendant advertised its firearms in magazines that were aimed at militarists and survivalists, “such as Soldier of Fortune, SWAT, Combat Handguns, Guns, Firepower, and Heavy Metal Weapons.” In addition, Navegar highlighted the paramilitary character of its products in promotional materials that extolled their “military non-glare finish and combat-type sights.” The court also observed that the defendant called

115 Id.
116 Id.
117 Id.
118 Id. at 543.
119 Id. at 530.
120 Id.
121 Id.
123 See Pelman ex rel. Pelman v. McDonald’s Corp. (Pelman III), 396 F.3d 508, 512 (2d Cir. 2005).
125 Id.
126 Id. (internal quotation marks omitted).
attention to the fact that its firearms were equipped with combat slings and threaded barrels and were resistant to fingerprints. \(^{127}\) Finally, the court noted that Navegar displayed its products at the sort of gun shows that attracted violence-prone people and provided TEC-DC9s for use in violence-oriented movies and television shows. \(^{128}\) This was enough for the court to rule that this form of conduct could constitute negligent marketing. \(^{129}\)

A more common form of negligent marketing involves distribution practices that facilitate retail sales of a dangerous product to unsuitable consumers. \(^{130}\) One of the leading cases is *Hamilton v. Accu-Tek*, \(^{131}\) where the plaintiffs alleged that the defendants shipped large numbers of firearms to southeastern states, which had relatively weak gun control regulations, knowing that these products would subsequently be transported to northeastern states, such as New York, where they would be sold illegally in black market transactions. \(^{132}\) The lower court allowed the case to go to trial and the jury found fifteen of the defendants liable. \(^{133}\) These defendants appealed to the Second Circuit Court of Appeals, \(^{134}\) which certified the following questions to the New York Court of Appeals: (1) Does New York impose a duty of care on those who market and distribute firearms? (2) Can damages in negligent marketing cases involving multiple defendants be apportioned according to principles of market share liability? \(^{135}\)

The New York court discussed the duty issue first, declaring that gun manufacturers did not owe a general duty of care to society at large; rather, their liability for negligent marketing had to be based on a specific duty owed to the injured plaintiff. \(^{136}\) According to the court, such a duty might arise from a relationship between the defendant and the plaintiff, as in the case of the duty of care owed by a common carrier to a passenger, or it might arise from a relationship between the defendant and the third party tortfeasor, such as employer and employee,
that enabled the defendant to exercise some control over the acts of the third party. 137

In this case, the court felt that both the connection between handgun manufacturers and criminals and between manufacturers and victims of handgun violence was extremely tenuous. 138 As the court pointed out, the typical chain of distribution for firearms would include the manufacturer, wholesalers and distributors, the first retailer, subsequent legal purchasers, and ultimately the person who injured the plaintiff. 139 Because of this attenuated connection between the manufacturer and either the victim or the criminal, the court determined that it was virtually impossible for the manufacturer to exercise any control over the conduct of others in the chain of distribution. 140 Consequently, the court concluded that it would be inappropriate to impose a duty on handgun manufacturers to protect victims against criminal acts by third parties. 141 Upon receipt of the New York court’s answers to these certified questions, the federal Circuit Court ordered the plaintiffs’ lawsuit to be dismissed. 142

In sum, by focusing on the defendant’s marketing practices, negligent marketing claims provide a way for plaintiffs to avoid troublesome issues with design defects and inherently dangerous products. In particular, negligent marketing can be used against manufacturers who target their products at underage or unsuitable consumers or who create distribution structures that facilitate illegal sales of their products at the retail level.

E. Negligence Per Se

According to the Restatement, “[a]n actor is negligent if, without excuse, the actor violates a statute that is designed to protect against the type of accident the actor’s conduct causes, and if the accident victim is within the class of persons the statute is designed to protect.” 143 In effect, a court relies upon the statute to define the applicable standard of care in a negligence case. 144 Thus, if the plaintiff can prove that the defendant violated the statute, the court will instruct the jury that the defendant has

137 Id.
138 Id. at 1061-62.
139 Id. at 1062.
140 Id.
141 Id. The court also concluded that it was not proper under New York law to apply the principle of market share liability to negligent marketing cases such as this. Id. at 1066-68.
142 Hamilton v. Beretta U.S.A. Corp. (Beretta III), 264 F.3d 21, 32 (2d Cir. 2001).
failed to exercise the requisite standard of care and the defendant will be
held liable if the plaintiff can prove causation and injury.145 Relying on
the concept of negligence per se, plaintiffs have argued that product
manufacturers who violate FDA regulations should be held liable in tort
for any injuries that are proximately caused by such products, regardless
of whether the products are defective or not. In addition, plaintiffs have
urged courts to treat violations of consumer protection acts as
negligence per se.

1. Violation of FDA Regulations

In *Talley v. Danek Medical, Inc.*,146 the plaintiff alleged that the
defendant obtained FDA approval for its product as a Class II medical
device and then promoted it as a pedicle screw fixation device.147 If the
manufacturer had sought formal FDA approval of the device for use in
pedicle screw fixation procedures, it would have had to secure premarket
approval for the product as a Class III device.148 By seeking FDA
approval of its device for use on long bones and then promoting its off-
label use for back surgery, the defendant avoided having to satisfy the
FDA’s requirements for premarket approval as a Class III device.148 By seeking FDA
approval of its device for use on long bones and then promoting its off-
label use for back surgery, the defendant avoided having to satisfy the
FDA’s requirements for premarket approval as a Class III device. The
plaintiff in *Talley* suffered injuries when the defendant’s device was used
in her back surgeries and sued Danek, contending that by deliberately
marketing its product for an unapproved use, the defendant had violated
the FDCA and therefore was negligent as a matter of law.149 The lower
court granted the defendant’s motion for summary judgment and the
plaintiff appealed.150 On appeal, the court declared that the requirement
that medical devices receive FDA approval before being marketed did
not embody a substantive standard of care.151 Furthermore, the court
determined that the plaintiff had failed to show that the defendant’s
failure to obtain proper FDA approval had proximately caused her
injuries.152 Consequently, the court upheld the dismissal of the plaintiff’s
negligence per se claim.153

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145 See *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 790
(3d Cir. 1999).
146 179 F.3d 154 (4th Cir. 1999).
147 Id. at 160.
148 Id.
149 Id.
F.3d 154 (4th Cir. 1999).
151 Talley, 179 F.3d at 161.
152 Id.
153 Id.
2. Violation of State Consumer Protection Law as Negligence Per Se

Many states have enacted unfair trade and consumer protection statutes that are designed to protect consumers against false advertising and other unethical business practices. Although these statutes are concerned with fraud against consumers, they are often less restrictive than common law fraudulent misrepresentation. Not surprisingly, consumers have often attempted to recover for personal injuries against defendants on the basis of their alleged violations of these statutes. In some cases, however, these lawsuits have failed because the statutes in question were only intended to protect against economic losses. For example, in Gorran v. Atkins Nutritionals, Inc., the plaintiff sued a promoter of the Atkins Diet, claiming that the low-carbohydrate diet caused heart problems that required angioplasty. The plaintiff contended that the defendant violated the Florida Deceptive and Unfair Trade Practices Act (FDUTPA), which prohibited “[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce . . . .” According to the plaintiff, the defendant violated FDUTPA by:

(1) promoting the Diet and products as safe for all customers “when they well knew that, for at least a substantial minority of their customers, the [D]iet and their products carried potential serious risks,” (2) failing to give adequate warnings about the adverse health consequences of the Diet, and (3) claiming that the Diet was “fool proof” and a guaranteed success “when they well knew that there would be people for whom the [D]iet would not be safe.”

Notwithstanding these allegations, the court ruled that the plaintiff’s FDUTPA claim must fail because the statute only applied to economic losses.

Plaintiffs who have based their claims on violations of consumer protection statutes have encountered other problems as well. For example, in LaBelle ex rel. LaBelle v. Philip Morris, Inc., a federal district court granted a defendant’s motion for summary judgment on a claim based on an alleged violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law because the plaintiff was unable
to prove that the deceased smoker relied on any of the defendant’s false statements about smoking and health.\footnote{Id. at 525-26.} Similarly, a claim based on an alleged violation of the Virginia Consumer Protection Act failed in McCauley v. Purdue Pharma L.P.\footnote{331 F. Supp. 2d 449 (W.D. Va. 2004).} because the plaintiff was unable to prove causation.\footnote{Id. at 462.} In that case, the plaintiffs alleged that the defendant’s sales representatives falsely claimed that its product, OxyContin, was “safer, less addictive, and less prone to abuse than other oxycodone-based pain medications.”\footnote{Id. at 451.} However, it appeared that the plaintiffs were already addicted to pain medication long before their physicians first prescribed OxyContin.\footnote{Id. at 452-59.} Furthermore, the plaintiffs continued to take other opioid pain medications at the same time that they were using OxyContin.\footnote{Id.} This caused the court to conclude that the plaintiffs had failed to prove that OxyContin caused their injuries because there was “inadequate evidence to differentiate between the plaintiffs’ use of OxyContin and the other medications taken by them.”\footnote{Id. at 462; see also Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 551-52 (E.D. Pa. 2006), aff’d, 521 F.3d 253 (3d Cir. 2008) (holding that false advertising claim against drug company under N.Y. Consumer Protection Act was preempted by federal law), vacated, No. 08-437, 2009 WL 578682 (U.S. Mar. 9, 2009).}

However, other plaintiffs have achieved some success against product sellers based on alleged violations of state consumer protection statutes. For example, in the Pelman case,\footnote{Pelman ex rel. Pelman v. McDonald’s Corp. (Pelman I), 237 F. Supp. 2d 512 (S.D.N.Y. 2003).} discussed earlier,\footnote{See supra notes 113-123 and accompanying text.} the parents of two overweight children sued McDonald’s Corporation and two fast food restaurants, alleging, inter alia, that the defendants had violated sections 349 and 350 of the New York Consumer Protection From Deceptive Acts and Practices Act (“Consumer Protection Act”).\footnote{Pelman I, 237 F. Supp. 2d at 519, 524.} Section 349 of the Consumer Protection Act prohibited “[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state . . . .”\footnote{N.Y. GEN. BUS. LAW § 349 (McKinney 2004).} Section 350 banned “[f]alse advertising in the conduct of any business.”\footnote{Id. § 350.} The plaintiffs did not cite any particular practices or advertisements in their complaint that might have violated the Consumer Protection Act, but they later identified statements in McDonald’s advertising campaigns that they claimed were deceptive.\footnote{Pelman I, 237 F. Supp. 2d at 527.} One campaign contained the slogans “McChicken Everyday” and “Big N’ Tasty Everyday,” which suggested that

\begin{itemize}
\item \footnote{Id. at 525-26.}
\item \footnote{331 F. Supp. 2d 449 (W.D. Va. 2004).}
\item \footnote{Id. at 462.}
\item \footnote{Id. at 451.}
\item \footnote{Id. at 452-59.}
\item \footnote{Id.}
\item \footnote{Id. at 462; see also Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 551-52 (E.D. Pa. 2006), aff’d, 521 F.3d 253 (3d Cir. 2008) (holding that false advertising claim against drug company under N.Y. Consumer Protection Act was preempted by federal law), vacated, No. 08-437, 2009 WL 578682 (U.S. Mar. 9, 2009).}
\item \footnote{Pelman ex rel. Pelman v. McDonald’s Corp. (Pelman I), 237 F. Supp. 2d 512 (S.D.N.Y. 2003).}
\item \footnote{See supra notes 113-123 and accompanying text.}
\item \footnote{Pelman I, 237 F. Supp. 2d at 519, 524.}
\item \footnote{N.Y. GEN. BUS. LAW § 349 (McKinney 2004).}
\item \footnote{Id. § 350.}
\item \footnote{Pelman I, 237 F. Supp. 2d at 527.}
\end{itemize}
customers could safely consume McDonald’s fast food products on an everyday basis.\textsuperscript{176} In another campaign, the statement, "McDonald’s can be part of any balanced diet and lifestyle," appeared on the defendant’s website.\textsuperscript{177} In addition, the plaintiffs argued that the defendant’s failure to post nutritional information in its restaurants or on its product packaging was a deceptive practice within the meaning of the Act.\textsuperscript{178}

The trial court rejected all of these arguments. First, it declared that the exhortation to eat McDonald’s products "everyday" made no specific health claims and was nothing more than "mere puffery."\textsuperscript{179} The court also determined that the statement on the defendant’s website, which suggested that moderate consumption of McDonald’s products could be part of a healthy diet and lifestyle, was not deceptive.\textsuperscript{180} Finally, the court concluded that the Consumer Protection Act did not require McDonald’s to provide nutritional information in its restaurants as long as this information was otherwise available online.\textsuperscript{181}

The plaintiffs subsequently filed an amended complaint that also alleged various violations of the Consumer Protection Act.\textsuperscript{182} Specifically, the amended complaint stated that McDonald’s advertising misled the plaintiffs by assuring them "that its fast food products were nutritious" and could be safely consumed on a daily basis.\textsuperscript{183} The complaint also claimed that McDonald’s failed to disclose the fact that its processing methods and use of artificial ingredients resulted in products that were less healthy than those depicted in its advertising. Finally, the complaint alleged that the defendant falsely stated that it provided nutritional information about its products in all of its restaurants.\textsuperscript{184} The court agreed that the plaintiffs had properly pleaded that they had relied on McDonald’s claims about the nutritional content and healthiness of its food\textsuperscript{185} but dismissed the complaint again because the plaintiffs failed to show that consumption of McDonald’s products was a significant cause of their health problems.\textsuperscript{186}

On appeal, the Second Circuit Court of Appeals determined that proof of actual reliance was not required to bring a deceptive practices...
claim under section 349 of the Consumer Protection Act. However, the appellate court reversed the trial court’s dismissal of the complaint, holding that the plaintiffs did not have to provide any specific information in their complaint alleging that the consumption of McDonald’s products caused their obesity and resulting health problems. According to the court, information on the causation issue could best be obtained at a later stage in the proceedings through the discovery process.

Although negligence per se may not be a viable theory when it is based upon alleged violations of FDA regulations, plaintiffs have successfully invoked it in connection with violations of state consumer protection laws. Negligence per se is often more advantageous for plaintiffs than fraudulent misrepresentation or fraudulent concealment because consumer protection statutes tend to be broader in scope than common law fraud doctrines.

III. ADVANTAGES OF FAULT-BASED LIABILITY THEORIES

At first blush, there would seem to be many disadvantages to using fault-based liability theories instead of traditional strict liability in tort. Thus, in theory, it would seem to be much easier to prove that a product is defective than to prove that the manufacturer or seller failed to exercise due care. As a matter of fact, one of the early arguments for strict liability was that it would be more consumer friendly than negligence. To be sure, this was probably true in manufacturing defect cases, where strict liability relieves the plaintiff of the duty of proving by expert testimony that the producer’s manufacturing and quality control processes were negligent. However, many plaintiffs now believe that the advantages of fault-based liability theories, at least in certain cases, outweigh their disadvantages. These advantages include avoiding the Restatement’s requirement that a product be defective, avoiding federal preemption of certain types of common law tort claims, and enabling plaintiffs to focus attention on the conduct of the defendant instead of the condition of the product.

187 See Pelman ex rel. Pelman v. McDonald’s Corp. (Pelman III), 396 F.3d 508, 511 (2d Cir. 2005).
188 Id. at 511-12.
189 Id. at 512.
A. Avoiding the Defect Requirement

Defectiveness is a core concept in American products liability law. However, the defectiveness requirement may cause difficulties for some plaintiffs. First of all, it is virtually impossible to prove that inherently dangerous products are defective under traditional tests for defectiveness. In addition, juries have trouble understanding the risk-utility test in design defect cases. Furthermore, the Products Liability Restatement’s alternative reasonable design requirement may create difficulties for plaintiffs in design defect cases. The existence of obvious hazards is a common pitfall for plaintiffs in failure to warn cases. Finally, in most states, the standard for defectiveness is narrower for prescription drugs and medical devices than for other products.

1. Inherently Dangerous Products

Inherently dangerous products are products whose danger cannot be eliminated without impairing their intended function. Neither section 402A nor the Products Liability Restatement treat inherently dangerous products as defective, at least when their risks are commonly known, and most courts have followed their lead. Consequently, consumers who cannot satisfy the defect requirement must rely on other liability theories. Some of these theories have been relatively successful, particularly when invoked against manufacturers of cigarettes and handguns. Fraud and civil conspiracy theories have been especially effective against tobacco companies. For example, in Estate of Schwarz v. Philip Morris, Inc., an appellate court upheld a jury verdict in favor of the personal representative of a deceased smoker who alleged that the defendant cigarette manufacturer had made false statements about the health risks of smoking. Plaintiffs have also used negligent marketing in order to avoid having to prove defectiveness. In Hamilton v. Accu-

191 See OWEN, supra note 66, § 6.1 at 342.
193 See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. c (1998); RESTATEMENT (SECOND) OF TORTS § 402A cmt. i (1965).
Tek\textsuperscript{196} and Pelman ex rel. Pelman v. McDonald’s Corp.,\textsuperscript{197} for example, plaintiffs focused on the marketing practices of handgun and fast food sellers instead of basing their claims solely on the alleged defectiveness of their respective products.

2. The Risk-Utility Test and the Reasonable Alternative Design Requirement

The prevailing test for design defect is known as the risk-utility test.\textsuperscript{198} Under this approach, a plaintiff must show that the utility of the product with a feasible safer alternative design (that is, with an additional safety feature) outweighs the utility of the product as actually designed.\textsuperscript{199} The Restatement (Third) has adopted this version of the risk-utility test, declaring that a design is deemed to be defective if the foreseeable risks of the product, as designed, “could have been reduced or avoided by . . . a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonably safe.”\textsuperscript{200} Unfortunately, the risk-utility test is frequently confusing and difficult to apply.\textsuperscript{201} To make matters worse, jurors are often hostile to the concept of balancing risks and benefits.\textsuperscript{202} Consequently, plaintiffs sometimes prefer to utilize a fault-based theory that jurors can more easily understand and accept.

The reasonable alternative design requirement also presents difficulties for plaintiffs in design defect cases. According to the Products Liability Restatement formulation, a design is considered defective if the foreseeable risks of the product, as designed, “could have been reduced or avoided by . . . a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonably safe.”\textsuperscript{203} The Restatement’s requirement of a “reasonable alternative design” is highly controversial and is not recognized in every state.\textsuperscript{204}


\textsuperscript{197} 237 F. Supp. 2d 512 (S.D.N.Y. 2003) (discussing the complaint allegations). For a discussion of Pelman, see supra notes 113-123, notes 170-188, and accompanying text.

\textsuperscript{198} See OWEN, supra note 191, § 8.4 at 508.


\textsuperscript{200} See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 (b) (1998).


\textsuperscript{203} See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 (b) (1998).

However, when a court does require proof of an alternative design, this can seriously compromise a plaintiff’s case.205 For this reason, plaintiffs may find it advantageous to look for other liability theories in design defect cases in order to avoid the alternative design requirement.

The Merrill case206 discussed earlier,207 provides a good example of this strategy. In Merrill, the plaintiffs objected to various aspects of an assault weapon’s design.208 If the plaintiffs had sued under a theory of defective design, they would have had to suggest alternatives to each of the offending design features. The resulting weapon would have borne no resemblance to the product that the defendant actually produced, and it is unlikely that a court would have regarded the plaintiffs’ version of the defendant’s product as a reasonable alternative design. The plaintiffs apparently tried to sidestep this problem by formulating their claim as a negligent marketing claim instead of a design defect claim.209 Interestingly, on appeal, the California Supreme Court saw through the plaintiffs’ ruse and declared that their negligent marketing case was really a design defect case in disguise.210

3. Obvious Hazards and the Duty to Warn

Many courts have concluded that product sellers have no duty to warn consumers about “open and obvious” hazards.211 To avoid the effect of this rule, plaintiffs have eschewed traditional failure to warn claims and relied instead on fraudulent misrepresentation or negligent marketing theories. In a fraudulent misrepresentation case, the issue is whether the defendant lulled consumers into a false sense of security by falsely assuring them that a known risk was not as great as they might otherwise expect. This was the issue in most of the fraudulent misrepresentation cases brought against the tobacco industry. In these cases, the focus was not on whether the health risks of smoking were open and obvious, but


206 89 Cal. Rptr. 2d 146 (Ct. App. 1999), rev’d, 28 P.3d 116 (Cal. 2001).

207 See supra notes 92-111 and accompanying text.

208 Id. at 154-57.

209 Id. at 162.


whether the plaintiff reasonably relied on the tobacco companies’ assurances that smoking did not cause lung cancer or other diseases. 212 Having vigorously denied that smoking was harmful for almost half a century, it was difficult for cigarette companies to argue that the hazards of smoking were matters of common knowledge or that smokers would not believe the industry’s health claims. 213

Another response to the obvious hazard problem is to rely on negligent marketing instead of failure to warn. Negligent marketing might be especially effective when the defendant has targeted children or some other vulnerable group whose knowledge or judgment may not be as good as that of the general population. 214 The tobacco industry’s use of cartoon characters like “Joe Camel” and other promotional efforts to encourage underage consumers to smoke is a good example of this type of negligent marketing. 215 There is also evidence that fast food purveyors have targeted children and teenagers, knowing that they are “notoriously capricious in their reasoning skills” and “much more likely to be motivated by mere emotion or peer pressure than are adults.” 216 In fact, this very issue arose in the Pelman case. 217 The court in Pelman rejected the plaintiffs’ failure to warn claim, concluding that the health risks of consuming too much fast food were open and obvious to the general population. 218 However, the plaintiffs in Pelman also alleged that McDonald’s advertising was targeted at small children. 219 The court also dismissed this claim, but only because the plaintiffs failed to provide any examples of this type of targeting in their complaint. 220 Furthermore, the court suggested that a targeting claim might be successful if the plaintiffs referred to specific statements by the defendant and alleged that the plaintiffs relied upon them. 221

213 Id. at 492. But see Horton v. American Tobacco Co., 667 So. 2d 1289, 1293 (Miss. 1995).
214 See Ausness, supra note 91, at 913.
216 See John Alan Cohan, Obesity, Public Policy, and Tort Claims Against Fast-Food Companies, 12 WIDENER L.J. 103, 112 (2003).
217 See supra notes 113-123, 170-189.
219 Id. at 530.
220 Id.
221 Id.
4. Special Rules for Pharmaceutical Products

Pharmaceutical products, such as prescription drugs and medical devices, received special treatment in section 402A.222 For example, the drafters of section 402A created an exception to strict liability in comment k for “[u]navoidably unsafe” but useful products.223 Specifically, comment k provided that the manufacturer of “a product that is incapable of being made safe for its intended use” would not be subject to strict liability as long as the utility of the product “outweigh[ed] its apparent risks and an adequate warning [was] given.”224 According to comment k, an unavoidably unsafe product was neither defective nor unreasonably dangerous even though it caused harm to consumers.225 Almost all courts agreed that comment k exempted prescription drugs and medical devices from strict liability, provided that they were properly prepared or manufactured and accompanied by adequate warnings.226

The Products Liability Restatement also creates a separate, and more restrictive, liability standard for pharmaceutical products.227 According to the Restatement, a prescription drug or medical device may be “not reasonably safe due to defective design if the foreseeable risks of harm . . . are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers . . . would not prescribe the drug or medical device for any class of patients.”228 This standard protects drug manufacturers against design defect liability, no matter how dangerous their products may be, as long as they have therapeutic value for at least one class of users.229

To avoid this limitation on manufacturer liability for prescription drugs and medical devices, plaintiffs have begun to abandon strict products liability in favor of fraudulent misrepresentation.230 While many

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222 See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).
223 Id.
228 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(e) (1998) (emphasis added).
of these claims have failed because the injured plaintiff could not prove causation or reliance, the others have been more successful. For example, in Freeman v. Hoffman-LaRoche, Inc., the Nebraska Supreme Court upheld a fraudulent misrepresentation claim against the manufacturer of Accutane, an acne medication. The plaintiff in Freeman alleged that the defendant manufacturer falsely represented that Accutane was safe to use as directed when in fact it knew of the drug’s danger and “misled the medical community with incomplete and inaccurate information about the safety of the drug.” The plaintiff also alleged that she had relied on the defendant’s assurances of safety. The court concluded that the plaintiff had stated a claim for fraudulent misrepresentation and reversed the lower court’s dismissal of her suit.

B. Avoiding Federal Preemption of Tort Claims

The preemption doctrine, which is rooted in the Supremacy Clause of the United States Constitution, gives Congress the power to override state law. Courts and commentators traditionally divide preemption into two basic categories, express and implied, and further divide implied preemption into field and conflict preemption. Express preemption occurs when a federal statute or administrative regulation specifically excludes state regulation in a particular area. Congress may also enact a regulatory scheme that is so comprehensive that it completely “occupies the field” and excludes any form of state screw fixation device); Khan v. Shiley, Inc., 266 Cal. Rptr. 106, 112 (Ct. App. 1990) (heart valve); Adams v. G.D. Searle & Co., Inc., 576 So. 2d 728, 730 (Fla. Dist. Ct. App. 1991) (Cu-7 IUD); Freeman v. Hoffman-LaRoche, Inc., 618 N.W.2d 827, 844-45 (Neb. 2000) (Accutane). Plaintiffs have tried to base their claims against drug companies on negligent marketing practices. See, e.g., Yurcic v. Purdue Pharma L.P., 343 F. Supp. 2d 386, 388 (M.D. Pa. 2004); Little v. Purdue Pharma, L.P., 227 F. Supp. 2d 838, 843 (S.D. Ohio 2002); Howland v. Purdue Pharma L.P., 821 N.E.2d 141, 143-44 (Ohio 2004).


regulation.\textsuperscript{241} Conflict preemption occurs when it is impossible to comply with both state and federal law\textsuperscript{242} or where state law stands as an obstacle to the achievement of federal regulatory objectives.\textsuperscript{243}

Federal statutes and administrative regulations not only preempt state statutes and local ordinances, they can also preempt state common law tort doctrines.\textsuperscript{244} In recent years, federal preemption has prevented injured smokers from recovering against cigarette companies who failed to warn them about the health risks of smoking. The leading case on this issue is \textit{Cipollone v. Liggett Group, Inc.}\textsuperscript{245} In \textit{Cipollone}, the United States Supreme Court, in a plurality opinion, concluded that the 1969 Federal Cigarette Labeling and Advertising Act expressly preempted the plaintiff’s failure-to-warn claims\textsuperscript{246} but did not necessarily preempt claims based on breach of express warranty, fraudulent misrepresentation, or conspiracy.\textsuperscript{247} This, in turn, encouraged plaintiffs to transform their failure to warn claims into fraudulent misrepresentation or conspiracy claims. Although a few courts have concluded that the federal cigarette labeling statute preempted fraudulent misrepresentation claims,\textsuperscript{248} most determined that such claims were not preempted.\textsuperscript{249}

\textit{Good v. Altria Group, Inc.}\textsuperscript{250} is a good example of the majority’s reasoning. In that case, a group of smokers sued various cigarette manufacturers, arguing that the manufacturers’ claims that their products were “light” and had “[l]owered [t]ar and [n]icotine” amounted to

fraudulent misrepresentations. The plaintiffs conceded that the defendants’ light brands produced lower levels of tar and nicotine in an FTC-approved test, but alleged that persons who smoked these types of cigarettes “compensated” by taking longer puffs or smoking more cigarettes than they would if they smoked “full flavor” brands. Consequently, the defendants’ implicit claims about the relative safety of their products were deceptive. The lower court ruled that the plaintiffs’ fraudulent misrepresentation claims were preempted by the Federal Cigarette Labeling and Advertising Act. However, on appeal, the First Circuit Court of Appeals concluded that the Supreme Court in *Cipollone* had distinguished between failure to warn, concealment, and dilution claims, which were expressly preempted, and affirmative misrepresentations of fact, which were not preempted even if they were concerned with the health effects of smoking. Consequently, the court reversed the lower court and allowed the plaintiffs to proceed with their fraudulent misrepresentation claims.

However, preemption has also caused problems for those who have been injured by prescription drugs. In such cases, plaintiffs have tended to rely on both failure to warn and fraudulent misrepresentation claims. In the past, a number of courts held that failure to warn claims based on FDA-approved labeling were impliedly preempted on actual conflict grounds. However, the United States Supreme Court’s recent decision in *Wyeth v. Levine* has greatly reduced the chances that failure to warn claims against drug companies will be preempted in the future. In that case, the plaintiff’s claim was based on an alleged failure to strengthen an FDA-approved warning in accordance with state law. In contrast to the courts above, the Supreme Court refused to find that the state regulation was impliedly preempted and allowed the plaintiff’s claim. On the other hand, the status of fraudulent misrepresentation in this area is somewhat unclear. So far, several courts have already held

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251 Id. at 30 (internal quotations omitted).
252 Id. at 30-31.
253 Id. at 31.
255 Good, 501 F.3d at 39-44.
256 Id. at 58-59. The Supreme Court has granted certiorari and will rule on the preemption issue in 2009. See Altria Group, Inc. v. Good, 128 S. Ct. 1119 (2008).
259 Id. at 1204.
that fraudulent misrepresentation claims based on FDA-approved labeling are impliedly preempted,\textsuperscript{260} although in an unreported New York trial court decision, one court has concluded that they are not.\textsuperscript{261} In this latter case, \textit{Smith v. Johnson & Johnson Co.}, the court refused to grant a summary judgment motion by the defendant, the manufacturer of Propulsid, a drug used in the treatment of diabetes.\textsuperscript{262} The plaintiff set forth a number of allegations against the defendant, including fraudulent misrepresentation and concealment, in connection with the risks of Propulsid use.\textsuperscript{263} The court declared that it agreed with the federal district court’s decision in \textit{Jones ex rel. Jones v. Lederle Laboratories},\textsuperscript{264} which held that Congress did not intend for federal prescription drug regulations to preempt state tort law claims.\textsuperscript{265}

\textbf{C. Playing the “Blame Game”}

Another advantage of fault-based theories is that they enable plaintiffs’ lawyers to use the “hot” rhetoric of fault instead of the “cold” rhetoric of strict liability.\textsuperscript{266} In addition, these theories reinforce claims for punitive damages.

Despite the fact that strict products liability was developed to make it easier for consumers to recover for their injuries, many lawyers prefer to rely on negligence instead of strict liability.\textsuperscript{267} As Paul Rheingold pointed out more than thirty years ago, “negligence is ‘hot’ and strict liability is ‘cold.’”\textsuperscript{268} In other words, it was easier for a plaintiff to persuade jurors that the defendant did something wrong than it was to convince them that the product in question was defective in some way.\textsuperscript{269} Other commentators have agreed with this observation.\textsuperscript{270} This may explain why fault-based liability theories, like negligent entrustment, negligent marketing, and negligence per se, are popular with plaintiffs’ lawyers. If jurors respond positively to fault-based claims against product sellers, one would expect them to be even more receptive to liability

\textsuperscript{260} See Horne v. Novartis Pharmaceuticals Corp., 541 F. Supp. 2d 768, 775, 782-83 (W.D.N.C. 2008); \textit{Colacicco} 432 F. Supp. 2d at 525, 549.
\textsuperscript{262} Id. at *1.
\textsuperscript{263} Id. at *2.
\textsuperscript{264} 695 F. Supp. 700, 710-12 (E.D.N.Y. 1988), aff’d, 182 F.2d 63 (2d Cir. 1992).
\textsuperscript{265} \textit{Johnson & Johnson}, 2004 WL 2964419, at *7.
\textsuperscript{266} See infra text accompanying note 268.
\textsuperscript{269} Id.
theories, like fraudulent misrepresentation or fraudulent concealment, which involve serious wrongdoing. What jury could resist doing its part to ensure that good triumphs over evil? The moral high ground for plaintiffs is even greater when the several defendants conspire together to behave badly. Hence, the popularity of civil conspiracy claims.

Sadly, examples of blameworthy behavior on the part of product manufacturers are not hard to find. For example, the manufacturer of the Dalkon Shield IUD marketed its product without conducting adequate testing and ignored reports of septic abortions and other injuries that were caused by its intrauterine device.271 Asbestos litigation revealed that asbestos manufacturers not only failed to disclose health risks associated with exposure to asbestos insulation products, but conspired to prevent information about these risks obtained by third parties from reaching workers, consumers, or the general public.272 Even more shocking was the forty-year campaign by the tobacco industry to conceal the health risks of smoking from the medical community and the public. Beginning in 1953, tobacco companies, either individually or through industry trade associations, allegedly issued misleading press releases, disseminated false information in articles, destroyed or concealed evidence about the health risks of smoking, denied that nicotine was addictive, and targeted their advertising at underage consumers.273 It is also claimed that tobacco companies manipulated nicotine levels in cigarettes to keep smokers addicted to their products.274

More recently, manufacturers of lead paint and their trade associations have been accused of conspiring to suppress information about the health risks of exposure to lead-based paint.275 The marketing practices of handgun manufacturers,276 pharmaceutical companies,277 and

fast food purveyors\textsuperscript{278} have come under fire as well. Therefore, it is not surprising that plaintiffs have been quick to discover the benefits of bringing fault-based claims against product manufacturers in lieu of those based on conventional strict liability theory in instances, such as those discussed above, where product sellers appear to have engaged in flagrant misconduct.

In addition, focusing on the defendant’s misconduct also directs attention away from the role that the plaintiff or others may have played in causing the plaintiff’s injury. This is illustrated by the history of tobacco litigation. In the early decades of this litigation, tobacco companies were able to persuade juries that smokers freely chose to smoke and were, therefore, responsible for their injuries.\textsuperscript{279} However, juries later began to sympathize more with smokers after they presented evidence of fraud and other misconduct by the tobacco industry.\textsuperscript{280} A similar result may eventually occur in fast food cases if plaintiffs continue to emphasize the questionable marketing practices of fast food companies.

Furthermore, basing claims for compensatory damages on fault-based liability theories may increase a plaintiff’s chances of obtaining a generous punitive damage award. Punitive or exemplary damages constitute an award to an injured party in addition to that which is necessary to compensate for his or her actual loss.\textsuperscript{281} The principal objectives of punitive damages are “(1) to punish the defendant for outrageous misconduct and (2) to deter the defendant and others from similarly misbehaving in the future.”\textsuperscript{282} However, in traditional products liability litigation, liability for compensatory damages is determined on a strict liability basis, while punitive damages are awarded on the basis of fault. Consequently, when the compensatory damage claim is fault-
based, the plaintiff may be able to support both damage claims with the same fault-based narrative.

IV. CONCLUSION

This Article has examined some of the liability theories that plaintiffs have used to supplement or to substitute for more conventional strict liability claims in products liability cases. They include fraudulent misrepresentation and fraudulent concealment, civil conspiracy, negligent entrustment, negligent marketing, and negligence per se. Plaintiffs find these fault-based theories appealing because they allow them to avoid some of the doctrinal limitations and proof problems associated with strict liability. These theories are more likely to resonate with juries than the efficiency-based approach that defines strict products liability. Consequently, plaintiffs will almost certainly continue to use these fault-based theories in the future.

However, this increased reliance on alternative liability theories raises a number of concerns. The first is whether it is appropriate for juries to take account of the defendant’s conduct when deciding product liability cases. The injection of fault-based liability theories would seem to threaten the doctrinal integrity of products liability law, which has traditionally been based on strict liability. Arguably, a liability regime that rests on two antithetical principles—fault and no fault—will not be able to retain its doctrinal integrity for long. In response, it must be acknowledged that conduct already plays an important role in products liability. For example, affirmative defenses such as assumption of risk, and, more recently, comparative fault, can reduce damage awards to victims in strict liability cases, or even prevent them from recovering any damages at all. In addition, jurors often focus on the defendant’s conduct now that punitive damages have become an integral part of products liability law. Moreover, the Products Liability Restatement itself has incorporated negligence principles into its definition of design defects and inadequate warnings. With a number of fault-based principles already fully incorporated into modern products liability law, it is probably too late to worry about doctrinal coherence.

Another concern is whether incorporating fault-based liability doctrines into products liability law might result in excessive liability for product sellers. Some of these theories, such as fraudulent misrepresentation, fraudulent concealment, civil conspiracy, and negligence per se, are established doctrines with clear requirements that plaintiffs must satisfy in order to recover. As such, they are limited in scope and therefore do not present much risk of excessive liability in their present form. On the other hand, newer, undeveloped doctrines, like negligent marketing, pose a greater risk to product sellers if they are

expanded to impose new obligations or restrictions on marketing practices. There is also a risk that plaintiffs will use fault-based theories in order to demonize unpopular defendants like tobacco companies or handgun manufacturers and thus increase the chances of large damage awards awarded by outraged juries. Another link between fault-based liability theories and the risk of excessive liability is that these theories may unfairly prejudice defendants when plaintiffs seek punitive damages.

To conclude, it appears that fault-based liability theories are here to stay and may ultimately be good for products liability law. However, courts should be cautious about embracing novel or expansive versions of these theories, especially when they are accompanied by claims for punitive damages.
Implied Reverse Preemption

Anita Bernstein†

With an elaborate Consumer Product Safety Improvement Act, prepared and signed during the doldrums of midsummer 2008, Congress signaled its revived attention to the safety of consumer goods sold in the United States. The new statute, which almost won unanimity in both chambers, announced a new scope and ambition: by increasing the powers of the Consumer Product Safety Commission (“Commission” or “CPSC”) rather than removing any of them, Congress took a turn in a direction not seen in decades. The 2008 law ordered the Commission to write new standards for all-terrain vehicles. It declared a provisional ban on six chemicals that it suspected of disrupting human reproductive systems. It prohibited lead in products for children under twelve—this ban an outright rather than a provisional rule. It required testing of all new children’s products offered for sale. It wrote new protections for consumer-minded whistleblowers. It augmented the existing penalties

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2 The 2006 election had given the Democratic Party control of both houses for the first time in twelve years, making passage of this legislation possible. See Eric Lotke, Downsizing Government to Death: Thanks to “E. Coli Conservatism,” Weakened Government Watchdogs Have Put Us All at Risk, L.A. TIMES, Jul. 20, 2008, at M7.
4 See Aliya Sternstein, Product Safety Law Overhaul on Track to Clear Senate After Passing House, CONG. Q. TODAY, Jul. 30, 2008 (declaring that the new statute was “the most significant overhaul” of consumer safety laws in forty years (quoting Rep. John Dingell)); Editorial, The President and Product Safety, N.Y. TIMES, Aug. 5, 2008, at A18 (praising the new statute).
6 Id. § 108, 122 Stat. at 3036-37.
9 Id. § 219.
for violating consumer law.\textsuperscript{10} It invited state attorneys general into the federal courts to enforce some of its provisions.\textsuperscript{11}

Federal intervention in consumer safety as a plenary category began in the 1960s, when Congress established a National Commission on Product Safety to explore what the United States government could do to reduce product-caused injuries.\textsuperscript{12} Congress passed the Consumer Product Safety Act ("CPSA") in 1972.\textsuperscript{13} In its original form the CPSA defined consumer products broadly,\textsuperscript{14} exempting only a handful of manufactured items from its provisions.\textsuperscript{15} Congress bestowed on the newly created Consumer Product Safety Commission a wide array of "enforcement tools," including powers to set standards, seize and condemn goods, prohibit the sale of products, and order recalls.\textsuperscript{16}

Soon after its inception, burdened by onerous procedures that Congress had mandated, however, the Commission began to perform at a disappointing level.\textsuperscript{17} Its bureaucratic weakness got a boost from conservative ideology in 1981, when Congress started to roll back the federal presence in consumer regulation.\textsuperscript{18} A "deregulation-minded chairman," Terry Scanlon, arrived in the mid-1980s to lead the Commission into quiescence.\textsuperscript{19} Reagan-era retrenchments from consumer

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\textsuperscript{10} Id. § 217.
\textsuperscript{11} Id. § 218.
\textsuperscript{14} 15 U.S.C. § 2052(a)(1) (2006) (referring to "any article, or component part thereof, produced or distributed for sale to a consumer").
\textsuperscript{15} Scalia & Goodman, supra note 13, at 902 (noting tobacco, firearms, and products covered by other federal legislation, such as boats, cosmetics, food, and aircraft).
\textsuperscript{16} Schwartz, supra note 12, at 42-43. The Consumer Product Safety Commission ("CPSC" or "Commission") was established by statute in 1972. 15 U.S.C. § 2053. In this Article I occasionally refer to the Commission as an "agency," a term some prefer to reserve for a single-administrator entity more closely associated with a presidential administration; Congress, led by Democrats, originally wrote the Consumer Product Safety Act ("CPSA") to make the Commission "independent" from the Nixon presidency. Robert S. Adler, From "Model Agency" to Basket Case—Can the Consumer Product Safety Commission Be Redeemed?, 41 ADMIN. L. REV. 61, 82 n.123, 83 n.125 (1989). It functions as a "collegial body" of commissioners. See id. at 82. Commissioners are appointed by the President with the advice and consent of the Senate, cannot all be members of the same political party, and serve staggered terms of seven years, subject to removal by the President "for neglect of duty or malfeasance in office." 15 U.S.C. § 2053.
\textsuperscript{17} See Schwartz, supra note 12, at 34-35.
\textsuperscript{18} See infra Part III.B.
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Following CPSC practice, I refer to the head of the CPSC as its chairman, even though women heads of the agency occupy more space in this Article than do CPSC chairmen S. John Byington, Terry Scanlon, Richard Simpson, and Hal Stratton.
safety regulation stayed in place through subsequent presidential administrations until the 2008 mandate and appropriations.20


In this Article, I contend that congressional oscillation on consumer safety can inform the most incendiary topic in current American products liability: the law of preemption. Within products liability discourse, the term preemption (which has a large set of other meanings outside the scope of the Article) refers specifically to the affirmative defense that will extinguish actions for personal injury brought under the common law of torts.21 In a preemption scenario, a plaintiff attributes an injury to a product defect. The defendant seller responds by saying that a particular federal regulation on point preempts the claim—because Congress, exercising a supreme legislative power, has said so—and accordingly any court applying state law must dismiss it.

Preemption divides into two categories. “Express” preemption is present when Congress makes an overt statement about its intent to foreclose common-law tort liability.22 Congress rarely chooses to make such a statement, perhaps because its members, in perpetual pursuit of campaign funds to get reelected, worry that taking a stand on the divisive

20 But see The Gale Group, Inc., Small Business Encyclopedia: Consumer Product Safety Commission (CPSC), www.answers.com/topic/consumer-product-safety-commission (last visited Mar. 13, 2009) (identifying 1999 as a “vigorous” year for the Commission; in 1999 it “issued more than 300 product recalls” and “levied approximately ten times the amount of fines on companies that it had assessed a decade earlier”). As this Article goes to press, I cannot confirm my provisional belief that the 2008 legislation marks a significant shift. Should the Consumer Product Safety Improvement Act reforms prove thin or illusory, my thesis remains the same.

21 DAVID G. OWEN, PRODUCTS LIABILITY LAW 940 (2d ed. 2008) (describing preemption as a defense to liability). This working definition of preemption excludes broader alternative understandings. See id. at 969 (discussing preemption of state regulations); Richard C. Ausness, “After You, My Dear Alphonse!”: Should the Courts Defer to the FDA’s New Interpretation of § 360k(a) of the Medical Device Amendments?, 80 TUL. L. REV. 727, 734 & n.50 (2006) (describing applications of preemption that do not entirely immunize defendants); Betsy J. Grey, Make Congress Speak Clearly: Federal Preemption of State Tort Remedies, 77 B.U. L. REV. 599, 562 n.14 (1997) (noting that, in addition to common law claims, state statutory remedies and punitive damages are amenable to preemption). Professor Ausness’s list of preemption cases includes International Paper Co. v. Ouellette, 479 U.S. 481, 491 (1987) (permitting tort liability, but holding that the Clean Water Act restricted plaintiffs to the law of one state), and Arkansas Louisiana Gas Co. v. Hall, 453 U.S. 571, 582-84 (1981) (permitting liability, but holding that state doctrine on the calculation of contract damages was preempted under the Natural Gas Act). Id. at 734 n.50. This Article, by contrast, discusses preemption only insofar as it forecloses state tort liability.

22 OWEN, supra note 21, at 941.
subject of liability will offend financers.\(^{23}\) When Congress does speak overtly about preemption, it frequently will do so from two sides of its mouth: the same statute can contain both a preemption clause purporting to displace all contrary state regulation, perhaps including regulation by tort law, and a savings clause, purporting to preserve state tort liability.\(^{24}\)

By these means Congress punts its dilemma to the judiciary,\(^{25}\) and so preemption is found mainly in the other category, “implied” preemption, where courts read into a statute a pertinent congressional intent: that is, either to occupy a field through federal regulation (“field preemption”) or to set up a regulatory scheme inconsistent in its particulars with what injured litigants could receive if they prevailed under state tort law (often called “conflict preemption”).\(^{26}\) Conflict preemption is the type that often arises as an affirmative defense to personal injury claims, but either type of preemption can keep injured plaintiffs out of court. Part I gives a summary of implied preemption doctrine. This Part functions here mainly as background for the Article’s more novel claim.

Congressional oscillation, I argue, shows the need for another judge-made doctrine about preemption of tort liability. The consumer product safety example shows that Congress will occasionally move in more than one direction with respect to regulating industries, services, or public safety generally. The existence of implied preemption calls for a complementary judicial inference to recognize the abandonment of an earlier regulatory design. Any court empowered to infer that Congress


\(^{25}\) Grey, supra note 21, at 618; id. at 617 (“Congress knows how to preempt state common law claims expressly and has demonstrated its ability to do so a number times. Therefore, courts should not preempt matters beyond the express language of a federal statute.”) (footnotes omitted); Catherine M. Sharkey, Products Liability Preemption: An Institutional Approach, 76 GEO. WASH. L. REV. 449, 450 (2008) [hereinafter Sharkey, Institutional Approach] (using the punt metaphor).

intended to occupy a field or impose a scheme, when Congress did not announce this path expressly, is also empowered to infer a congressional retreat.27

The parallel from express preemption is repeal. Here is an illustration. Suppose that in year X, Congress passes the Goldhelmet Safety Act (“GSA”), declaring in the statute that compliance with federal regulations pertaining to the manufacture and sale of solid-gold motorcycle helmets insulates sellers from tort liability. To keep complication out of the hypothetical, the statute contains no savings clause of any kind. It plainly preempts. The President signs the new law. As long as the GSA is in effect, plaintiffs who attribute injury to helmets made in accord with GSA requirements may not sue manufacturers or other sellers: express preemption kills their claims. Sometime after year X, in year Y, Congress takes the federal government out of the gold-helmet regulation business by repealing the GSA. Or it leaves other parts of the GSA in the United States Code, but repeals the express-preemption provision. When the repeal goes into effect, persons who attribute injury to their gold helmets may sue. Congress has abandoned its express preemption.28

Similar reasoning should govern implied preemption. Any congressional scheme to occupy a field or establish comprehensive regulation can be abandoned. Overt, express takeovers of fields or comprehensive regulatory schemes done through federal legislation and rulemaking are relatively easy to observe; by contrast, a takeover or a comprehensive design that a court can educe only through inference disappears by means other than a written declaration. Abandonments of these preemptive initiatives render obsolete any earlier judicial inference that might have found a congressional intent to preempt. Just as courts find implied preemption where circumstances warrant, they must also, again only where circumstances warrant, infer a retreat from implied preemption. I discuss this inference of retreat by Congress, which I call “implied reverse preemption,”29 in Part II.

27 This proposal joins others I have presented as recommendations to judges who hear claims of injury. See, e.g., Anita Bernstein, Enhancing Drug Effectiveness and Efficacy Through Personal Injury Litigation, 15 J.L. & Pol’y 1051, 1082-98 (2007) (proposing a cause of action for persons who can show they suffered physical harm from a drug’s failure to live up to the promises on its label); Anita Bernstein, Treating Sexual Harassment with Respect, 111 H ARV. L. REV. 445, 521-24 (1997) (offering a draft jury instruction for hostile-environment sexual harassment claims).


29 “Reverse preemption” is sometimes used to describe restraint or abstention by Congress in deference to state prerogatives. Courts apply the term to regulation of the insurance industry under the McCarran-Ferguson Act. See Safety Nat’l Cas. Corp. v. Certain Underwriters at Lloyd’s, 543 F.3d 744, 752 (5th Cir. 2008); Genord v. Blue Cross & Blue Shield, 440 F.3d 802, 805 (6th Cir. 2006); In re Med. Care Mgmt. Co., 361 B.R. 863, 871 (Bankr. M.D. Tenn. 2003). Commentators extend it to judicial refusals to apply federal law in a domain that is traditionally left to state authority. Reverse preemption of this sort has both detractors and admirers. Compare Daniel
As scholars have noted, the indicators of a tacit decision by Congress to bar state tort claims are both unclear and controversial, and analogous difficulties necessarily occlude the reverse-preemption analysis. Implied reverse preemption is, however, easier to use than implied preemption in one crucial respect: Congress manifests its retreat from a domain more transparently than it manifests its intent to preclude tort liability. Implied reverse preemption, in this respect very different from implied preemption, gives courts distinct markers of congressional intent to look for. In Part II, I propose some criteria for courts to find implied reverse preemption. Fulfillment of the criteria suggests that Congress has pulled back from an inferred early agenda and no longer forecloses tort liability.

Both courts and scholars of preemption recognize that although Congress, as the originator and source of congressional intent, is central to any analysis of preemption, the executive branch of government—represented here by the agency charged with enforcement of a statutory mandate—plays its own role in determining whether injured persons can bring claims under state law. Constitutional and administrative laws recognize the possibility of delegation, whereby Congress cedes decisionmaking power to a federal agency. Federal agencies have manifested their belief that this delegation has given them the power to preempt state tort claims. Some courts have accepted these announced beliefs as authoritative. With more unanimity, courts have held that agencies must comply with statutory obligations even when Congress has not appropriated the necessary funds. Accordingly, any federal

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A. Crane, Antitrust Antifederalism, 96 CAL. L. REV. 1, 27 (2008) (identifying an unhealthy reverse preemption in state laws that defeat the purposes of antitrust law as written by Congress), with Michael J. Zydney Mannheimer, When the Federal Death Penalty is “Cruel and Unusual,” 74 U. CIN. L. REV. 819, 879-80 (2006) (extolling a form of reverse preemption whereby the choice of a state to have no death penalty would outweigh a federal statutory death penalty for crimes committed in that state). I use “implied reverse preemption” here very differently, as a short form of “inferred retreat from a previously inferred preemption.”

30 See Caleb Nelson, Preemption, 86 VA. L. REV. 225, 298 (2000) (commenting that the Supreme Court has left the presumption against preemption indeterminate); Sharkey, Institutional Approach, supra note 25, at 454 (“It is exceedingly difficult to demonstrate that any consistent principle or explanatory variable emerges from the Supreme Court’s products liability preemption jurisprudence.”). See generally OWEN, supra note 21, at 939-40 (summarizing the consensus among commentators that preemption is “a mess” (citation omitted)).


32 Among federal agencies, the Food and Drug Administration (“FDA”) has attracted the most attention on this point. See Horn v. Thoratec Corp., 376 F.3d 163, 167 (3d Cir. 2004) (noting the FDA’s participation in the appeal as amicus curiae); Ausness, supra note 21, at 55-56. Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 534 (E.D. Pa. 2006), aff’d, 521 F.3d 253, 275-76 (3d Cir. 2008), vacated, No. 08-437, 2009 WL 578682 (U.S. Mar. 9, 2009), marked the first successful attempt in the federal appellate courts to invoke the FDA preamble as establishing preemption.

33 Cherokee Nation v. Levitt, 543 U.S. 631, 640-42 (2005) (forcing the Department of Health and Human Services to pay sums it owed to two Indian tribes, notwithstanding its contention that Congress had not appropriated the money it needed); N. Y. Airways, Inc. v. United States, 369 F.2d 743, 748 (Ct. Cl. 1966).
agency holding assigned authority over safety, be it “independent” or subordinated to a Cabinet department, has a presence distinct from that of Congress in the setting of regulatory policies that pertain to preemption.  

For judges and policymakers receptive to the thesis of this Article, it remains an open question which statutes and agencies will give the judiciary instances of implied reverse preemption to find; the experience of consumer safety is clear enough to provide a model of the phenomenon. Beginning either in 1976 or 1981, and continuing until 2008, Congress knocked the teeth from the Consumer Product Safety Act and weakened the Consumer Product Safety Commission, whose leaders appeared to welcome rather than resist the stripping of their power. Unity and bipartisanship pervaded this reversal; both Democrats and Republicans pursued statutory rollback and a reduction in agency power. Part III presents these undisputed developments without argument or criticism: I have my views about the federal interest in consumer safety, but they are of no moment here. The point of Part III is that at some point during a period of seventeen years, Congress ceased to intend, if it ever did intend, to assert a federal safety-regulatory stance that precluded tort liability for injuries attributed to consumer products. Congress chose not to occupy the field of consumer safety, nor to establish a comprehensive regulatory scheme. This absence or withdrawal of preemption left consumer product safety open to the powers and prerogatives of state law, especially state tort liability. 

Implied reverse preemption and traditional preemption function together harmoniously in the adversary binary of manufacturer-defendants versus consumer-plaintiffs. I will even claim that acceptance

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35 Though unanimous on the point that the CPSC plunged into somnolence during the Reagan years, commentators disagree on when this descent began. One publication that focuses on industry rather than consumers, the Small Business Encyclopedia, deemed 1999 a turnaround year. See supra note 20; see also infra Part III.B. (exploring the ambiguous decline of federal consumer safety regulation in the late Carter and early Reagan presidential administrations).


37 This inference rests on my understanding that preemption is different from a congressional grant of mere immunity. Implied preemption presumes that Congress has substituted federal regulation for state-based tort liability as a means to promote consumer safety; it casts tort claims as obstructing a scheme that benefits consumers. If this premise is correct, then implied reverse preemption becomes a necessary counterpart to implied preemption, because as soon as Congress no longer desires to promote safety through federal regulation, immediately tort claims, or “regulation through litigation,” become the only available instrument of safety law. Retaining preemption under those circumstances would therefore generate only immunity, not safety. See generally Big Loss for Big Tobacco, N.Y. TIMES, Dec. 16, 2008, at A36 (praising the Supreme Court for insisting that preemption law does not require immunity for cigarette manufacturers).
of this new doctrine would make the work of preemption litigation more satisfying for lawyers and judges. At present, with only preemption and not implied reverse preemption available to them, lawyers on both sides immerse themselves in assembling decisional law that favors their clients’ stance on a yes/no affirmative defense and try to distinguish the contrary line. Judges find either preemption or no preemption. Everyone on the battleground has a set of tasks that are relatively mechanical.

The new front opened by implied reverse preemption brings a healthy challenge to precedents that had barred tort liability. Lawyers build an answer to the question of whether old findings of a congressional intent to preempt have been superseded. Because the evidence to support implied reverse preemption comes from relatively intelligible and accessible sources—amendments, budgets, agency announcements—courts could adjudicate the issue “on papers,” using memoranda and exhibits rather than costly stagings like Daubert hearings. Through this doctrine, judges would make preemption more even-handed and more consistent with law as legislators make it.

I. IMPLIED PREEMPTION OF STATE TORT LIABILITY: INFERRING A FEDERAL LEGISLATIVE DESIGN TO BAR PERSONAL INJURY CLAIMS

A. To Begin: Congressional Intent

Under varied sources of doctrine, of which the Supremacy Clause of the United States Constitution has garnered the most attention, state law must yield to contrary federal law. The eighteenth-century declaration of congressional supremacy in the Constitution probably did not anticipate the twentieth-century rise of federal power under the Commerce Clause, suggesting that the searches for congressional intent to preempt inconsistent state law that courts now undertake may be inconsistent with the framers’ design. Nevertheless, the constitutional base from which courts find preemption today is solid. In its preemption decisions, the Supreme Court frequently pauses to pledge fealty to legislative intent, which it has called “the ultimate touchstone” in preemption analysis.

38 See infra Part III.A (assembling cases that support an inference of preemption by the CPSA).
39 U.S. CONST. art. VI, cl.2.
42 For expressions of the Court’s devotion to congressional intent in preemption decisions, see Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1013 (2008); Sprietsma v. Mercury Marine,
Courts considering assertions of implied preemption must, at least in principle, construe statutes with a “presumption against preemption,” a canon first declared by the Supreme Court in 1926. Although this presumption appears to be of doubtful force, the Court has never declared it dead, and in more recent preemption decisions the Court has reiterated the presumption to hold that tort claims could proceed. Any attempt to understand or enhance preemption doctrine accordingly must reckon with the canon of construction that reminds courts not to rush to this inference unless Congress has made clear its preemptive intent. Looking ahead to the implied reverse preemption thesis of this Article, we can make use of the canon: A presumption against preemption, if it has any impact at all, should affect interpretations not only of whether preemption exists, but how long it stays alive in a statute. The canon tells courts to recognize the possibility that Congress has abandoned an earlier ambition to preempt.

Another point of statutory interpretation that can inform implied reverse preemption relates to drawing inferences from a legislature’s failure to act. Following what William Eskridge has called the acquiescence rule, federal courts, led by the Supreme Court, have held that a failure by Congress to respond to the judicial construction of a statute signals congressional acceptance of that decision. This inference will often be ill-founded in fact. Congress might not have considered the judicial decision in question; it might have disagreed with it but failed to make a priority of reversing the holding; it might have rejected it but become frozen on the question of how to respond. Nevertheless, courts will sometimes draw this inference of acceptance.

Inferring legislative acceptance from legislative inaction suggests a precedent for courts as they consider whether to infer retreat

537 U.S. 51, 69 (2002); see also supra note 41 and accompanying text. But see Keith N. Hylton, Preemption and Products Liability: A Positive Theory, 16 SUP. CT. ECON. REV. 205, 206 (2008) (arguing that courts do not care about congressional intent and instead choose to find preemption when they perceive the relevant agency to be independent and when they perceive a high “degree of congruence between the regulatory and common law standards” (emphasis omitted)).


44 See Davis, Unmasking, supra note 40, at 972 (questioning whether the presumption against preemption ever existed).


46 Eskridge cites Apex Hosiery Co. v. Leader, 310 U.S. 469, 488 (1940) (declaring that this mission “is persuasive of legislative recognition that the judicial construction is the correct one”) and Toolson v. New York Yankees, 346 U.S. 356, 357 (1953) (“Congress has had the ruling under consideration but has not seen fit” to write new law). WILLIAM N. ESKRIDGE, JR., DYNAMIC STATUTORY INTERPRETATION 242 (1994).


48 I thank Deborah Widiss for her careful articulation of this point.
by Congress from an earlier inferred preemption. Any inference of an acquiescence by the legislature, to which many courts are quick to leap, makes strenuous demands on judges. They must ignore the realities noted above that contradict acquiescence by Congress (ignorance of the new judicial interpretation, inability to agree on an expression of disagreement, and so on), as well as the larger reality that this legislature “is a discontinuous decision maker.”

Membership in the body turns over. Even if membership in a legislature could stay fixed, the focus of its legislation will change form. These demands do not burden judges who apply the implied reverse preemption that this Article advocates. Judges can proceed without blinkering themselves to the probabilities, well gathered by Eskridge, that suggest a misunderstanding of congressional inaction. Inferring distraction, disengagement, or the abandonment of a once-held legislative goal calls for much less conjecture than the established inference of embrace and agreement.

B. Speculating About Why Congress Would Want to Bar Personal Injury Claims

The doctrine of preemption recognizes that Congress can have plans that are inconsistent with state tort liability. Two of these legislative designs are familiar to courts. First, Congress might intend to occupy a field so completely that any state-level contribution to the regulatory endeavor could not supplement it. Second, Congress might have particular purposes that state tort law would obstruct by opening the possibility of a contrary result.

Both state-tort and federal-agency modes of regulation can make sense as sources of safety, and Congress might desire either path to the destination of fewer injuries in particular and public welfare in general. When policymakers understand the federal regulatory path as preemptive, however, they add asymmetry to the paths: federal rulemaking extinguishes tort claims, but tort claims do not extinguish

49 Eskridge, supra note 46, at 247.

50 Eskridge, a gay activist as well as a scholar of statutory interpretation, gives the example of the Immigration and Nationality Act of 1952, written to bar mentally ill persons from entering the United States. The Public Health Service, enforcing a 1950s view of mental health, understood the statute to exclude homosexual persons. In 1979 the PHS reversed this position, reinterpreting the statute in light of charged circumstances. Id. at 51-55.


federal rulemaking. Even at its most potent, tort liability can only hamper or obstruct a federal regulatory scheme. Because a finding of preemption makes the federal regulatory role a destroyer—in contrast to a finding of no preemption, which does not destroy the regulatory alternative—an inference of preemption requires courts to identify a congressional agenda consistent not only with favoring the federal-regulatory mode but with actively rejecting and repudiating tort liability.

A couple of rationales for this congressional agenda are available. Both have implications for implied reverse preemption as well.

1. Conflict Preemption and Field Preemption

Conflict or obstacle preemption is the plausible type of implied preemption for personal injury claims. The alternative, “field preemption,” usually applies to traditionally federal domains, and tort law governing personal injuries is traditionally left to the states. State governments hold a “police power” to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons. Tort liability is central to their police power.

Field preemption could plausibly arise, however, should Congress decide that state tort liability interferes with its regulation of a field. Discussing preemption of drug claims, for example, Richard Epstein has nominated as a possible “field” the effort by Congress to enhance innovation in the pharmaceutical sector, making regulation more streamlined and centralized. Should courts agree that Congress has chosen this field preemption, a range of personal injury actions would fall away from American dockets. Though cogent, the suggestion has not persuaded judges to identify field preemption of pharmaceuticals complaints in particular, or of products liability complaints in general. Field preemption appears too vast and ambitious for courts to assert its existence without clearer guidance from Congress.

Judges and commentators are more inclined to find conflict preemption of personal injury claims when the result that a plaintiff is seeking through litigation would diverge from what Congress intended.

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53 The anomaly has drawn scholarly attention. See OWEN, supra note 21, at 969 (noting that “there is in fact no reason, as a general matter, why products safety regulation and products liability litigation cannot comfortably co-exist”).
54 See supra note 26 and accompanying text.
55 See Grey, supra note 21, at 622 (arguing that field preemption “has no legitimate role when the issue is whether Congress has preempted state tort remedies”).
57 Grey, supra note 21, at 613.
The clearest example of such an inferred congressional design appears in *Geier v. American Honda Motor Co.*,\(^9\) where the Supreme Court, in a five-to-four decision, determined that the plaintiff had to lose because what she desired clashed with a federal mandate to deny her this desire. Implied preemption in *Geier* came from the National Traffic and Motor Vehicle Safety Act of 1966, which forbade states from maintaining a motor vehicle standard not “identical” to the federal safety standard.\(^6^0\) Alexis Geier objected to the lack of an airbag in a Honda vehicle, contending that the vehicular design was defective; the standard in effect at the time had condoned the no-airbag design.\(^6^1\) Because the plaintiff could prevail only through a state-tort judgment that would condemn the absence of an airbag, the Court concluded that her claim conflicted with the permissiveness that federal standards had conscientiously installed and thus was preempted.\(^6^2\)

As applied to defeat products liability under state tort law, both field preemption (which courts do not use for this purpose) and conflict preemption as exemplified by *Geier* rest on a premise that Congress has installed a federal regulatory scheme that functions actively and deliberately to foster safety. Although inferring preemption has the same effect on liability as does simple immunity for defendants—plaintiffs’ claims are dismissed—the rationale for this effect is very different from any rationale for immunity.\(^6^3\) Congress might want to immunize a sector from tort liability for numerous varied reasons, but the reason for a preemptive regulatory scheme must be safety.\(^6^4\) Should Congress lose its desire to foster safety through the regulatory scheme and, through its actions or inactions, cause the scheme to lose force, then this shift eliminates both field preemption and conflict preemption.

2. Regard for an Agency

Going beyond the doctrinal categories of field preemption and conflict preemption, another rationale can underlie the congressional decision to foreclose tort liability: Congress might regard a federal agency as the more competent regulator. For this suggestion I rely on, and extrapolate from, Catherine Sharkey’s work on agency deference.\(^6^5\)

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\(^6^0\) *Id.* at 867.
\(^6^1\) *Id.* at 865.
\(^6^2\) *Id.* at 866.
\(^6^3\) See *supra* note 37 and accompanying text.
\(^6^4\) Or so I presume. I thank Cathy Sharkey for urging me to state the premise and thereby clarify my argument for readers who may have joined the preemption debate from a contrary starting point.
Sharkey argues that the best predictor of what the Supreme Court will do with a preemption claim is the position on preemption that the relevant agency has asserted.\textsuperscript{66} This position will vary: agencies turn out “just as likely, if not more likely,” to oppose preemption as favor it.\textsuperscript{67} The same agency will articulate more than one stance. For example, the Food and Drug Administration argued for preemption in \textit{Buckman Co. v. Plaintiff’s Legal Committee}\textsuperscript{68} and \textit{Riegel v. Medtronic, Inc.}\textsuperscript{69} but against preemption in \textit{Medtronic, Inc. v. Lohr};\textsuperscript{70} the National Highway and Traffic Safety Administration wanted Alexis Geier to lose on preemption\textsuperscript{71} but opposed preemption in \textit{Freightliner Corp. v. Myrick};\textsuperscript{72} the Supreme Court, finding preemption in three of these cases and declining to find it in the other two, sided with the agency in all five.\textsuperscript{73} Because the Court “has been cryptic at best” on “what stands behind such deference to agency views,”\textsuperscript{74} Sharkey is forced to supply her own rationale for deference to an agency in its interpretive (as contrasted to regulatory) role. Concluding that agencies are often well situated to know the relative merits of a state-tort versus a federal-agency fix, Sharkey encourages courts to apply “Skidmore deference” to agency views on preemption.\textsuperscript{75} A Skidmore judicial stance would respect the comparative advantage of an agency to know “whether a uniform federal regulatory policy should exist.”\textsuperscript{76}

This panoramic version of deference makes a point pertaining to congressional intent and agency power: Regardless of whether the Supreme Court should accept or reject a particular claim of preemption (a question Sharkey builds a model to answer), any particular instance of regulation originates at least in part in a view that Congress had about relative institutional competence. On occasions that warrant deference to agency wishes, Congress would have believed that the empowered agency is better positioned than state tort liability to resolve one iteration of the recurring question: \textit{Do we need a uniform federal rule here?}\textsuperscript{77} Like regulation might be more competent than tort liability at achieving particular ends, see Hylton, \textit{supra} note 42, at 219-20 (noting the importance of judicial, as contrasted to congressional, regard for an agency); Peter H. Schuck, \textit{FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot}, 13 ROGER WILLIAMS U. L. REV. 73, 76 (2008) (comparing the “regulatory toolkit” that state tort liability and federal rules each offer).

\begin{itemize}
  \item \textsuperscript{66} Sharkey, \textit{Institutional Approach, supra} note 25, at 471.
  \item \textsuperscript{67} \textit{Id.} at 475.
  \item \textsuperscript{68} \textit{See} 531 U.S. 341, 347-51 (2001).
  \item \textsuperscript{69} 128 S. Ct. 999, 1009 (2008).
  \item \textsuperscript{70} \textit{See} 518 U.S. 470, 498-500 (1996).
  \item \textsuperscript{72} \textit{See} 514 U.S. 280, 285 (1995).
  \item \textsuperscript{73} Sharkey, \textit{Institutional Approach, supra} note 25, at 477.
  \item \textsuperscript{74} \textit{Id.} at 471-72.
  \item \textsuperscript{75} \textit{Id.} at 491-96 (citing Skidmore, 323 U.S. 134 (1944)).
  \item \textsuperscript{76} \textit{Id.} at 484.
  \item \textsuperscript{77} Ascribing this inquiry to Congress, keeper of the vaunted congressional intent, seems strained, as Keith Hylton has contended. \textit{See generally} Hylton, \textit{supra} note 42 (arguing that it is
any other faith, congressional faith in the superior power of an agency can dwindle or disappear. If the judgment about agency superiority rests on facts rather than, or in addition to, faith or ideology, this judgment too can recede when facts change.

II. IMPLIED REVERSE PREEMPTION OF STATE TORT LIABILITY: INFERRING THE WITHDRAWAL OF ANY JUDICIALLY INFERRED BAR OF PERSONAL INJURY CLAIMS THAT MAY HAVE ONCE EXISTED

Here we pursue the thesis of this Article: The exercise of drawing inferences about what a legislature once intended with respect to regulation necessarily entails the possibility of inferring that the legislature has relinquished an older inferred intent on this point. Any doctrine of implied preemption that does not recognize the possibility of abandoning a once-held preemptive scheme cuts courts off from reality. Dropping the regulatory ball is as normal and predictable—just as integral to regulation—as picking it up. This Part builds on the standard account of congressional intent by exploring congressional retreat from safety initiatives. After considering the markers of abandonment that Congress makes public, the Part proceeds to discuss abandonment as manifested by an agency.

A. Congressional Abandonment

Congress has at hand three devices to express its intentions regarding the launch of a regulatory agenda. To start, it can vote to approve a new statute that provides for agency rulemaking. Second, it can appropriate funds to support a federal agency in this initiative. Third, it can return to the statute as needed, codifying amendments to take into account developments in the regulated sector. The last two prerogatives are also at the center of any inferable withdrawal of regulation. Congress can withdraw from previous levels of appropriation, and it can enact amendments that contract or undermine the original regulatory endeavor.78

1. Appropriations in Retreat

The monolithic Congress that, according to preemption doctrine, chooses to express what lies at the core of preemption—its singular intent to occupy a field or establish a comprehensive scheme of regulation incompatible with tort liability, or perhaps to opine on agency judges who hold a view about relative institutional competence). Regardless of who asks it, however, the question is central to any analysis of preemption.

78 Overt repeal of a statute, a reversal of the first prerogative, eliminates the need for inferring.
competence 79 —is a fiction, as explained by the literatures on public choice, game theory, and other academic genres. 80 With respect to any issue before it, Congress has many intents and agendas, never just one. An aspect of its multiplicity that pertains to implied reverse preemption is the gap between substantive law-writing and appropriations. To effect a legislative change that requires money to proceed, a safety-reform coalition must first get the new statute written and then get it funded. Both houses of Congress have powerful appropriations committees that hold authority over federal disbursements. 81 It is fairly common for Congress not to appropriate funds to pay for a new law it voted to enact. 82

This manifested ambivalence complicates the use of an appropriations criterion to draw any legal conclusion, not just the implied reverse preemption conclusion of this Article, because Congress can express conflicting desires about a new piece of legislation. Legislators can vote for a measure (implying congressional acceptance) yet not fund it (implying congressional rejection). Regardless of whether they find the response mixed or even contradictory, however, courts must consider the money-message that Congress sends to them. Their acceptance of implied preemption as doctrine has committed courts to drawing inferences about what Congress wants. As the case law on implied preemption indicates, manifestations of these wants emerge shrouded in ambiguity and doubt. 83

Committed to an appropriations analysis, courts considering implied reverse preemption could begin with a metric of decline in spending. This metric would direct judicial attention to an inflation-adjusted drop in appropriations over a period of years for the regulatory entity empowered to enforce what Congress has mandated. A court can infer that other things being equal, fewer dollars appropriated expresses

79 See supra Part I.B.
81 The authority of appropriations committees in Congress derives from the Constitution, which provides that “[m]oney shall be drawn from the treasury” only “in Consequence of Appropriations made by Law,” in a section describing the powers of Congress. U.S. CONST. art. I, sec. 9, cl. 7.
82 “New programs receive funding only if they can fit within predetermined limits. They can succeed legislatively only if some previously funded programs receive fewer funds or no money at all.” WILLIAM N. ESKRIDGE, JR., PHILIP P. FRICKEY & ELIZABETH GARRETT, LEGISLATION AND STATUTORY INTERPRETATION 184 (2000).
83 See supra note 30 and accompanying text. For courts reviewing claims of implied reverse preemption, a plausible response to the funding gap would be to accept the enactment of substantive regulatory legislation as an expression of congressional interest, and after a reasonable interval (perhaps two years) to require Congress either to show observers the money, so to speak, or acknowledge that its earlier enactment did not articulate a serious regulatory plan.
Use of this metric requires attention to the surrounding budgetary scene: agency budgets often include increases unrelated to regulatory policy. Federal agencies sometimes have to augment their expenditures on such items as mandatory pay raises, added premiums for employees’ insurance, increased pension contributions, and escalation in rents for its office spaces. Whenever such upticks are beyond the control of agency budgets at a time that appropriations remain flat—especially if the agency carries out its mission using human employees more than hardware—Congress has in effect diminished its spending on regulation.

An alternative metric would focus on whether a level of funding suffices to fulfill the statutory agenda. This conclusion may appear beyond the judicial ken, replete as it is with tradeoffs and indeterminate variables piled on top of the question of what the statute seeks to achieve. Courts are familiar with it, however, having issued numerous judgments in response to contentions that the federal government lacks the money to pay a claim or cannot afford to fund entitlements.

For judges who resist accepting implied reverse preemption in the belief that it is too novel or too potentially far-reaching, one last metric could limit the doctrine to extraordinary circumstances. A court could choose to find implied reverse preemption only when the relevant agency appears unfunded to the point of utter dysfunction: a de facto abolition of the entity. This conservative approach to implied reverse preemption is at odds with the ready inference of preemption to immunize tort defendants, a locus of what might be called judicial

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84 Courts could refine this analysis with attention to circumstances as they arise. For example, a domestic spending freeze might dictate a reduction in dollar appropriations throughout the federal bureaucracy. Such a reduction does not express retreat from the particular regulatory mandate. Another possible metric that attends to circumstances would consider relative decline in spending. Similarly situated agencies or entities might have received more money while the agency in question is receiving less. Courts may infer that this shift in expenditure manifests a reduced desire to affect the statute’s design. Relative decline, like the absolute decline mentioned above, would require data from a period of years to show the diminution in congressional interest, as well as an understanding of the relevant comparators.

85 Telephone Interview with Rachel Weintraub, Dir. of Prod. Safety and Senior Counsel, Consumer Fed. of Am. (Dec. 29, 2008) [hereinafter Weintraub Interview].

86 Id.

87 See supra note 33 and accompanying text. A state-law analogy emerges in education cases. When local governments contend that they cannot afford to honor state constitutional rights to education, courts often insist that they must. See generally Christopher E. Adams, Comment, Is Economic Integration the Fourth Wave in School Finance Litigation?, 56 EMORY L.J. 1613, 1620-23 (2007) (describing judges’ willingness to enforce rights by ordering expenditures).

88 I have in mind a collapse in funding that in turn generates consensus that the agency has fallen to the level of the Federal Emergency Management Agency (“FEMA”) following Hurricane Katrina. See Clif Chitwood, Study Risk of Quake Before Adopting Codes, ARK. DEMOCRAT-GAZETTE, Jan. 19, 2008 (available on LEXIS) (“In FEMA’s world view, hurricanes, floods, tornadoes, earthquakes and any other event that might cost the federal government money are all of one kind and demand the same response: more money spent by others in the form of unfunded mandates”); Carol Eisenberg, FEMA Falls Short on L.I., NEWSDAY (N.Y.), Dec. 14, 2007, at A30 (referring to “the Katrina debacle”).
 activism;\textsuperscript{89} but it offers courts a principled basis to reject implied reverse preemption for the common run of cases while having it available whenever dire appropriation levels support the inference.

2. Manifested Regulatory Design in Retreat: Later Amendments

Courts can find implied reverse preemption manifested in decisions by Congress to pull back from its earlier safety mandates. We have already noted the possibility of repeal, the plainest signal of congressional retreat from an agenda.\textsuperscript{90} Less overt, but just as probative of abandonment, is a pattern of amendments that weaken the original swath of regulatory powers.

The inference gains strength the more numerous such weakening amendments become. A single piece of amending legislation that appears to express withdrawal from a preempting scheme, if ambiguous, ought to receive the benefit of the doubt: it could look like relinquishment but might amount to a different approach to the same safety agenda that had been, and remains, incompatible with tort liability. After the withdrawing amendments accrete, however, they express in the aggregate a congressional intent to do less to maintain the original safety-enhancing federal regime.

B. Agency Abandonment

Judicial inquiries into implied preemption, a construct rooted in legislative supremacy and, from there, in congressional intent, also consider the policies that an agency has manifested, distinct from the statutory provisions that empower it.\textsuperscript{91} As constitutional actors, agencies respond to the direction of Congress. Courts call this direction delegation.\textsuperscript{92} Like preemption itself, delegation is a judicial construct that need not—and typically will not—be manifested in overt action by Congress.\textsuperscript{93}

\textsuperscript{89} The writings of Mary Davis are on point. See generally Mary J. Davis, The Supreme Court and Our Culture of Irresponsibility, 31 WAKE FOREST L. REV. 1075 (1996) (summarizing the Supreme Court’s energetic embrace of doctrines to protect products liability defendants); Davis, Unmasking, supra note 40.

\textsuperscript{90} See supra note 28 and accompanying text.

\textsuperscript{91} See generally Sharkey, Institutional Approach, supra note 25; see also Ausness, supra note 21, at 758-71 (noting the complications of deferring to an agency position that has shifted over time).


\textsuperscript{93} See Chevron, 467 U.S. at 865-66.
1. Authority: Recognizing Delegation to Make a Decision About Reversing a Regulatory Direction

Every federal agency brings its own expertise and methods to a legislative agenda. Under the version of congressional intent that courts use to hold that a plaintiff may not proceed with a personal injury claim, courts infer that Congress, instead of (or in addition to) writing safety regulations of its own, gave an administrative authority the power to craft rules superior to those that would emerge from state decisional law. The competence that makes delegation plausible in a particular context necessarily includes a distinct identity.

Accompanying this premise, so central to implied preemption, is the mirror-premise central to implied reverse preemption: An agency that once was inclined to codify and enforce safety regulations can become disinclined to stick to this task.\(^{94}\) Inertia keeps old rules in the Code of Federal Regulations and other repositories long after individuals who effect agency policy have ceased to care about particular regulatory goals that the agency used to pursue. So seen, delegation represents a congressional grant of power that assigns an agency not only the prerogative to write rules potent enough to preempt tort liability, but also the prerogative to let go of its erstwhile preemptive ambition.\(^{95}\)

Any judge who reaches a conclusion of abandonment by an agency does not necessarily condemn this inaction. Agency restraint might bespeak a “no harm, no foul” conclusion about an industry or sector that has been functioning well, independent of or unaffected by the federal code. Alternatively, a problematic condition—sloth, corruption, capture by industry, or inadequate funding from Congress—might explain the torpor of a do-little agency.

Judges’ power to find implied reverse preemption has effects that are benign when the industry is functioning well and salutary when it needs intervention. If an agency has declined to write rules because the sector it regulates is not hurting anyone, then personal injury litigation will not clog the courts,\(^ {96}\) and no harm to the congressional design will

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\(^{94}\) Cf. Owen, supra note 21, at 954 (observing, in another context, that “even a federal agency has the right to change its mind, and that an agency’s current views on preemption are entitled to respect”).

\(^{95}\) See generally Sharkey, Institutional Approach, supra note 25 (emphasizing the role of agencies as safety decisionmakers).

\(^{96}\) I assume an inverse relation between the safety of the sector’s activity and the rate of personal injury claiming. I do not mean to suggest that every claim filed bespeaks a real injury, only that preemption is not the solution to fraudulent or exaggerated allegations of injury by malingerers and their attorneys. Preemption functions to bar claims of true harm on the premise that giving plaintiffs the relief they seek, or forcing sellers to proceed with manufacture and distribution in anticipation of being sued, would retard rather than advance public safety. See supra text accompanying notes 59-62 (discussing Geier v. Am. Honda Motor Co., 529 U.S. 861 (2000)). Like all other affirmative defenses, preemption does not catch or discourage dishonest claiming. Fears of the falsity problem have no place in the law of preemption. When applying the doctrine, courts may reasonably assume that attempts to bring personal injury claims bespeaks real injuries, and, conversely, that the lack of such attempts suggests a track record of safety.
follow. The existence of an industry flourishing—and hurting few people—with few agency-written rules and little liability provides an instance of success with which implied reverse preemption will not interfere.\textsuperscript{97} If the agency ought to have written and enforced rules but became inactive for malign reasons, then reversing the inference of preemption helps to cure a pathology.

2. Manifestations: Scant Rulemaking Activity, Budgetary Passivity, and a Subdued Public Presence

The Congressional Review Act, passed in 1996 as part of the famed anti-regulatory Contract With America, requires federal agencies to submit their proposed rules to Congress for approval.\textsuperscript{98} The statute declares that a proposed rule may fall into the “major” category; a major rule is defined as a rule expected to have an annual impact on the economy of at least $100 million.\textsuperscript{99} During the first decade of enactment, federal agencies duly conveyed to Congress and the General Accounting Office 41,218 non-major rules and 610 major rules,\textsuperscript{100} thereby setting a baseline quantity.

The rules appear numerous, but might not be so in relation to the amount of regulation needed. Scant rulemaking activity—or at least an attitude against rulemaking—occupied federal policy before the Contract With America. Calls for regulatory relief emerged loudly in the Reagan administration,\textsuperscript{101} critics who claimed that the government was wasting money on irrational and inefficient rules advocated successfully within the executive branch for cost-benefit analysis as a policy tool. The cost-benefit criterion compels administrators to justify proposed rules as tending to produce gains that exceed losses.\textsuperscript{102}

The premise behind the requirement is that administrators would otherwise overregulate. Advocates of regulatory rollback have argued that when unchecked by constraints like cost-benefit analysis, bureaucrats write rules more burdensome than what rational, informed

\textsuperscript{97} An example of this success from my own long-concluded experience as a litigator: I used to defend personal injury claims for toxic shock syndrome, a disease attributed to tampons. Lawyers once specialized in this category of products liability work. Today, as a result of improved product design and well-written FDA-mandated warnings, tampon-associated toxic shock syndrome arises so much less often, and the decisional law about it has become so clear, that lawyers can no longer make a living prosecuting or defending these claims. Judges agree that claims of defective warning are preempted by compliance with the FDA script, see, e.g., Papike v. Tambrands, Inc., 107 F.3d 737, 740-41 (9th Cir. 1997); Nat'l Bank of Commerce v. Kimberly-Clark Corp., 38 F.3d 988-90 (8th Cir. 1994), but because of the absence of injuries and claims, a contrary understanding of preemption would leave manufacturers and consumers in the same position.


\textsuperscript{99} Id. § 804(2)(A).

\textsuperscript{100} Cindy Skrzycki, Reform's Knockout Act, Kept Out of the Ring, WASH. POST, Apr. 18, 2006, at D1.


\textsuperscript{102} See id. at 449-50.
governments and individuals would choose. This claim, which critics have contested vigorously, may be stated in less controversial terms: Rule-promulgating is the core business of an agency. Administrators who do not occupy themselves with the creation of new rules are relatively inactive.

These administrators have other activities as well. Accompanying the truism that “rulemakers make rules” is the proposition that individuals who head agencies seek to maximize their budgets. Anyone actively heading a federal agency would desire larger appropriations from Congress and want decisionmakers within the executive branch like the Office of Management and Budget to support the agency’s petition for more money. Finally, administrators who manage agencies actively will pursue public relations, understanding that media visibility tends to bolster taxpayer support for the mission. Administrators of any agency whose mission includes public safety will want recognition of its safety-enhancing efforts.

Vital signs like these have their antonyms. Reduced rulemaking activity, budgetary passivity, and a subdued public presence all manifest retreat from a regulatory agenda. Any agency that writes few or no major rules, or an exceptionally low number of non-major rules, is doing relatively little regulating. Lack of advocacy for budgetary largesse implies lack of participation in the regulatory endeavor. The public-visibility aspect of agency strength, though harder to quantify than the other two indicators, is amenable to observation of the agency head at work.

III. CONSUMER PRODUCT SAFETY AS AN INSTANCE OF IMPLIED REVERSE PREEMPTION

Evaluating consumer product safety in terms of implied reverse preemption calls for two steps of analysis. The first step, undertaken in the first section of this Part, looks for preemptive effects of federal statutes (focusing on the Consumer Product Safety Act) to show why readers of a statute might draw the inference of preemption and to explore the consequences of a retreat from preemption. The second section of the Part proceeds to evidence supporting an inference of retreat from preemption as manifested by both Congress and the Consumer Product Safety Commission.

103 See, e.g., id. at 448 (summarizing studies by John F. Morrall, Robert W. Hahn, and Tammy O. Tengs and John O. Graham).
104 See id. at 448-52.
105 See William A. Niskanen, Bureaucrats and Politicians, 18 J.L. & ECON. 617, 630 (1975); Shapiro & Schroeder, supra note 101, at 452 (noting “that agency heads seek to increase their budgets”).
A. Statutory Language Supporting an Inference of Preemption

Congress empowered the Consumer Products Safety Commission to regulate under several statutes: the CPSA, the Federal Hazardous Substances Act, the Refrigerator Safety Act, the Flammable Fabrics Act, and the Poison Prevention Packaging Act. Preemption is not an issue for three of the five. Because the Poison Prevention Packaging Act and the Refrigerator Safety Act have been invoked only rarely in personal injury litigation, a preemption defense has not emerged in decisional law. The Flammable Fabrics Act is settled, at least as of this writing, in the opposite direction: even though this statute contains a preemption clause, “the courts have ruled that [it] does not preempt products liability claims for flammable clothing.”

As for the Federal Hazardous Substances Act (“FHSA”), this statute authorizes the Commission to establish mandatory labeling requirements for certain chemicals marketed for household use. Cipollone v. Liggett Group, Inc., which in 1992 held that congressionally mandated words on cigarette packaging preempted tort liability, invites a similar interpretation of CPSC-decreed warning language, and so one might have predicted the pattern reported in the leading products liability hornbook: cases from the 1970s find no preemption and cases post-Cipollone find that the FHSA does indeed preempt. Because the FHSA gives the Commission authority to script acceptable warnings, courts interpreting this statute after Cipollone have found the inference of preemption straightforward.

Although its case law is sparse, the Consumer Product Safety Act presents a more varied preemption picture. The CPSA contains both express-preemption and savings clauses. Express preemption appears in the CPSA provision that no state may establish a safety standard or regulation about a consumer product if a federal safety standard issued under authority of the CPSA already addresses this risk.

107 Looking for cases, I found none where a defendant contended that a claim was preempted by the Refrigerator Safety Act and, on the Poison Prevention Packaging Act, I located only unpublished ones that provided little doctrine: Miles v. S.C. Johnson & Son, Inc., No. 00 C 3278, 2002 U.S. Dist. LEXIS 22695, at *18 (N.D. Ill. Nov. 22, 2002) (holding that the plaintiff’s claim was preempted by “nearly identical” language in the Federal Hazardous Substances Act and the Poison Prevention Packaging Act); Pinckney v. Zep Mfg. Co., No. 94-CV-0742, 1997 U.S. Dist. LEXIS 5172, at *19 (N.D.N.Y. Apr. 15, 1997) (conceding that the packaging statutes might preempt, but holding that they did not apply to the product in question).
108 OWEN, supra note 21, at 966 n.215.
109 Id. at 967.
111 Compare OWEN, supra note 21, at 967 & n.225, with id. at 967 & n.226.
112 See Davis, Unmasking, supra note 40, at 1028 (noting judicial confusion on this question).
113 See supra note 24 and accompanying text (noting that several federal statutes combine the two clauses).
of injury.\textsuperscript{114} Two savings clauses are also present in the statute. One clause saves remedies available under state law for violation of CPSA provisions.\textsuperscript{115} The second, more familiar, savings clause provides that compliance with federal consumer safety rules will not relieve a seller from liability at common law.\textsuperscript{116}

Since 2000, federal courts have used \textit{Geier v. American Honda Co., Inc.}\textsuperscript{117} for guidance in navigating the inclusion of these apparently contradictory preemption messages. Although \textit{Geier} ruled in favor of a seller-defendant, the opinion of the Court insisted that the presence of a savings clause in a statute mandates a narrow reading of preemption language: a broad reading would mean that “little, if any, potential ‘liability at common law’ would remain. And few, if any, tort actions would remain for the savings clause to save.”\textsuperscript{118} Thus, despite the failure of the plaintiff’s personal injury claim in \textit{Geier}, consumer-safety decisions that cite \textit{Geier} agree that the multiple clauses of the CPSA must preserve at least some tort liability.\textsuperscript{119}

Framing the CPSA preemption question in terms of \textit{Geier} means that courts must scrutinize the particulars of the plaintiff’s claim, which typically will allege a warning or design defect. If the remedy sought does not conflict with a regulation promulgated under the statute, then the claim is not preempted, and the plaintiff may seek redress in tort. If what the plaintiff seeks is at odds with federal consumer safety regulations, then the CPSA preempts the claim.

Courts applying the CPSA to particular complaints have reached different conclusions on preemption. Most of what might be called the lawnmower cases have concluded that the CPSA preempts claims of design defect and failure to warn.\textsuperscript{120} The other product-specific set of cases, attributing harm to cigarette lighters, has produced more mixed results.\textsuperscript{121} Presenting no unanimity on the question of preemption, in sum,

\begin{itemize}
\item \textsuperscript{114} 15 U.S.C. § 2075(a) (2006).
\item \textsuperscript{115} Id. § 2075(b).
\item \textsuperscript{116} Id. § 2074(a).
\item \textsuperscript{117} 529 U.S. 861 (2000).
\item \textsuperscript{118} Id. at 868.
\item \textsuperscript{120} See Moe v. MTD Prods., Inc., 73 F.3d 179 (8th Cir. 1995) (holding that warning claims but not design claims were preempted); Frazier v. Heckingers, 96 F. Supp. 2d 486, 491 (E.D. Pa. 2000) (holding that the CPSA preempts both design and warning claims); Cortez v. MTD Prods., Inc., 927 F. Supp. 386, 389 (N.D. Cal. 1996).
\item \textsuperscript{121} Compare Hittle v. Scripto-Tokai Corp., 166 F. Supp. 2d 142, 149 (M.D. Pa. 2001) (finding no preemption), and Colon, 136 F. Supp. 2d at 209 (same), with Ball v. BIC Corp., No.
decisional law does feature several judicial conclusions that the Consumer Product Safety Act, coupled with actions taken by the Consumer Product Safety Commission, can bar injured persons from bringing claims against product sellers.

B. Manifestations of a Lesser Federal Regulatory Interest

1. Amendments Marching Backward

Staffers at the Consumer Product Safety Commission recently prepared a list of amendments to the Consumer Product Safety Act enacted through 2008, in the form of an unofficial compilation. Of the ten pieces of legislation named, two pertain directly to implied reverse preemption: the 1981 amendments are most central, but amendments of 1976 are of interest as well. To show the arc of withdrawal, I review the 1976 and 1981 changes in chronological order.

The Consumer Product Safety Commission Improvements Act of 1976 achieved its “improvements” prominently by removing Commission authority to regulate tobacco and firearms. As early as 1973 it had been clear enough to then-professor Antonin Scalia and his co-author Frank Goodman that the Act did not give the Commission any power with respect to these two products, but the 1976 amendment took the form of an overt ban on CPSC authority. An anti-regulatory sentiment is manifest throughout the 1976 amendments, which widened the swath of preemptable state law: the original CPSA had encouraged uniformity via its express preemption clause but allowed state consumer regulation to differ from CPSC-authorized rules whenever the CPSC approved these state alternatives as amenable to co-existence. The 1976 amendments ordered the CPSC to deem such state regulations

4:97-CV-02467, 2000 U.S. Dist. LEXIS 19699, at *7-8 (E.D. Mo. Feb. 8, 2000) (holding that the plaintiff’s design claims were preempted, and that the warning claim failed for other reasons), and Frith v. BIC Corp., 863 So. 2d 960, 967 (Miss. 2004) (holding that design defect claim was preempted because the CPSC had issued cigarette lighter regulations that did not require the safety feature at issue), and BIC Pen Corp. v. Carter, 251 S.W.3d 500, 509 (Tex. 2008) (same).


123 Six of the others, being narrower or more modest in scope, do not bear on the question of retreat; the Consumer Product Safety Improvements Act of 1990 focuses mainly on reporting obligations and does not relate directly to tort liability; the 2008 Act is written as a congressional volte-face. See supra notes 4-11 and accompanying text.

124 Pub. L. No. 94-284, §§ 3(c), (e), 90 Stat. 503, 504 (1976).

125 Scalia & Goodman, supra note 13, at 902.

inconsistent when manufacturers’ economic difficulties with compliance were included in the “burden” these state regulations created.127

The maneuvers of 1976 show the need for a doctrine of implied reverse preemption. Implied reverse preemption perceives the difference between, on the one hand, a national scheme of safety regulation, which tort liability might obstruct and thereby harm public welfare and, on the other hand, an unprincipled gift of immunity to the injuring sector, which tort liability might also obstruct and thereby enhance public welfare. Mere enactments do not of themselves evince congressional occupation of a field or comprehensive regulation. As a judge can easily tell, the 1976 amendments did nothing to make consumer products safer. They took away from the CPSC regulatory authority over two products without giving this power to any other federal agency, and they squelched safety-fostering rules that states could otherwise have promulgated by adding an anti-safety economic-burden element to what the CPSC had to weigh when reviewing state regulations. Putting too much faith in the surface of the 1976 amendments—Look! The amendments extend federal control. Congress must have intended to preempt!—yields a wrong answer to the intent question. Implied reverse preemption, with its criteria for showing abandonment, repairs the error.

The Reagan-vintage 1981 amendments occupy the peak of congressional withdrawal from consumer product safety regulation. Declaring that the CPSC must do less and exercise less power, they display the retreat that is central to implied reverse preemption. Congress provided in 1981 that the CPSC could no longer write “requirements governing the contents, composition, design, construction, finish, or packaging of products.”128 Instead, it had to limit its standards to the domain of “performance, labeling, and warning.”129 Congress also prevented the Commission from releasing reports that manufacturers had provided about product hazards, removed amusement park rides from CPSC jurisdiction, and established a panel that had to be convened before the Commission could begin rulemaking about toxins.130

More notoriously, in the 1981 amendments Congress prohibited the Commission from promulgating mandatory rules. “Voluntary” standards became the regulatory mode of choice.131 Under this reform, rather than write a mandate, the Commission must publish an advance notice of proposed rulemaking and invite the submission of an existing

129 Id. (internal quotation marks omitted).
130 Adler, supra note 16, at 98 n.204.
131 Schwartz, supra note 12, at 70.
voluntary standard or the intent to draft one.\(^{132}\) Only when no adequate voluntary standard emerges or when industry fails to comply with voluntary standards may the Commission resort to a mandatory rule.\(^{133}\)

The legislative history of the 1972 statute had expressed scorn for voluntary standards as a source of consumer safety.\(^{134}\) According to the 1970 report that Congress commissioned, any voluntary standard that originated in an industry’s “consensus” about what would be good typically will amount to “little more than an affirmation of the status quo.”\(^{135}\) An earlier report by the Department of Health, Education and Welfare, also included in the legislative history, viewed mandatory safety standards as necessary to eliminating as much as twenty percent of household accidents.\(^{136}\) When it was young, the Commission habitually “expressed strong reservations about voluntary standards.”\(^{137}\)

It would be naïve to celebrate mandatory standards as desirable per se; they have had a problematic record in American consumer product safety. Writing in 1973 about the Commission’s administrative procedures, Scalia and Goodman described the extraordinarily cumbersome routes to mandatory rules that Congress had imposed on the fledgling agency.\(^{138}\) One especially burdensome process—a road probably paved with good intentions—banned the CPSC from writing its own mandatory standards; instead it had to receive petitions from the public (individual citizens, regulated industries, and dilettantes alike) that contained draft standards for its review.\(^{139}\) This “offeror” method of rulewriting, now gone, had the effect of compelling the Commission to dance to outsiders’ tunes, causing its second chairman, S. John Byington, to install new rules that streamlined the bulky procedures at the price of shifting more work onto petitioners.\(^{140}\) Thus, by the time Congress rejected mandatory standards in 1981, the CPSC had had negative experiences with such rules.

\(^{132}\) 15 U.S.C. § 2058(a)(5)-(6) (2006). Once it receives such a submission, the Commission is charged to assist in the development of voluntary standards. Id. § 2054(a)(3)-(4).

\(^{133}\) Id. § 2058(b)(2).


\(^{135}\) Id. at 1400 (quoting the Nat’l Comm’n on Prod. Safety, Final Report of the National Commission on Product Safety 62 (1970)).


\(^{137}\) Adler, supra note 16, at 94.

\(^{138}\) See Scalia & Goodman, supra note 13, at 908.


Arguably, then, the mandatory-to-voluntary shift could manifest mindfulness—a carefully chosen regulatory policy—rather than pathology. As one lawyer who advocates for manufacturers before the Commission recently argued, any agency with jurisdiction over many varied products will function more flexibly using voluntary industry standards, other things being equal.141 Proposed new federal rules, the only alternative type of administrative regulation, must clear “cumbersome notice-and-comment requirements.”142 A plenary mandate means that the Commission can have little comparative advantage as a writer of new product-specific regulations and thus can delegate rulemaking effectively to industry evaluations.143 Under this approach, the Commission abstains conscientiously from the writing of standards (rather than fails to write them) and intervenes primarily through its power to find a “substantial product hazard” warranting a recall order.144

To conclude that this mode of regulation supports a finding of implied reverse preemption is not to criticize the decisionmakers who choose it, nor the merits of any scheme that rests on voluntary standards. Undoubtedly both regulated sectors and Commission regulators could deploy the voluntary-standards method in good faith and with due regard for consumer welfare. The question for courts considering implied preemption, however, is not whether regulators are doing a bad job but whether the behavior of an agency bespeaks a retreat from overt intervention that had once been sufficient to indicate the occupying of a field or the imposition of a regulatory design incompatible with tort liability.145 Laissez-faire execution of a statutory mandate, whatever virtues it may offer, does not comport with field preemption or conflict preemption. Instead it manifests a plan to refrain from telling the regulated sector what to do. When such a plan is in place, tort liability fills the regulatory void, and to the extent it tells a manufacturer what to do, it defies no contrary orders from an agency or Congress. Taken as a whole, the Consumer Product Safety Amendments of 1981 identify federal regulation—rather than danger to consumers—as an ill to be eradicated. Tort liability becomes necessary whenever federal regulation is cast as problematic.

This necessity remains even when regulators praise the effectiveness of voluntary controls. In a 1995 report, the Commission claimed to have enjoyed “great success in working cooperatively with

142 Id.
143 See id.
145 See Wilson v. Bradlees of New Eng., Inc., 96 F.3d 552, 557 (1st Cir. 1996) (observing that “[f]ederal regulation may be a substitute for common-law liability; industry self-regulation is not”).
industry to develop voluntary standards."\footnote{U.S. CONSUMER PROD. SAFETY COMM’N, REGULATORY REFORM INITIATIVE—SUMMARY REPORT (June 1995), available at http://www.cpsc.gov/businfo/8005.html.} No better route to consumer safety, it asserted: “Indeed, the Commission has found that with the products it regulates, negotiating such standards can be far more efficient than rulemaking or even negotiated rulemaking.”\footnote{Id.} Perhaps. This Article has no ideological quarrel with standards that industries write to govern themselves; such precepts might function better than mandatory rules.\footnote{Id.} Used to suppress personal injury claiming, however, voluntary standards obstruct the entitlements of all who did not consent to them and could otherwise bring tort actions. In function these standards become just as mandatory as they are voluntary. Courts cannot escape the inference of compulsion; faced with preemption disputes in the context of consumer safety, they can weigh in on the “mandatory” question only by determining who will be compelled, manufacturers or the persons alleging injury from defective products. The libertarian 1981 amendments are coercive indeed without a doctrine of implied reverse preemption to ameliorate what they compel.

2. Defunding

By whatever metric a court might apply—absolute defunding, relative defunding, funding insufficient to meet the agency’s statutory mandate, perhaps even defunding to the point of dysfunction—appropriations to support the Consumer Product Safety Commission were too low to sustain an inference of preemption for the period 1981 to 2008. Though less dramatic than the statutory retreat of 1981, the appropriation pattern of that same year lends further support to an inference of reverse preemption. Fiscal year 1982 manifested a shrunken budget for the CPSC: the Commission had to close offices and retrench its operations.\footnote{Eliot Klayman, Comment, Standard Setting Under the Consumer Product Safety Amendments of 1981—A Shift in Regulatory Philosophy, 51 GEO. WASH. L. REV. 96, 98 & n.15 (1982).} The ideology ascendant in the early 1980s—deregulation coupled with tax cuts to “starve the beast”\footnote{For a summary of this ideology as put into effect in 1981, see Jon Margolis, Reagan Revolution Stronger Now than During Presidency, Chi. TRIB., June 6, 2004, at Cl.}—helped to impose a view that one writer has described, with a straight face, as “Let the Market Protect Consumer Safety.”\footnote{Hood, supra note 19.}
Commission funding never regained the level of the benchmark year 1974. In 1997, the General Accounting Office (“GAO”) studied the appropriation of money to the CPSC and how the agency used these funds. During that year, the CPSC budget was $42.5 million, and the agency employed 480 full-time equivalents. The GAO calculated that these numbers represented a 60% drop in funding (adjusting for inflation) and a 43% cut in the staff compared to 1974. The Commission had noted with pride in 1994 that it had the same budget (unadjusted) that it had in 1979.

Flat levels of appropriation and staffing for the CPSC represent a retreat from regulation because “since 1974, many of the industries the CPSC regulates have experienced explosive growth.” Injury rates too have increased: for example, “toy-related injuries [went] from about 130,000 in 1996 to about 220,000 in 2006,” a rise that exceeds the concomitant growth in population. Similarly, the rise in deaths associated with all-terrain vehicles, “from 55 in 1985 to 734 in 2004,” far exceeds their rise in sales.

Reductions in federal budgets result from a combination of lessened inclination among legislators to appropriate money and lessened agency requests. Negotiations among the CPSC, the Office of Management and Budget, and congressional committees yield each annual appropriation. Courts attuned to the negotiation dynamic can conclude that reduced appropriation for an agency may bespeak not only congressional retreat but an agency’s disinclination to spend money on regulation. Observed through this lens, the CPSC at least cooperated with, and may have hastened, the decline in congressional funding that supports an inference of reverse preemption.

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152 “From FY 1974, when the agency first became fully operational, to FY 2008, CPSC’s budget has been cut almost 40 percent when adjusted for inflation.” OMB Watch, Product Safety Regulator Hobbled by Decades of Negligence, Feb. 5, 2008, http://www.ombwatch.org/article/articleview/4154/1/527 [hereinafter OMB Watch].

153 FELCHER, supra note 36, at 195.

154 Id.

155 Id.


157 FELCHER, supra note 36, at 195. Sectors that have burgeoned since the 1970s include home improvement equipment (marketed through the Home Depot chain, which grew enormous over those years), recreational equipment like snowmobiles and scooters, and items used to transport small children. Id.

158 OMB Watch, supra note 152.

159 Id.; see also Robin Ingle, Which Toys are Okay? Don’t Ask the Safety Police, WASH. POST, Dec. 24, 2007, at B3 (observing, from an inside-the-agency perspective, that by 2004 “[d]eaths and injuries [from all-terrain vehicles] had grown to such alarming numbers that my supervisor [at CPSC], a meticulous statistician, asked me to recalculate them several times”).

160 Weintraub interview, supra note 85.
3. Almost No Strong Rules

We have seen that two adjectives modify the word “standards” or “rules” to connote heft: “mandatory” and “major.” Rules in the mandatory category indicate that the Consumer Product Safety Commission deems the danger too strong for rulemaking by industry consensus. Rules in the major category have a significant effect on the economy. Both adjectives are vanishingly rare in the annals of consumer safety rulemaking from 1981 to 2009.

When the Consumer Product Safety Commission was formed, its first chairman, Richard Simpson, predicted that the Commission would promulgate about a hundred mandatory standards during its early years. Commissioner Simpson was off by a factor of about a hundred. Agency frustration with the mandatory-standard approach can account for only part of this slender record.

Over its entire history, the Consumer Product Safety Commission has written only one rule that falls into the “major” category: a rule on mattress flammability promulgated in 2006. Given the wide jurisdiction of the agency—“consumer product” describes many things, even after retrenchments from the original statutory language—it is hard to suppose that no other hazard belongs in the $150 million category. An output this slender shows a disinclination to write important rules.

4. Lassitude in Leadership

Torpor at the Consumer Product Safety Commission before the 2008 amendments exudes from the public behaviors of commissioners and those who appointed them. The two years preceding the 2008 legislation are particularly salient: in this period the Bush administration manifested its lack of interest in robust regulation of consumer safety. When the chairman of the CPSC, Hal Stratton, left the agency in 2006 to join “a law firm that specialize[d] in attacking class-action lawsuits filed by consumers,” the President did not appoint anyone to replace him,

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161 See supra text accompanying notes 131-133 (noting the exceptional status of mandatory rules in contemporary CPSC rulemaking); text accompanying notes 99-102 (describing major rules as classified in the Congressional Review Act).
162 Schwartz, supra note 12, at 44.
163 Felcher, supra note 36, at 29-30 (noting that by 1977 the Commission “had issued only three mandatory standards”).
164 See id.; see also supra notes 138-140 and accompanying text.
165 See infra notes 178-186 (discussing this rule).
166 See Schwartz, supra note 12, at 42-43 (noting “expansive jurisdiction” of the statute and reporting estimates that the CPSC regulates about “ten thousand consumer products and over a million producers and sellers of such products”).
and left office without having named a chairman. 168 Starting in January 2008, until a stopgap in August 2008 was set up to run for the remainder of the calendar year, the CPSC lacked a quorum of commissioners and was thus precluded from doing much of its work. President Bush nominated an employee of the National Association of Manufacturers to one of the Commission’s vacant seats; this nominee withdrew two months later when members of the Senate insisted on seeing his severance agreement from this defense-side lobby.169

This void at the Commission is sufficient of itself to evince an absence of field preemption or conflict preemption—that is, emptiness signifies inaction—and the public behaviors of its chairman during this period confirm the inference. It bears mention that regulators working in an era suspicious of regulation are under pressure not to look like zealots.170 That said, a CPSC commissioner can stick out as especially disinclined to regulate.

The CPSC chairman holding office at the time of this writing embodies such disinclination. Back in 2007, when Congress began to plan its increased appropriations for consumer safety, Nancy Nord declared she did not want what a news story at the time called “more money and more power.”171 A Senate panel had proposed to increase the agency’s budget from $63 million to nearly $142 million in 2015 and raise its cap on penalties from $1.8 million to $100 million. 172 The commissioner “said thanks but no thanks to the Senate’s offer.”173 She wrote two letters to members of the Senate Commerce Committee, asking them “not to approve the bulk of legislation that would increase the agency’s authority, double its budget and sharply increase its dwindling staff.”174

168 See William M. Welch, Lead Law Throttles Youth Powersports, USA TODAY, Feb. 17, 2009, at 3A (reporting information announced to the media by the chief of staff to the acting chairman). In May 2009, when this Article was going to press, President Barak Obama named Inez Moore Tenenbaum as chairman and Robert S. Adler, a scholar of product safety regulation, as commissioner. Andrew Zajac, Head of Product Safety Is Named, L.A. TIMES, May 6, 2009, at B4; see also supra note 16 (citing Adler’s work on the CPSC).


170 One chairman appointed by President Clinton and remembered as a consumer activist, Ann Brown, mentioned early in her tenure that “being an advocate and being a regulator are very different, and they should be. I have to bring all the disparate interests together. I can’t just be advocating for any one group.” Julie Gannon Shoop, The New, Improved CPSC: Under Ann Brown, A Consumer Protection Revival, TRIAL, Sept. 1, 1994, at 22 (reporting an interview with Brown).

171 Lazarus, supra note 167.

172 Id.

173 Id.

174 Stephen Labaton, Bigger Budget? No, Responds Safety Agency, N.Y. TIMES, Oct. 30, 2007; see also id. (noting that the Commission had only one employee to test toys and only 15 inspectors handling imported consumer products, “a marketplace that last year was valued at $614 billion”).
The acting chairman made artful arguments against the proffered largesse. She did not say that she found the prospect of actually regulating anyone to be repugnant. Instead she spoke about agency expertise and unintended consequences. The whistleblower protection provision would, she protested, give the CPSC a “dramatic and unprecedented mission.”175 The proposed increase in penalties would motivate manufactures to blanket the CPSC with self-protective documentation. Both new powers—apparently, any new powers—could have the perverse effect of “hampering, rather than furthering consumer product safety,” she said.176 She also protested the absence of immediate appropriations to fund the expanded mandates, even though Congress always mandates first and funds second.177

Similar resistance to overt regulatory effort—if not out-and-out bad faith—emerges from the Commission’s long-awaited 2006 standard for mattress flammability.178 Here the Consumer Product Safety Commission practiced preemption by preamble, a measure that Congress banned two years later.179 One commentator describes the wording of this preemption statement as “expansive.”180 It was more than expansive; it was something of an ambush. In January 2005, the CPSC issued a far blander preamble in its Notice of Proposed Rulemaking.181 Both the January 2005 and the March 2006 notices in the Federal Register discuss preemption, as federal agencies must when they announce purposed new regulation;182 but whereas the 2005 notice purported only to summarize the existing effect of rules and standards created pursuant to the Flammable Fabrics Act,183 in 2006 the Commission wrote that it “intends and expects that the new mattress flammability standard will preempt inconsistent state standards and requirements.”184 It included “common law” as a source of such inconsistent input from the states,185 and deplored the possibility that “each state could use its tort law to enforce whatever flammability standard it deemed appropriate, potentially creating fifty different mattress fire standards across the nation.”186

175 Stephen J. Hedges, Toy Recalls Spur Call for Ouster, CHI. TRIB., Oct. 31, 2007, at Cl.
176 Id.
177 Lazarus, supra note 167.
179 See infra note 190-192 and accompanying text.
180 O’Loughlin, supra note 141, at 1038.
185 Id.
186 Id. at 13,497.
The 2008 amendments to the statute articulated a clear position on preemption-by-preamble that suggests 2008 was indeed a turning point.\textsuperscript{187} Under Section 231 of the Consumer Product Safety Improvement Act, the Commission and all other administrative units of the federal government writing rules pursuant to the CPSA, the Federal Hazardous Substances Act, and the Flammable Fabrics Act may not practice “preemption by preamble.”\textsuperscript{188} Congress drew up a comprehensive list—“any preamble, statement of policy, executive branch statements, or other matter associated with the publication” of a rule—of administrators’ devices that have been misused to declare a preemptive effect.\textsuperscript{189} The statement amounts to an “admonishment from Congress.”\textsuperscript{190} Implicitly it recognizes the dangers of preemption-by-preamble assertion. By repudiating this technique, Congress expressed its skepticism about the value of preempting tort claims. The statutory prohibition directs courts to infer preemption more parsimoniously post-2008 than did the courts willing to cede preemption-power to agency statements.

Observers investigating the CPSC for signs of withdrawal from regulation might also consider the informed impressions of a recently departed employee who left the agency saddened (rather than, as she noted, “disgruntled”).\textsuperscript{191} One year before the 2008 volte-face, a former statistician for the CPSC published an editorial in the \textit{Washington Post} claiming that the agency had “lost the will to perform the function it was created for.”\textsuperscript{192} To say that an entity has lost the will for something is hard to document: the writer, Robin Ingle, met the challenge with a couple of telling anecdotes from the office. In 2004, after Ingle documented an astounding rise in all-terrain vehicle (“ATV”) deaths, the general counsel of the agency, who happened to have been a former lawyer for the industry, first tried (unsuccessfully) to get two CPSC statisticians to modify the presentation of data and then declined to release the report for three months. According to Ingle, CPSC employees circa 2007 labor inside “a defeatist anti-regulation atmosphere,” where no matter which product one worked on—ATVs, portable heating generators, hydroxides that poison children—individual efforts were impeded by industry resistance to rulemaking and even basic research on safety.\textsuperscript{193}

\textsuperscript{187} See supra note 1.
\textsuperscript{190} O’Loughlin, supra note 141, at 1038-39.
\textsuperscript{191} Ingle, supra note 159.
\textsuperscript{192} Id.
\textsuperscript{193} Id.
CONCLUSION

The doctrine of preemption as applied in federal courts contains a troubling asymmetry: Courts regularly infer that Congress intended to forestall tort liability, but have not been willing to infer that Congress, later on, abandoned this old intent. A longstanding tradition in accident law encourages judges (and juries) to examine circumstantial evidence in order to draw plausible conclusions.\(^{194}\) Consumer safety offers an illustration of what courts should be inferring: Strong circumstantial evidence supports the inference that no later than 1981, Congress and the Consumer Product Safety Commission jointly weakened federal consumer safety law. During a period of years that may have ended in 2008,\(^ {195}\) any inference that the 1973 statute preempted tort liability—the only other law-based source of consumer safety—became no longer tenable.

I conclude with two anxieties about, and one extension of, the thesis of this Article.

Anxieties first. The Consumer Product Safety Act and Consumer Product Safety Commission present a strong illustration of implied reverse preemption—perhaps too strong, in that it may set the bar too high. Should courts come to see CPSA-levels of retreat as necessary to reverse a preexisting inference that had precluded state tort liability, several difficulties ensue. Parties and their lawyers will forfeit certainty about the presence of implied reverse preemption vel non. Judges will share in this uncertainty. Perhaps worse, it will become relatively easy for both members of Congress and agency administrators who want to foreclose tort liability to feign stronger commitments to federal regulation than they really hold. Recall the announcements by the acting chairman of the CPSC that Congress should decline to appropriate the money and power it had offered the agency.\(^{196}\) This individual, Nancy Nord, disclaimed her regulatory power transparently. Fearing implied reverse preemption, a savvier successor-bureaucrat could probably come up with a more convincing gesture toward real regulation while stymieing the agency’s mission as laid out in the statute. Other criteria proposed here are vulnerable to the same tactic.\(^{197}\) Congress has also feigned regulatory vigor. Courts inferring a retreat from preemption must proceed forewarned that the paradigm explored in this Article presents an instance of the phenomenon, rather than a set of tests and hurdles. What

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194 See DAN B. DOBBS, THE LAW OF TORTS 372 (2000) (explaining that although res ipsa loquitur is a form of circumstantial evidence, negligence law is replete with other circumstantial inferences).
195 See supra note 20 (expressing uncertainty about whether 2008 marks a distinct end).
196 Asked to name a power that her agency had and that she actually wanted, Commissioner Nord named only an obscure one, the prerogative to seize assets of companies convicted of crimes. Hedges, supra note 175.
197 See supra note 127 and accompanying text (summarizing the 1976 amendments to the CPSA, which appear busy but retreat from regulation).

Another peril presented in implied reverse preemption that could diminish safety is what the philosopher Albert Hirschman called “perversity” and “jeopardy”\(^{198}\)—here the possibility that this reform would extinguish more tort liability than it can preserve. Implied reverse preemption protects or revives personal injury claims that defendants could otherwise get dismissed as preempted. Fairness as parity between injured persons and product sellers suggests that sellers should lose access to shelter that only they now enjoy. In principle, implied reverse preemption puts plaintiffs and defendants on a level playing field, where each can benefit or suffer from judicial inferring. But just as a Congress desirous of reducing tort liability can feign regulation by appearing to empower an agency, it can also use the federal commerce power to abrogate state regulation altogether\(^{199}\)—and thereby extinguish tort liability, if courts agree that tort liability remains a form of state regulation. Congress has already eliminated whole categories of products liability from the reach of state courts.\(^{200}\) Risk-adverse defenders of tort liability might prefer to take their chances with preemption as it now exists, which the Supreme Court occasionally deems no obstacle to plaintiffs,\(^{201}\) rather than seek a pro-plaintiff rewrite that might tempt Congress to wipe out products liability categorically.

This misgiving noted, implied reverse preemption is desirable even at the level of trench-war realpolitik. Like Betsy Grey, who faced a similar dilemma when she proposed to “make Congress speak clearly” every time it wants to preempt,\(^{202}\) I hope that compelling candor on the part of Congress would permit liability to coexist with codified regulation as a source of safety. Over the years since the tort reform movement began, Congress has declined to enact more proposed curbs

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\(^{198}\) See Albert O. Hirschman, The Rhetoric of Reaction: Perversity, Futility, Jeopardy 133 (1982); see also supra notes 172-176 (reporting the protestations of CPSC chairman Nancy Nord, to the effect that giving the agency more money and prerogatives would lower consumer safety).

\(^{199}\) Winokur & Robbins, supra note 106, at 233-35 (citing Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1 (1824)).


\(^{202}\) Grey, supra note 21.
on liability than it has codified. Should this pattern come to an end, and comprehensive liability-killing legislation enter the United States Code, I doubt that judicial recognition of retreats from preemptive intent will be the culprit. A doctrine of implied reverse preemption is more likely to foster awareness within Congress of the relation between its work product (for this purpose, new statutory language and appropriations) and liability.

Now, the more radical extension. Like implied preemption, the doctrine of implied reverse preemption has what I have called markers. Judges would frame and apply criteria for this legal conclusion just as they have framed and applied criteria for the conclusion of preemption. I have suggested a few available to courts, nominating two broad categories: amendments that move away from an earlier regulatory agenda and de-funding of the agency empowered to enforce safety statutes.

Markers from Congress—though inadequate as currently used for implied preemption—are a source of transparency and fairness for implied reverse preemption. As a matter of due process, manufacturers are entitled to notice about any shift in their status that removes an affirmative defense. Whenever old conclusions of preemption that had once sheltered them are no longer present, they have a right to know. Injured persons and their lawyers are entitled to the same information. Under a judicial regime that accepts implied reverse preemption, these persons and entities would keep alert to the indicators of retreat that Congress can manifest: amendments moving away from old regulatory agendas and de-funding of the agencies authorized to regular under federal statutes. Attorneys for both plaintiffs and defendants will know when the ground has given way under a preemption fortress.

The central criterion of intelligibility would also permit another application of the implied reverse preemption doctrine, one available to judges who accept the thesis of this Article. I have argued that any court competent to infer preemption is also competent to infer a retreat from preemption. The same competence can alter express preemption. As was noted, the line between express preemption and implied preemption is not bright: when the Supreme Court finds express preemption in a statutory clause that prohibits contrary state regulation, it uses inference, rather than explicit language from Congress, to deem tort liability a form of regulation. Nuance and ambiguity, in other words, are present in express preemption as well as implied preemption. Implied reverse

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204 See supra Part III.B.

205 See supra note 30 and accompanying text.

preemption could empower judges to return to old holdings that tort liability is expressly preempted, inferring from circumstantial evidence that a clause in a statute forbidding inconsistent state regulation has lost its inferred meaning of “no tort liability,” and so a personal injury claim can proceed. This mode of reading statutes places language once deemed as expressly preemptive within reach of judicial reinterpretation.207

A decision by the United States District Court of the District of Massachusetts provides an example of how judges can give effect to a congressional retreat from express preemption. In Andrews-Clarke v. Travelers Insurance Company,208 “one of the classic broadsides” against preemption by the Employee Retirement Income Security Act of 1974 (“ERISA”),209 the court noted with regret that Congress had expressly preempted the tort and contract claims that the plaintiff tried to bring.210

“Congress intended to relieve employers and ERISA plans from the burdens of compliance with conflicting state laws not as an end in and of itself,” wrote Judge Young, “but rather as a means to promote the principal object of ERISA as a whole,” i.e. protecting plan participants.211

Back in 1974, according to Judge Young, “ERISA did provide an adequate remedy for the wrongful denial of health benefits. The present gap in remedies is therefore attributable . . . to the failure of Congress to amend ERISA’s civil enforcement provision to keep pace with the changing realities of the health care system.”212

Implied reverse preemption recognizes, as did Judge Young, the existence of “changing realities”213 that render obsolete an earlier conclusion that Congress cut off, expressly or by implication, the opportunity for an injured person to seek redress in a state court. Diane Andrews-Clarke had to do without a remedy for the harm she suffered; Judge Young implored Congress to modify what he called “a law that has gone conspicuously awry from its original intent,” adding, “Does anyone care? Do you?”214 This Article has argued that Judge Young had in his hands the interpretive tool for which he longed. Any power to draw an inference favoring defendants necessarily includes the power to draw an inference favoring plaintiffs.215

Judicial determinations of preemption not only may, but should, evolve in response to new circumstantial evidence that Congress has lost

207  See generally ESKRIDGE, supra note 46 (arguing that the meaning of statutory language can change over time).
209  E-mail from Anthony Sebok, Professor of Law, Benjamin N. Cardozo School of Law, to author (Feb. 16, 2009) (on file with author).
210  Andrews-Clarke, 984 F. Supp. at 55–56;
211  Id. at 58.
212  Id.
213  Id. at 53.
214  Id. at 65.
215  I thank Tony Sebok not only for alerting me to Andrews-Clarke but for adding a cogent analysis.
its earlier desire to thwart tort liability. What Peter Schuck has called “the sweet spot”\textsuperscript{216}—a balance between tort and administrative rules as a regulatory design—varies in response to what Congress, exercising legislative supremacy, installs. Courts attuned to this balance will find implied reverse preemption just as fundamental as preemption.

\textsuperscript{216} Schuck, \textit{supra} note 65.
The Tort-Proof Plaintiff

THE DRUNK IN THE AUTOMOBILE, CRASHWORTHINESS CLAIMS, AND THE RESTATEMENT (THIRD) OF TORTS

Ellen M. Bublick

State courts face a difficult challenge when they review crashworthiness claims that arise in conjunction with drunk driving. Under ordinary doctrines of crashworthiness, if a product defect causes enhanced injury, the product seller is subject to liability for the enhanced portion of the injury. For example, if an airbag fails to deploy during a car accident, the car maker may be required to compensate for increased injury caused by the defect.

At the same time, courts are increasingly asked to apportion responsibility among all tortfeasors involved in a single injury. Although apportionment traditionally included only negligent torts, in the last decade a growing number of states have expanded the divisors to include strict liability, recklessness, and even intentional torts.

In a claim involving both crashworthiness and drunk driving the two sets of doctrines—crashworthiness liability and comparative apportionment—appear set for a collision course. The liability that one doctrine provides, the other takes away. The mechanism through which this conflict is created works as follows: juries in crashworthiness cases involving drunk drivers are asked to determine the defendants’ liability to the plaintiff, but also are asked to compare the responsibility of the car maker that produced the defective airbag with that of the drunk driver.

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1 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 16(a) (1998). In certain cases, if proof does not support determination of the enhanced harm, the manufacturer may be liable for all of plaintiff’s harm. Id. § 16(e).

2 See, e.g., Estep v. Mike Ferrell Ford Lincoln-Mercury, Inc., 672 S.E.2d 345, 355 (W. Va. 2008) (holding that evidence by engineer was sufficient to support finding that truck in which airbag failed to deploy during accident was defective); Batiste v. General Motors Corp., 802 So. 2d 686, 689-90 (La. App. 2001) (holding that expert testimony was required to show that properly functioning airbag would have deployed and res ipsa loquitur did not apply).

who caused the initial accident. Given a comparative metric that uses fault as a central measure\(^4\) and requires zero-sum trade-offs of responsibility, the moral blame inherent in a reckless tort like drunk driving may simply swamp the apportionment process. Even if a jury finds that the manufacturer’s product is not crashworthy and that the defective product led to enhanced injury, the product seller’s liability may be buried under the moral blame assigned to the drunk driver in the apportionment.

Accordingly, crashworthiness cases involving drunk drivers present one instance of a crucial but newly configured challenge in tort law: how to preserve the structural accountability of negligent and strictly liable tortfeasors within an apportionment system that is not only dominated by several liability, but for the first time in the long history of tort law, apports responsibility not only to negligent actors but to strictly liable, reckless, and intentional wrongdoers as well.

The problem of preserving structural accountability after strict liability, reckless, and intentional torts are added to the comparative apportionment mix is not a problem exclusive to the case of the drunk driver and the automobile.\(^5\) Indeed, the concern permeates many contexts in which the high moral blame of one actor can unmake the systemic responsibility for care of another.\(^6\) Nevertheless, vanishing structural liability—creating tort-proof plaintiffs through apportionment—is well-illustrated by and inadequately addressed in this setting.

The term “tort-proof plaintiff” recalls an analogous doctrine from mid-1970s defamation law: the libel-proof plaintiff. The libel-proof plaintiff was a person whose reputation was so poor that even actionable false and defamatory statements heaped on could not count as extra damage.\(^7\) When a drunk driver is the crashworthiness plaintiff, the tort-proof plaintiff analogy is most complete. When the plaintiff’s misconduct is highly blameworthy in itself, as in the case of drunk driving, why should even actionable manufacturer negligence give rise to a cause of action to any significant degree? The answer, of course, depends on the nature of the interest that the tort law seeks to protect. Are crashworthiness protections designed to benefit all drivers and passengers, even the negligent and reckless, or only those drivers and passengers who are exercising reasonable care for themselves?

An extra wrinkle makes apportionment’s tort-proof plaintiff more difficult to dismiss than her defamation-proof kin. The tort-proof plaintiff in a crashworthiness case may not be the drunk driver, but rather the innocent victim of that driver. Even when the plaintiff with the failed

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airbag is the victim of the drunk driver, the plaintiff may find that, with respect to the manufacturer, she is tort-proof. Actionable misconduct of the manufacturer that causes the plaintiff injury, even severe injury, may not afford the plaintiff any significant cause of action against the manufacturer after responsibility has been apportioned.

This result—recognizing crashworthiness liability but then realizing it only to the extent that the high moral blame of a drunk driver does not lay it to rest in the apportionment process—is not prescribed by any single legal rule, but rather stems from a combination of separate products liability rules and comparative apportionment rules. In fact, this combined approach appears to hold sway from the face of the three completed projects of the Restatement (Third) of Torts.

Yet courts concerned about preserving crashworthiness liability have crafted a doctrine that avoids apporting away that liability. Specifically, in the ten years since the Restatement (Third) of Torts: Products Liability (“Restatement Third of Products”) was adopted, several state courts have embraced a doctrine that refuses to apportion liability between the crashworthiness defendant and the driver who occasioned the original crash.

In this Article, I argue that this court-created doctrine of non-apportionment preserves the structural liability of manufacturers and provides incentives for baseline safety protections for product users as a whole. Courts have embraced the doctrine in two related but distinct contexts of crashworthiness and apportionment: cases in which a drunk driver hits the crashworthiness plaintiff and cases in which the drunk driver is the crashworthiness plaintiff. Each context raises somewhat different concerns and will be addressed in turn.

Although state court decisions that refuse to apportion responsibility between those responsible for initial and secondary collisions appear on their face to reject the Restatement (Third) of Torts, at a deeper level, the decisions are quite consistent with Restatement principles. In particular, the state court decisions reflect two important types of ameliorative rules incorporated into the Restatement (Third) of Torts: Apportionment Liability (hereinafter Restatement Third of Apportionment) after the Restatement Third of Products was enacted—

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8 See, e.g., D’Amario v. Ford Motor Co., 806 So. 2d 424, 427-28, 431-33 (Fla. 2001) (per curium) (acknowledging that the majority view is that “the fault of the plaintiff or a third party in causing the initial accident is recognized as a defense to a crashworthiness case against a product manufacturer”).

9 The term “Restatement Third of Torts” refers collectively to all of the segments of the Restatement (Third) of Torts project. As of 2008, those projects include the Restatement (Third) of Torts: Products Liability, the Restatement (Third) of Torts: Apportionment of Liability, and the Restatement (Third) of Torts: Physical and Emotional Harm.

10 Gianinni v. Ford Motor Co., No. 3:05CV244 (SRU), 2007 WL 3253731, at *3-*4 (D. Conn. Nov. 2, 2007) (holding that plaintiff negligence that leads to the underlying accident should not be available as a comparative fault defense to a crashworthiness claim); D’Amario, 806 So. 2d at 433-35 (reviewing the reasoning behind cases that do not apportion between initial causes of the accident and crashworthiness claims and adopting the view that refusing to apportion is preferable).
defendant “very duty” rules and plaintiff “no-duty” rules. Defendant “very duty” rules define a defendant’s duty to use reasonable care to protect against specific types of risk. Plaintiff “no-duty” rules limit defenses of plaintiff comparative negligence based on special reasons of principle or policy.

Rather than urge courts to conform their decisions to the facially applicable doctrines of the Restatement (Third) of Torts, this Article urges the Restatement (Third) of Torts to confront more systematically the structural accountability issues that lie at the intersection of the Restatement projects but may have fallen in between them.

I. PRESERVING STRUCTURAL LIABILITY: MANUFACTURER CRASHWORTHINESS ACCOUNTABILITY TO THE VICTIM OF THE DRUNK DRIVER

Perhaps the case that best illustrates the problem with the Restatement (Third) of Torts approach to comparative apportionment in crashworthiness cases is the Florida Supreme Court case, D’Amario v. Ford Motor Co. That case examined two consolidated claims. One was a claim filed by Maria Nash, who was driving to church with her two children when a drunk driver crossed over the center line and crashed head-on into her vehicle. Because the seatbelt in her Chevy Corsica failed, Nash’s head struck a metal post that separated the windshield from the driver’s door. Nash later died from her injuries.

Nash’s estate sued General Motors, the maker of her car, for “a design defect which had been discovered in the seatbelt of the 1990 Chevrolet Corsica.”

At trial against GM on the crashworthiness claim, Nash’s estate sought to exclude evidence of the other driver’s .15 blood alcohol content. According to the estate, the driver-intoxication information was irrelevant and prejudicial to the jury’s consideration of comparative fault. Despite the estate’s objection, the trial court ruled that the jury should apportion responsibility between General Motors and the drunk driver who hit Ms. Nash. Given this mandate to apportion responsibility, the court found that the jury should be permitted to hear evidence of the driver’s intoxication. When presented with that evidence at trial, the jury found no liability on the part of General Motors. On appeal, the estate

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13 806 So. 2d 424 (Fla. 2001).
14 Id. at 426-30 (addressing the claims of Clifford Harris and Maria Nash).
15 Id. at 429.
16 Id.
17 Id.
18 Id. at 429-30.
argued that the evidence of the other motorist’s intoxication had been “unduly prejudicial to the issue of whether General Motors was negligent in designing a defective seatbelt.”

Before discussing the Florida Supreme Court’s disposition of the case, it is useful to examine the *Restatement (Third) of Torts* approach to the problem. That approach to apportionment in crashworthiness cases bridges two separate segments of the *Restatement (Third) of Torts* project—the *Restatement Third of Products* and the *Restatement Third of Apportionment*.

The *Restatement Third of Products* adopts crashworthiness liability of manufacturers. When a product is defective at the time of commercial sale and the defect is “a substantial factor in increasing the plaintiff’s harm beyond that which would have resulted from other causes, the product seller is subject to liability for the increased harm.”

In cases in which harm is caused by multiple actors, as it nearly always is in crashworthiness cases, the *Restatement Third of Products* then provides a structure for two types of apportionment. First, causal apportionment is undertaken when proof supports a determination of the harm that would have resulted from other causes in the absence of the product defect. When causal apportionment cannot divide the harms, the crashworthiness defendant is either jointly and severally liable or severally liable for the harms, in accordance with the rules of the applicable jurisdiction. Next, the *Restatement Third of Products* leaves further apportionment of responsibility among multiple defendants to “generally applicable rules apportioning responsibility.” Those generally applicable rules of apportionment can be found in the *Restatement Third of Apportionment*. The *Restatement Third of Apportionment* instructs courts to apportion “responsibility” between all causes of action—intentional, reckless, negligent or strict liability—according to a metric that compares fault and causation.

Given these combined rules, if a court wanted to follow the *Restatement (Third) of Torts* in *Nash*, it would first segregate any harm that the defendant could prove was attributable only to the drunk driver and not the manufacturer—harm that would have occurred even if Ms. Nash’s seatbelt had not failed. Liability for that harm would be assigned to the drunk driver alone. Then harm caused by both the drunk driver’s collision and the seatbelt’s failure—apparently, the plaintiff striking her head against the car and her ultimate death from the head injury—would.

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19 Id. at 430.
21 Id. § 16(a).
22 Id. § 16(b).
23 Id. § 16(d).
24 id. § 17.
25 *Restatement (Third) of Torts: Apportionment of Liab.* § 1 cmts. b, c (2000); id. § 8.
be left to local rules of joint and several or several liability. In most jurisdictions, including Florida, several liability typically would apply.\textsuperscript{26} Accordingly, whatever percentage of the remaining responsibility was assigned to other parties in the action, GM would not be required to pay.

With respect to the responsibility apportionment, the Restatement Third of Apportionment would in turn advise a jurisdiction to compare the responsibility of all actors involved in the crash, whether strictly liable, negligent, reckless, or intentional.\textsuperscript{27} Under this approach, a jury would be instructed to hear evidence regarding each party’s fault and assign percentages of responsibility for the harm in turn. In this case, the jury would assign responsibility to the drunk driver and the car manufacturer respectively. These percentage assignments would be required to equal 100%. The factors that the jury would be instructed to use in its responsibility assignment include “the nature of the person’s risk creating conduct” and “the strength of the causal connection” between that conduct and the harm.\textsuperscript{28}

After testimony, the jury might assign percentages of responsibility to the two defendants in a few different ways. First, a jury asked to weigh the risk-creating conduct of drunk driving against the risk-creating conduct of negligent seatbelt design or manufacture might assign most or all of the responsibility to the reckless drunk driver based on a calculus of moral blame. The zero-liability ruling in \textit{Nash} may have been a result of such a comparative calculation. Of course, the reverse is also possible. A jury could assign more responsibility to the manufacturer responsible for the car’s defect than it did to the drunk driver. In either scenario, the apportionment result presents some significant problems.

If juries weight apportionments heavily toward the morally blameworthy misconduct of drunk driving, apportionment becomes a back-door route to eliminate crashworthiness liability in a significant percentage of cases. Just how significant the apportionment-based reduction might be is suggested by Center for Disease Control estimates that drunk driving causes nearly a third of all vehicle fatalities.\textsuperscript{29} The evisceration of crashworthiness liability in such a large percentage of claims threatens the very purpose of imposing crashworthiness liability as an initial matter.

\textsuperscript{26} See id. \S 17, at 151-59; FLA. STAT. ANN. \S 768.81 (West 2009).
\textsuperscript{27} RESTATEMENT (THIRD) OF TORTS: APPORTIONMENT OF LIAB. \S 8 (2000).
\textsuperscript{28} Id.
\textsuperscript{29} NAT’L CTR. FOR STATISTICS AND ANALYSIS, NHTSA, DOT HS 810 801, TRAFFIC SAFETY FACTS 2006 DATA: ALCOHOL IMPAIRED DRIVING 1 (2008), available at http://www.nrd.nhtsa.dot.gov/Pubs/810801.PDF (alcohol-related traffic fatalities account for 32% of all traffic fatalities in the United States); Ctrs. for Disease Control and Prevention, Dep’t of Health and Human Servs., Impaired Driving, http://www.cdc.gov/nicpe/factsheets/driving.htm (last visited Apr. 2, 2009) (noting that drugs other than alcohol are involved in 18% of motor vehicle driver deaths).
The purpose of crashworthiness liability is described by the Restatement Third of Products as follows: “[a]lthough accidents are not intended uses of products, they are generally foreseeable. A manufacturer has a duty to design and manufacture its product so as reasonably to reduce the foreseeable harm that may occur in an accident brought about by causes other than a product defect.” To the extent that crashworthiness liability is designed to require manufacturers to reduce damage in foreseeable collisions, that liability must allow for collisions caused by drunk driving, which are constantly if tragically foreseeable. If apportionment eviscerates crashworthiness liability in the large percentage of accidents caused by drunk driving, manufacturers’ duty will demand little institutional attention. To the extent that crashworthiness liability promotes vehicle safety, diminution of liability may produce significant reductions in vehicle safety protections. Also, while crashworthiness liability plus comparative apportionment might net a no-liability or small-liability rule, the uncertain process of apportionment may result in large litigation costs on the path to that limited return—a lose-lose situation for manufacturers and injured consumers.

Though sold as a means for holding manufacturers liable only for their own fault or for the harm that they caused, apportionment does neither. Apportionment mechanisms in drunk driving cases do not exonerate car manufacturers based on the manufacturers’ own right conduct, but based on the additional culpable misconduct of a drunk driver. Imagine a driver injured by a collision in which his airbag fails to inflate because of a product defect. The driver suffers enhanced physical injuries valued at $100,000. If the cause of the car accident was not negligence, perhaps bad weather, the driver might recover in full from the manufacturer. If the accident was instead caused by another driver’s negligent act, perhaps looking away from the roadway, the driver might recover a portion of the damages from the manufacturer, perhaps 50%, or $50,000. Yet if the accident was caused by a drunk driver, a large percentage of responsibility, perhaps 90%, might be assigned to the drunk. Consequently, the victim might recover only one tenth of any enhanced injury from the manufacturer. In each case, the manufacturer created the same defective product which resulted in the same enhanced injury to the victim. In each case, the victim acted without fault. And yet, the victim of the drunk driver, by virtue of being the victim of both a reckless and a negligent actor, becomes tort-proof.

It might be argued that the Restatement (Third) of Torts itself did not create the inconsistency in the previous scenario. One way to resolve

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31 Ctrs. for Disease Control and Prevention, Dep’t of Health and Human Servs., National Drunk and Drugged Driving Prevention Month, http://www.cdc.gov/ncipc/duib/spotlitie/3d.htm (last visited Apr. 2, 2009) (stating that three in every ten Americans will be involved in an alcohol related crash in their lifetimes).
the problem would be through state-enacted legislation embracing joint and several liability in the case of single, indivisible harms. Yet this argument glosses over the role the Restatement Third of Apportionment played in dramatically magnifying the problem by adding strict liability, recklessness, and intentional torts to the apportionment mix after several liability was firmly established as the rule in most U.S. jurisdictions. Adding highly blameworthy conduct to the apportionment threatens the underlying structural liability more consistently, and to a far greater degree, than did previous comparisons because of the high moral blame associated with that conduct. Moreover, adding strict liability and specifically crashworthiness liability to the apportionment calculations broadens the possibility that liability imposed to assure structural safety will be undermined by the apportionment process.

In the years after crashworthiness liability was adopted but before comparative apportionment included torts beyond negligence, juries would not have been asked to apportion responsibility between the drunk driver and the manufacturer for either of two reasons. The first reason was the existence of joint and several liability. However, a second reason for absence of apportionment in these cases was the fact that intentional and reckless torts (and even at one point strict products liability) were not included in comparative fault systems.

Confronted with the concern that adding others’ highly blameworthy conduct to comparative apportionment calculations will eviscerate defendants’ duties of care, some courts have sustained jury verdicts that assign more responsibility to the negligent or strictly liable defendant than to the reckless or intentional tortfeasor.32 Under these rulings, a jury in a case like Nash could say that GM had 90% of the overall responsibility given its defective seatbelt, while the drunk driver shared only 10% of the total. Although upholding these institution-heavy apportionments may be a second-best solution for courts that want to preserve structural liability,33 those counterintuitive judgments also raise problems. In particular, allowing jurors to assign the full range of possible percentages of responsibility in a given case can magnify inconsistencies between the outcomes of different juries. Moreover, the normative statement of a jury in this case seems so contrary to public understanding of fault that the verdicts might further erode support for the tort system. Courts of appeal must then struggle with the question of whether such results can be justified under fault-based metrics, or whether, perhaps, these comparative metrics can be understood in a way that is not entirely fault-based.34

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33 Bublick, supra note 5, at 1530-43.
34 See, e.g., Nash, 856 N.Y.S.2d at 586-88.
Courts that want to retain crashworthiness liability but not face the vagaries endemic to an “any-apportionment-calculation-goes” system may refuse altogether to apportion responsibility in crashworthiness cases. This is the approach ultimately taken by the Florida Supreme Court in *D’Amario*. The *D’Amario* court held that “the principles of comparative fault involving the causes of the first collision do not generally apply to crashworthiness cases.”  

In reaching its determination, the court placed great weight on the purpose of crashworthiness liability and the concern that apportionment in this context would reduce or obliterate the defendant’s duty. The court drew an analogy to medical malpractice cases, in which an injury that occasioned the need for treatment is not apportioned with a doctor’s subsequent negligent care. Finally, the court rejected the specific argument that drunk driving falls into the state’s statutory intentional tort exception to comparative fault; drunk driving falls short of purpose or substantial certainty of harm—a necessary element of an intentional tort. Nevertheless, the court found the intentional tort exception analogous to the concern presented in the case of apportionment and drunk driving. The court expressed concern that without an exception to apportionment where the other defendant was a drunk driver, defendants were “permitted to effectively shift the focus of the trial from the existence of a defect to the driver’s conduct in driving while intoxicated, even though the existence of a defect was the fundamental liability issue to be tried in these cases.” Accordingly, the court ruled that the trial court’s focus on the evidence of drunk driving in *Nash* unduly confused the issues in the case. It therefore upheld the intermediate court’s reversal of that ruling.

Although the *Restatement (Third) of Torts* does not formally embrace the doctrine cited in *D’Amario*, principles from the *Restatement (Third) of Torts* lend support to that decision. The support stems from changes to the *Restatement Third of Apportionment* made after the *Restatement Third of Products* was adopted in 1997. At the time the *Restatement Third of Products* was enacted, the *Restatement Third of Apportionment* sought comparison of intentional, reckless, negligent, and strict liability torts without any ameliorative rules to blunt the effects of the assessment. The effects of unmitigated apportionment doctrines on

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35 D’Amario v. Ford Motor Co., 806 So.2d 424, 441 (Fla. 2001).
36 Id. at 434.
37 Id. at 436-37.
38 Id. at 438-39.
39 Id. at 439 n.15.
40 Id. at 441.
41 Id. at 441-42.
42 See *RESTATEMENT (THIRD) OF TORTS: APPORTIONMENT OF LIAB. 9-23* (Proposed Changes to Proposed Final Draft, 1998) (proposing to “[i]nsert the following new section [24.1]” entitled “Tortfeasors with a Specific Duty to Protect the Plaintiff From an Intentional Tort”).
substantive tort law subsequently became a flashpoint of controversy surrounding the *Restatement Third of Apportionment*. Although that Restatement had endeavored to leave “first-order” questions involving the basic rules of liability” out of the Restatement and address only “second-order” questions of apportionment, the Reporters conceded that the “line between first-order and second-order issues has been difficult to maintain.”

Consequently, the Reporters subsequently crafted additional black letter rules to preserve “first-order” rules of substantive liability. One of the most important of these ameliorative rules protected negligence liability in cases involving highly blameworthy intentional tortfeasor defendants. In particular, *Restatement Third of Apportionment* section 14 made tortfeasors jointly and severally liable for “failure to protect the [plaintiff] from the specific risk of an intentional tort.” Under this rule, for example, if a defendant’s duty was to provide adequate security to prevent a criminal attack, the defendant that provided negligent security could not apportion responsibility against the criminal assailant.

The Restatement Reporters justified this rule on the ground that application of comparative responsibility in the context of intentional tortfeasors and several liability creates “a difficult problem.” Specifically, “the great culpability of the intentional tortfeasor may lead a factfinder to assign the bulk of responsibility for the harm to the intentional tortfeasor,” leaving the negligent tortfeasor with little liability and the injured plaintiff with little compensation.

Because the rule is limited to intentional torts, section 14 would not directly address the problem of drunk driving. Moreover, to the extent that the *Restatement Third of Apportionment*’s ameliorative rule is premised on an intentional tortfeasor’s likely insolvency, the context of drunk driving may differ because some forms of insurance coverage may be available. Nevertheless, as the Florida Supreme Court noted, the concern for apportionment in the context of intentional torts shares many similar facets with the concern about apportionment in the context of drunk driving. Specifically, courts are appropriately concerned that the second-order rules of apportionment will have too great an effect on the first-order issues of crashworthiness liability.

The *Restatement Third of Apportionment* itself acknowledges that the ameliorative rule for intentional torts might appropriately stretch beyond the intentional torts context. Specifically, *Restatement Third of Apportionment* commentary suggests that there may be situations in

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43 *Restatement (Third) of Torts: Apportionment of Liab.* § 1, Reporters’ Note cmt. a (2000).
44 *Id.* § 14.
45 *Id.* § 14 cmt b.
46 *Id.*
which courts “extend the rule stated in this Section to those who fail to protect against less than intentional tortious conduct.”47 Apropos of the concern that drunk driving might present a case of high moral blame akin to an intentional tort, the Restatement Third of Apportionment lists negligent-entrustment and dram-shop liability in its list of potential extensions to the category.

Yet while adoption of the D’Amario ruling and an extension of Restatement Third of Apportionment section 14 would lead to similar results in the Nash case, the two approaches would yield somewhat different answers in other instances. Specifically, D’Amario would prevent apportionment in crashworthiness law regardless of the cause of the initial accident. That would preclude apportionment between a drunk driver and the car company in Nash, but it would also preclude apportionment between a careless driver and the car maker. As such, apportionment would be barred not only when it might eviscerate crashworthiness liability, but when it might merely reduce it. Also, under D’Amario, evidence of intoxication would be irrelevant to the case because no apportionment between the parties would be required. Under an extension of the Restatement Third of Apportionment Rule 14, on the other hand, a multi-party apportionment would still be made. However, under Restatement Rule 14, after the apportionment, the negligent defendant might be jointly and severally liable for the harm indivisibly caused by the manufacturer’s defect and the drunk driver’s misconduct.48 This latter approach of the Restatement might be easier to apply in the context of a multiple-party action.49 It also might better address the concern that apportioning between initial and second collisions is more of a legal fiction than a real description of separate injuries.50

Although these two solutions to the problem of preserving crashworthiness liability in cases of drunk driving are attractive, other solutions are equally plausible. For example, a special exception to apportionment rules might be designed for crashworthiness cases, which almost always involve another underlying accident. A different option would be to fix manufacturer reductions for the other driver’s fault at a constant percentage (as is done in cases involving driver failure to wear a seatbelt) or at a set dollar amount.51 The dollar amount option might be particularly attractive given auto insurance coverage, which tends to have determinable award limits. Still another approach would be to adopt a guidelines system under which the manufacturer’s crashworthiness

47 Id. § 14, Reporters’ Note cmt. a.
48 Id.
50 Dannenfelser v. DaimlerChrysler Corp., 370 F. Supp. 2d 1091, 1094 (D. Hawaii 2005) (“[T]he line between injuries caused by the primary collision and the secondary collision is rarely so clear as to permit a bright-line exclusion.”).
51 OWEN ET AL., MADDEN & OWEN ON PRODUCTS LIABILITY 1116-18 (3d ed. 2000).
liability might be reduced or expanded by various percentages based on mitigating and exaggerating factors concerning the manufacturer’s own misconduct, not based on any necessary relationship with the misconduct of another defendant. Finally, if comparisons are made, those comparisons might be less anchored to moral blame, and the importance of structural liability explained to the jury (as the Restatement suggests in a related context).\textsuperscript{52}

It is impossible to fully evaluate the many options for ameliorative doctrines in this Article. However, cases like \textit{D’Amario}, and doctrines developed to alleviate the effects of apportionment on substantive doctrines, create an effective method to preserve structural liability in the crashworthiness context and highlight the need for further review of methods of maintaining structural accountability.

II. **Defining the Baseline Duty of Care: Crashworthiness Liability to the Drunk Driver**

The more difficult case for preserving crashworthiness liability is not when the crashworthiness plaintiff is hit by a drunk driver, but when the crashworthiness plaintiff is the drunk driver. Such was the case in \textit{Giannini v. Ford Motor Co.}\textsuperscript{53} In \textit{Giannini}, the plaintiff was leaving a restaurant. Although subject to dispute, Giannini claimed that despite pressing the brake pedal, her vehicle accelerated uncontrollably, slamming into a concrete barrier and a lamp post. Giannini also claimed that the seatbelt she was wearing failed to restrain her in the crash, causing her injuries. Ford disputed the plaintiff’s story. It claimed instead that Giannini did not depress the brake pedal. Furthermore, Ford maintained that Giannini either was not wearing her seat belt or would have suffered the same injuries even if the seatbelt had not failed. Finally, Ford claimed that Giannini’s alcohol consumption that night contributed to the accident.\textsuperscript{54}

In a products liability action against Ford, the District Court of Connecticut granted Ford’s motion for summary judgment with respect to the brake system’s alleged failure to function properly. However, the trial court found sufficient evidence to preserve plaintiff’s claim that the seatbelt had malfunctioned in the crash. At the pretrial conference in the case, Ford proposed that it would present evidence at trial of the plaintiff’s intoxication that led to the single-car accident. The court examined the issue closely—should evidence of plaintiff fault in causing the initial accident be a defense in a crashworthiness case?\textsuperscript{55}

\textsuperscript{52} \textit{RESTATEMENT (THIRD) OF PRODS. LIAB.} § 16 cmt. f (1998).
\textsuperscript{53} No. 3:05CV244, 2007 WL 3253731 (D. Conn. Nov. 2, 2007).
\textsuperscript{54} \textit{Id.} at *1.
\textsuperscript{55} \textit{Id.} at *1-*4.
This issue, whether plaintiff fault was a valid defense to a crashworthiness claim, was also an important if controversial issue addressed in the Restatement Third of Products. The answer to the question varied in different drafts of the project. The initial Restatement Third of Products embraced the view that a crashworthiness defendant owed a duty of care to even negligent or reckless drivers. Accordingly, although plaintiff fault would reduce plaintiff recovery in most types of products liability actions, plaintiff fault would not reduce the plaintiff’s recovery in a crashworthiness case.56 When a car manufacturer had an obligation to create a crashworthy vehicle, a jury might find that the obligation was met or not met. However, why the plaintiff driver got into the accident in the first place—an icy road, talking on a cell phone, or driving drunk—wouldn’t enter into the assignment of liability and damages against the manufacturer, at least with respect to the enhanced portion of the injury.57

The theory underlying the Restatement Third of Products initial position was that “the requirement that an automobile be reasonably crashworthy” called for a different rule with respect to plaintiff fault defenses.58 “[I]f the risks created by plaintiff’s conduct are within the range that justifies crashworthiness protection, plaintiff’s conduct creates the very situation in which the plaintiff has a legitimate right to expect the automobile to provide reasonable protection.”59 Accordingly, the initial draft of the Restatement Third of Products would ignore plaintiff fault even though the situation might trouble courts “who find it objectionable that drunken drivers or drug abusers be allowed full recovery for increased harm.”60

The position that the Reporters originally espoused on crashworthiness and apportionment was subsequently overruled by a motion on the floor of the ALI.61 The motion was introduced and supported by a member of the defense bar.62 However, the Reporters of the Restatement Third of Apportionment also recommended backing away from the original rule.63 In light of the carried motion to amend the draft, the Restatement Third of Products changed course to provide, contrary to its original recommendation, that “the contributory fault of the plaintiff in causing an accident that results in defect-related increased harm [be] relevant in apportioning responsibility between or among the parties, according to applicable apportionment law.”64

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56 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 (Tentative Draft No. 1, 1994).
57 Id.
58 Id. § 6 cmt. f.
59 Id.
60 Id.
62 OWEN ET AL., supra note 51, at 1105.
63 Id. at 206.
64 Id.
the Restatement Third of Products acknowledges that this is a particularly “difficult issue” and the subject of a “sharp[ ] split” between jurisdictions.65 In a nod to that difficulty, the Restatement Third of Products lists as an important factor to the apportionment that a crashworthiness requirement “aims to protect persons in circumstances in which they are unable to protect themselves.”66

In Giannini, the Connecticut District Court cited the final rules adopted by the Restatement Third of Products and noted the split of authority discussed in that document. But while citing the final Restatement Third of Products rules, the court adopted the Restatement Third of Products’ initial view—that plaintiff negligence leading to the underlying accident should not be available as a comparative fault defense to the enhanced portion of the injury. Tracking the Restatement Third of Products’ original sentiment, the Giannini court reasoned that the crashworthiness doctrine presupposes that injuries will occur. In fact, the court viewed the duty to protect against enhanced injuries as an outgrowth of the inevitability of operator negligence.67 In light of foreseeable collisions, “a manufacturer’s duty is that of minimizing the injurious effects of contact however caused.”68 Given that definition of the defendant’s duty, the court limited the trier of fact’s analysis “to the nature and severity of the contact and the object’s response.”69 This focus on the crashworthiness issue, not on the origin of the crash, stems from the underlying principle that “[a] negligent operator is entitled to the same protection against unnecessary injury as the careful user of the same product is entitled.”70

Ironically, in the ten years since the Restatement Third of Products was enacted, most of the courts that have cited final Restatement Third of Products section 16(f) have not embraced the Reporters’ final position.71 A number of recent cases have held that the manufacturer’s duty in a crashworthiness case encompasses care for all drivers or that evidence of the cause of the initial injury is irrelevant to the enhanced injury case.72 However, while the majority of cases decided

66 Id. § 16 cmt. f.
68 Id. at *3.
69 Id.
70 Id.
72 See, e.g., Bearint ex rel Bearint v. Dorel Juvenile Group, Inc., 389 F.3d 1339, 1346 (11th Cir. 2004) (stating that “allowing a jury to allocate some of the fault to the initial tortfeasor would partially and unfairly absolve the manufacturer of liability for making a faulty device”); Ricci v. AB Volvo, 106 Fed. App’x 573, 574 (9th Cir. 2004); Black v. M & W Gear Co., 269 F.3d 1220,
after the Restatement Third of Products was passed adopt the Reporters’
original view, some cases have embraced the view taken in the final
Restatement Third of Products.73

Again, on one level, the courts’ decisions not to allow plaintiff
comparative fault defenses conflict with the Restatement (Third) of
Torts’ formal position. However, at a deeper level, the decisions can be
seen as a reflection of principles embraced by the Restatement (Third) of
Torts. In particular, subsequent doctrines from the Restatement Third of
Apportionment and the Restatement Third of Physical and Emotional
Harm suggest limits on the view that plaintiff comparative fault must
always serve as a defense. In particular, subsequent Restatement Third of
Physical and Emotional Harm provisions adopt “plaintiff no-duty rules”
rules that bar plaintiff comparative fault defenses in light of special
reasons of principle or policy.74

A plaintiff with a high level of fault, such as a drunk driver,
whose conduct might appropriately be sanctioned in any number of
ways, would seem an unlikely prospect for special reasons of principle or
policy to bar a comparative fault defense. Why might the tort law
recognize an interest in allowing a highly blameworthy plaintiff to
recover from a product manufacturer?

A previous examination of cases in which state courts bar
plaintiff comparative fault claims after the turn to comparative fault
defenses suggests that courts limit plaintiff fault defenses based on six
different types of principle or policy considerations.75 Two of these
policy rationales are particularly salient in the context of a drunk driver’s
crashworthiness claim.

First, courts sometimes limit plaintiff fault defenses in structural
safety cases—when systemic differentials in knowledge, experience, or
control suggest that the defendant can take better care of the plaintiff’s
safety than can the plaintiff herself. The cases involve defendants who
can foresee that some people in plaintiff’s position will not exercise
adequate self-care, and the defendants can control system-wide decisions
to ensure greater safety for the group.

In the crashworthiness cases, barring plaintiff comparative fault
claims may well promote greater driver and passenger safety. While
driving under the influence of alcohol is dangerous and distressing,
accidents from that conduct are certainly foreseeable. In fact, impaired driving is the single greatest risk factor for injury-producing automobile accidents.\textsuperscript{76} Given the great foreseeable risk and the defendant’s control over systemic safety decisions about driver and passenger protection, courts may feel that efforts to heighten plaintiff care through comparative fault defenses might be counterproductive to driver and passenger safety by undermining more important incentives for defendant care.\textsuperscript{77}

Another policy factor that courts have recognized as a limit on comparative fault defenses is one related to the role of the defendant. At times, even when defendants are not better situated than are plaintiffs to provide care for plaintiffs’ safety, courts may limit plaintiff fault defenses so that defendants cannot litigate away contractual or social obligations of care for even a faulty plaintiff. In this category, limits are placed on defendants’ use of comparative fault defenses in order to set baseline levels of care owed to even plaintiffs guilty of wrongdoing. Often, these cases involve a plaintiff’s right to receive subsequent aid.

This sort of principle and policy limit may apply to crashworthiness cases with drunk drivers. A person who drinks and drives may legitimately face many types of adverse consequences. The driver might have her driver’s license revoked, get into an accident and be jailed, be fined or required to pay tort damages, or be injured or killed herself. But even with all of these potential consequences, the drunk driver may still have some entitlements to care from others. For example, doctors must provide adequate emergency care,\textsuperscript{78} which may not be negligent.\textsuperscript{79} Moreover, police may not abuse the driver.\textsuperscript{80}

A manufacturer’s obligation to provide crashworthiness protection appears to fit within this category of subsequent protection owed to an even negligent or reckless person. The clearest analogy may be to a doctor’s obligation to provide non-negligent care to patients who were injured by their own fault. In the medical context, if a patient causes his own injury by drunk driving, a doctor cannot assert the plaintiff’s negligence in causing the accident as a basis for a comparative fault claim in an action for subsequent malpractice.\textsuperscript{81}

\textsuperscript{76} See supra notes 29, 31 and accompanying text.
\textsuperscript{77} See W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS § 65, at 452 (W. Page Keeton ed., 5th ed. 1984) (“It has been said that . . . the rule [of contributory negligence] is intended to discourage accidents by denying recovery to those who fail to use proper care for their own safety. But the assumption that the speeding motorist is, or should be meditating on the possible failure of a lawsuit for his possible injuries appears contrary to human experience; and it might be as reasonable to say that the rule promotes accidents by encouraging the negligent defendant to hope that the person he injures will be negligent too.”).
\textsuperscript{79} Mercer v. Vanderbilt Univ., 134 S.W.3d 121, 130 (Tenn. 2004); RESTATMENT (THIRD) OF TORTS: APPORTIONMENT OF LIAB. § 7 cmt. m (2000).
\textsuperscript{81} RESTATEMENT (THIRD) OF TORTS: APPORTIONMENT OF LIAB. § 7 cmt. m (2000).
The special rule excluding comparative-fault defenses in these cases can be understood in part by the nature of the duty to provide rescue protections that could not be waived by contract. A thought experiment might be useful here. Imagine that a car dealer knows that five of its cars have airbags that have a high risk of failing to open on impact in a collision. Anticipating potential liability but not wanting to pay for repairs, the dealer decides to sell the defective cars only to people known to be alcoholics because with comparative fault, the damage payouts will be slight. Would the dealer be permitted to make such a calculation?

Even if the dealer gave adequate disclosure of the defect to the specific purchasers, such a decision would violate the dealer’s legal and contractual obligations. Laws requiring car makers to provide airbags in all cars after a certain date are designed to minimize injuries to drivers and passengers as a whole, not only to careful drivers.

Similarly, a doctor could not tell a patient that she was going to exercise less care than she would for other patients because of the patient’s prior carelessness for her own health. The policy interest here is in providing a level of care to all patients, not just those who have occasioned their injuries and illnesses without fault.

Plaintiff no-duty rules may not have been applied to comparative fault claims in crashworthiness cases in part because these rules were not well-developed or defined at the time the Restatement Third of Products was enacted. There is no reason that plaintiff no-duty rules could not be used to reach the result reached by the court in Giannini. If plaintiff no-duty rules are applied, the plaintiff may recover in full from the manufacturer for the crashworthiness case.

But the potential for adopting plaintiff no-duty rules to the crashworthiness and drunk driving context is not an open-and-shut case. The shift to comparative fault from contributory negligence not only undermines but was meant to undermine all-or-nothing results. With both parties in the case at fault to some degree, contemporary norms suggest some form of splitting.

While splitting is plausible in theory, the history of apportionment cases in this area provides less reassurance that splitting is a feasible option. In practice, when courts ask juries to apportion responsibility between a crashworthiness defendant and a drunk driver, comparison of the two types of conduct seems generally to resemble a no-liability rule for the crashworthiness defendant. Even if a product defect causes injury to the plaintiff, when faced with the moral blameworthiness of a drunk driver, it is not clear that juries can balance structural safety interests in maintaining crashworthy vehicles with moral blame for drunk drivers. Instead, the many 100-0 results in cases

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82 See id. § 3 cmt. b.
83 See, e.g., D’Amario v. Ford Motor Co., 806 So. 2d 424, 437 (Fla. 2002) (per curiam).
involving one highly blameworthy party suggests that plaintiff’s highly blameworthy conduct may swamp all other factors.84

In essence then, when juries compare a plaintiff’s reckless conduct and a defendant’s failure to design a crashworthy vehicle, the plaintiff may well be tort-proof. This is true even though the injuries are not, in the words of one famous case, “entirely” the fault of the plaintiff.85 For courts that want to preserve some crashworthiness liability even to reckless parties, comparative apportionment becomes a poor option. Plaintiff no-duty rules, or the equivalent doctrine, refusing to apportion fault between the causes of the first and second collision, preserves a more robust doctrine of crashworthiness liability.

There are other viable options for creating a real split solution. One would be to proceed as seatbelt cases do, with fixed percentage reductions for plaintiff fault. However, this sort of compromise would have to be drawn by legislative solution. Given political currents, however, plaintiffs may not receive anything under these statutes either.86

A different option would be to allow reckless plaintiffs to obtain full recovery in cases involving manufacturing defects, which are often more clear in terms of wrongs done to the plaintiff, and an apportioned (or typically zero recovery) in design defect cases.

CONCLUSION

The Restatement Third of Products has now turned ten. In terms of the project’s contribution to products liability defenses, there is much to celebrate. The project’s framework of causal and then fault apportionment is conceptually clear and analytically sound.87 The disappearance of special defenses like misuse promises to simplify adjudication.88 The removal of disclaimers as a bar to liability reduces manufacturers’ ability to waive liability to uninformed consumers who, for the most part, do not consciously choose added product risk.89 And where fault lines emerge in the case law, the Reporters not only mark those hazards, but supply cogent explanations of the various routes that might be taken.

84 Richard C. Ausness, Products Liability’s Parallel Universe: Fault-Based Liability Theories and Modern Products Liability Law, 74 BROOK. L. REV. 635 (2009) (discussing ways in which courts avoid comparative apportionment and revert to all-or-nothing solutions when plaintiffs are guilty of highly blameworthy conduct).
86 See, e.g., FLA. STAT. ANN. § 337.195 (West 2006).
Yet, as this round of celebrations ends, a wish for the future seems in order. After ten years of case law following the *Restatement Third of Products* and a more complete *Restatement (Third) of Torts* project, it is time to reexamine how structural liability can survive the advent of comparative apportionment’s inclusion of highly blameworthy torts. Crashworthiness cases with drunk drivers are the first example.

In part, the need for reexamination of the structural liability issue stems from the fragmentary nature of the *Restatement (Third) of Torts* project. From the beginning of the project, the American Law Institute made an important decision that the subject of Torts had “become too broad and too intricate to be encompassed in a single project.”90 The decision to proceed in “segments” was pragmatic, perhaps essential to the project’s completion.91 But now that three segments are complete—the *Restatement Third of Products* in 1998,92 the *Restatement Third of Apportionment* in 2000,93 and the *Restatement Third of Physical and Emotional Harm*, likely in this coming year94—questions of fit remain.

If the *Restatement (Third) of Torts* meant to obliterate structural liability it could have staked this position in an outright claim. But it will be unfortunate if this is truly the way crashworthiness liability ends, not with a bang but a whimper.

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91 *Id.*
I. INTRODUCTION

On the whole, the Restatement (Third) of Torts: Products Liability\(^1\) represents a fundamentally restrictive view of products liability. It both reflects and has encouraged an era of contraction in the courts following the explosive growth of products liability doctrine and litigation in the 1960s and 1970s. This Article analyzes prescription product designs as illustrative of an area in which the Restatement (Third) took an especially restrictive stance. The Article considers the Restatement (Third)’s standard for prescription products, particularly its standard for prescription product design defect claims, in light of the preemption doctrine’s rising strength over the past two decades, as well as its recent limitation in 2009.

The Restatement’s prescription product design standard, set forth in section 6(c), has proved to be one of the project’s more controversial aspects.\(^2\) In section 6(c) the Restatement took the position that, with regard to design defect claims, a prescription product manufacturer may not be liable unless no reasonable health care provider would have prescribed the product to any class of persons.\(^3\)

In a 1994 article I criticized this approach as a “near-immunity standard,” and I noted that it lacked foundation in case law while

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\(^1\) John W. Wade Professor of Law, Pepperdine University School of Law. I thank Jennifer Allison and Michael Floryan for their outstanding research assistance, and I thank Pepperdine University School of Law for supporting my work on this Article with a research grant. I am also thankful to Anita Bernstein and Aaron Twerski for inviting me to participate in this symposium, and to Mike Green for providing feedback regarding some of the ideas addressed in this Article. Responsibility for any mistakes in the Article is of course mine alone.


\(^3\) See infra Part II.

\(^3\) RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) (1998).
expressing doubts about whether it would serve public policy interests.4 Others also voiced these criticisms,5 but the drafters defended their position6 and included the standard in their 1997 final version of the Restatement.7

In 1999, I participated in a symposium in which I reviewed case law and scholarly commentary that had developed since my 1994 article and section 6(c)’s formal adoption in 1997. In an article written for the symposium I noted that both courts and scholars were mostly critical of the Restatement’s approach; its near-immunity standard was not catching on with judges or with the academic community.8 It was broadly perceived as too pro-manufacturer and not sufficiently protective of consumers, in addition to being inconsistent with case law.9

This Article compares and contrasts the rocky (on the whole) reception section 6(c)’s restrictive prescription product design standard has received with the rise of an increasingly active judicial approach to preemption from the 1990s through the late 2000s, which may have to some extent crested (at least for now) with Riegel v. Medtronic10 in 2008, and which showed signs of possible contraction (again, at least for now) with Wyeth v. Levine11 in 2009. In particular, this Article analyzes preemption’s overall effect of developing a generally more restrictive approach to prescription product design defect claims, along with other prescription product defect claims. Part II begins by setting the stage for the Restatement (Third)’s development as a fundamentally restrictive approach to products liability. It fleshes out section 6(c)’s standard of allowing liability for prescription product design defect only if no reasonable health care provider would prescribe it to any class of patients, and it explains why this “near-immunity” standard (which is my

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7 The drafters of the Restatement (Third) continued participating in debate regarding this issue well after the final version of the Restatement (Third) was published. See, e.g., James A. Henderson, Jr. & Aaron D. Twerski, Drug Designs Are Different, 111 YALE L.J. 151 (2001) (defending the Restatement (Third)’s prescription product design defect standard).
8 Richard L. Cupp, Jr., The Continuing Search for Proper Perspective: Whose Reasonableness Should Be at Issue in a Prescription Product Design Defect Analysis?, 30 SETON HALL L. REV. 233, 244-52 (1999) (citing and discussing cases and law review articles addressing the Restatement (Third)’s prescription product design defect standard); see also infra notes 27-28 and accompanying text.
9 See infra notes 27-28 and accompanying text.
description, not the Reporters’) is one of the most restrictive specific aspects of the generally restrictive Restatement project.

This Part also briefly addresses cases that have cited section 6. It notes that the number of cases addressing section 6 is relatively small. Further, a surprisingly large percentage of these cases addresses design defect claims, despite broad agreement that warning defect claims are much more common in cases involving prescription products. The Part addresses some potential reasons for this. It concludes by explaining that, whatever the reasons, few would likely describe the Restatement’s near-immunity standard for prescription product design defect claims as a smashing success with courts and commentators.

Part III focuses on the two cases argued before the Supreme Court in 2008 addressing prescription product preemption: Riegel and Wyeth (which, though argued before the Supreme Court in 2008, was decided in 2009). It also briefly discusses a third major preemption case heard by the Supreme Court in 2008 involving a products liability-related claim, albeit one involving cigarette labeling rather than prescription products—Altria Group, Inc. v. Good.12 The Part begins by providing a brief background on the rise of preemption since Cipollone v. Liggett Group, Inc.,13 which was decided in 1992 at around the time formal work on the Restatement (Third) was beginning. It then analyzes Riegel, the 2008 Supreme Court case that preempted lawsuits for defects in prescription medical devices that have been subjected to premarket FDA approval under the Medical Device Amendments Act of 1976.

Although Riegel is analyzed in some depth, Justice Scalia’s discussion in the majority decision directed toward perceived shortcomings in the American tort system merits particular consideration. In his decision, Justice Scalia demonstrates both skepticism regarding the civil jury system and what may be a fundamental misunderstanding of aspects of products liability law. This aspect of the Riegel decision—which was more recently repeated by the dissenters in Wyeth—is especially powerful in demonstrating that even when courts are using the language of preemption doctrine, they may to some extent be seeking to reform products liability litigation.

As further evidence of broader policy concerns about litigation involving prescription products exerting influence on preemption’s rise, Part III next addresses the Food and Drug Administration (“FDA”)’s shift in position during the George W. Bush administration regarding whether FDA approval should create preemption. It also explores the backlash against this policy shift from FDA career officials, President Bush’s political opponents, from Justice Ginsberg in her Riegel dissent, and from the majority in Wyeth.

Part III then analyzes *Wyeth*, the even more heralded prescription product preemption case considered by the Supreme Court in 2008 and decided in 2009.\(^{14}\) *Wyeth* addressed whether implied preemption should apply broadly to cases involving warnings for FDA-approved products, and concluded that preemption should be limited in this context.\(^{15}\) This Part considers the Vermont Supreme Court’s approach to the issues, intense political wrangling related to the case prior to its being heard by the United States Supreme Court, reactions to oral arguments before the Supreme Court, and the Court’s decision.

Part III concludes with a brief analysis of *Altria*, the 2008 Supreme Court case in which the Court narrowly decided to continue the approach of finding that state fraud-related cigarette labeling claims are not a requirement related to smoking and health, and thus are not preempted by federal law. *Altria*’s flirtation with extending preemption to fraud-related claims in cigarette litigation—the dissent came within only one vote of succeeding in this position—provides further evidence of pressure within the Court to expand the doctrine beyond its previous limits.

Finally, Part IV concludes by suggesting that the restrictive tone of section 6(c) may have to some extent caught the “mood” of courts regarding prescription product design liability, even if the specific details of the unfamiliar standard have not found much traction. Cases such as *Daubert v. Merrell Dow Pharmaceuticals*,\(^{16}\) decided near the time formal work on the *Restatement (Third)* began, reflect the Supreme Court’s increased willingness to craft decisions that would have the effect of significantly restricting products liability law. Preemption’s rise in products liability cases began in earnest just a year earlier in *Cipollone* and continued at least through *Riegel* in 2008. Whether *Wyeth* represents an end to the trend or a significant bump in its road remains to be seen.

Both *Riegel* and *Wyeth* involved prescription products, which corresponds with increasing political and judicial concern regarding whether prescription products liability is too expansive. Even though not all of the preemption cases since *Cipollone* have resulted in restrictions on products liability claims, on the whole they have narrowed the reach of products liability in prescription product design cases, as well as in other types of prescription product cases.

Indeed, some of the rationales provided for section 6(c) overlap with some of the rationales the Supreme Court employed in the 1990s and most of the 2000s to support its increasingly aggressive use of preemption analysis in prescription products cases. Thus, Part IV concludes that the currents underlying section 6(c)’s restrictive tone for prescription product design liability may have found a “back door” in

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\(^{14}\) *Wyeth*, 129 S. Ct. 1187.

\(^{15}\) *Id.* at 1203-04.

Supreme Court rulings such as Daubert and Riegel, despite most courts’ and commentators’ refusal to provide “front door” acceptance of the Restatement (Third)’s prescription product design defect standard.

II. THE RESTATEMENT (THIRD) ON PRESCRIPTION PRODUCTS

On the whole, defendants and their friends have been happier with the Restatement (Third) than have plaintiffs and their friends. The document was, and remains, a product of its time. Following years of explosive doctrinal expansion in the 1960s and 1970s, products liability doctrine began a gradual contraction through the 1980s. The contraction manifested itself in widespread legislative restrictions, in reported judicial decisions, and in jurors’ reactions to products liability lawsuits. It also increasingly manifested itself in critical scholarly analysis.

Professors James Henderson and Aaron Twerski were prominent leaders in this scholarly trend toward questioning products liability’s expansiveness. When they took up the mantle as the Products Liability

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18 See id. at 470-80 (describing the influence of the American Tort Reform Association, whose goal was to reform tort laws to make them more favorable to defendants, on federal and state legislative tort reform processes in the 1980s).

19 See, e.g., Theodore Eisenberg & James A. Henderson, Jr., Inside the Quiet Revolution in Products Liability, 39 UCLA L. Rev. 731, 733-35 (1992) (providing a more expansive analysis of the empirical data related to products liability cases of the late 1980s in furtherance of the conclusion that products liability jurisprudence during this time tended to favor defendants); Marc Galanter, News From Nowhere: The Debased Debate on Civil Justice, 71 Denver U. L. Rev. 77, 94-95 (1993) (citing and describing the results of multiple studies of tort cases in state federal courts that “depict a sustained contraction of product liability exposure” during the late 1980s); James A. Henderson, Jr., & Theodore Eisenberg, The Quiet Revolution in Products Liability: An Empirical Study of Legal Change, 37 UCLA L. Rev. 479, 481 (1990) (presenting an analysis of empirical data related to products liability judicial decisions from the 1960s to the 1980s, which supports the authors’ theory that “changes in judicial decision making are occurring and that current trends favor defendants”).


21 See, e.g., James A. Henderson, Jr. & Aaron D. Twerski, Closing the American Products Liability Frontier: The Rejection of Liability Without Defect, 66 N.Y.U. L. Rev. 1263,
Restatement’s Reporters in the early 1990s, few could be surprised that their concerns about expansive liability were reflected in their work on the project.

The Restatement’s position on prescription product design liability is one of the most restrictive sections of the project. Found in section 6(c), the standard allows liability for drug and prescription device designs only if no reasonable prescription health care provider knowing the therapeutic risks and benefits would prescribe them to any class of patients.22 Specifically:

A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.23

The Reporters understood that their approach was quite restrictive. Only in rare circumstances would a prescription product design be so bad that it would be unreasonable for a health care provider to prescribe it to any class of patients. Comment f to section 6(c) calls it a “very demanding” standard and says that under this rule “liability is likely to be imposed only under unusual circumstances.”24

In addition to addressing design defect claims, section 6 also sets forth liability standards for prescription products warnings defect claims25 and manufacturing defect claims.26 Manufacturing defect claims

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22 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) (1998).
23 Id.
24 Id. § 6(c) cmt. f.
25 Id. § 6(d). The Restatement’s standard for prescription product warning defect cases is as follows:

A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

(1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or

(2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

Id.
comprise only a small percentage of cases involving prescription products, and the Restatement’s liability standard for such claims has been uncontroversial. The largest category of product liability claims relating to prescription products involves alleged warnings defects; however, as with manufacturing defect claims, the Restatement’s approach to prescription product warning defect claims has been fairly uncontroversial.

The Restatement’s prescription product design defect standard has been by far the most disputed aspect of its approach to prescription drugs and medical devices. Numerous law review articles, many of them critical, have focused on this design standard. The Restatement’s approach to prescription product designs may be described as a near-immunity standard, because manufacturers would rarely produce a drug or prescription device that would not provide a net benefit to at least some patients, even if its overall harm is far greater than its overall benefits for patients as a whole. Some support for a near-immunity interpretation of section 6(c) may be found in Professors Henderson and Twerski’s pre-Restatement scholarship. In 1992 they published an article outlining what they would like to see in a Products Liability Restatement before the project began. In the article they argued that prescription

26 Id. § 6(b)(1) (incorporating the general manufacturing defect set forth in section 2(a)).


28 Cupp, supra note 4, at 99 (criticizing the Restatement’s approach as a “[n]ear-[i]mmunity standard”).

product designs should have complete immunity from tort liability.\(^\text{30}\) Although the reasonable physician approach they eventually developed in section 6(c) does not provide absolute immunity for prescription product designs, it is not far off from the Reporters’ original ideal of simply disallowing all liability in such cases.

In comment d to section 6(c) the Reporters note that design claims involving prescription products “[h]ave been the subject of appellate review in relatively few cases.”\(^\text{31}\) Although asserting that prescription product warning defect cases outnumber prescription product design cases is hardly controversial, since the Restatement’s adoption, a surprising percentage of the cases addressing section 6 have focused on design defect claims—not just warnings. Most of these design defect claims have involved prescription medical devices rather than drugs.

Specifically, by the end of 2007, the Restatement’s case citations list reported thirty-six decisions citing section 6.\(^\text{32}\) Fifteen of those thirty-six cases—approximately forty-two percent—are cited as involving design defect claims.\(^\text{33}\) Further, of the fifteen cases cited as involving design defect claims, ten of the cases—two-thirds of the total—involves prescription medical devices rather than drugs.\(^\text{34}\) One might

\(^{30}\) Id. at 1536. For a summary of Professors Henderson’s and Twerski’s argument and an alternative approach they suggested, see Cupp, supra note 4, at 96 n.126.

\(^{31}\) RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) cmt. d, Reporters’ Notes (1998).

\(^{32}\) RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB., CASE CITATIONS TO THE RESTATEMENT OF THE LAW (Supp. 2008) (citing cases from July 1984 through November 2007). Although the Restatement’s citation search technically goes back to 1984, the earliest case it cites addressing section 6 is from 1994, when the Restatement was a work in progress. Tansy v. Daconmed Corp., 890 P.2d 881, 892-94 (Okla. 1994).


\(^{34}\) The decisions involving prescription medical devices rather than prescription drugs are all of the cases cited above in note 33 except for Freeman, 618 N.W.2d 827 (acne medication),
suspect that a possible explanation for these surprising statistics might be found in the common practice of warning and design claims being pleaded concurrently. If such were the case, the cases might have remained largely focused on warnings issues even though design defect claims were also technically pleaded. However, many of the cases may not bear out this possibility. Of the fifteen cited cases involving design defect claims, only three are cited by the Restatement as specifically addressing warning defect claims in addition to design defect claims.35 Another factor to consider relates to the more solid grounding of the Restatement’s warning defect standard in existing case law than is the case with its design defect standard. Given that the Restatement’s warning standard is not particularly controversial or groundbreaking, courts may have less reason or inclination to cite or discuss it compared to the new and controversial design defect standard.

The prevalence of design cases involving prescription devices rather than prescription drugs is particularly interesting. I have argued previously that prescription device cases are different from prescription drug cases, and that arguments for design defect liability are stronger for devices than for drugs.36 In 1994, when the Restatement project was still in progress, I noted that prescription devices “generally offer the same universe of design options as do nonmedical devices”37 and that “[t]he argument that FDA approval eliminates the need for design liability is especially faulty as applied to medical devices.”38 In a 1999 article I wrote that “[p]roviding prescription medical devices the same near-immunity given to drugs under the reasonable physician standard is an especially troubling aspect of the Restatement (Third)’s approach.”39

The reasons for this concern remain relevant with the passage of time. My strongest concern about applying a near-immunity standard to prescription devices was, and remains, that, unlike many drugs, they often provide “a broad universe of design alternatives.”40 In some ways prescription medical devices are more like nonmedical devices than they are like prescription drugs and vaccines. A lot of design alternatives are available to manufacturers of all-terrain vehicles, just as a lot of design alternatives are available to manufacturers of pacemakers. In contrast, although drug manufacturers sometimes make what may be accurately described as design decisions, often their choices are limited. Because more conscious choices are involved in producing devices than in

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35 Those three cases are Freeman, 618 N.W.2d at 835, 837-40, Madsen, 477 F. Supp. 2d at 1034, 1037, and Parkinson, 315 F. Supp. 2d at 747-48.
36 Cupp, supra note 8, at 256.
37 Cupp, supra note 4, at 94.
38 Id. at 105.
39 Cupp, supra note 8, at 256 (alteration to original).
40 Id.
producing many drugs, design liability will be a genuine issue in more
device cases than drug cases.

Further, the scrutiny applied by the FDA to prescription devices
is different from the FDA scrutiny applied to prescription drugs; in many
cases the FDA scrutiny of prescription devices is less stringent. Also,
烃cription medical devices are proliferating, and, as demonstrated by
the 2008 Supreme Court decision in Riegel v. Medtronic, design defect
liability claims involving prescription medical devices have become an
increasingly important part of the products liability landscape.

Whatever the reasons, few would likely describe the
Restatement’s near-immunity standard for prescription drugs and devices
as a smashing success with courts and commentators. Although the
approach has some supporters, most of the law review articles that have
addressed the standard are critical. Courts have often bypassed the
standard, frequently continuing to cite the Restatement (Second)’s
section 402A while ignoring the Restatement (Third)’s approach to
prescription products. The strongest support for section 6(c)’s anti-
liability impulse, if not its explicit standard, would be indirect, and would
come from the Supreme Court’s application of the trump card of
constitutional law in the form of preemption doctrine.

III. PREEMPTION’S RISE IN DRUG LITIGATION: RIEGEL AND WYETH

As noted recently by Professor Catherine Sharkey, “[p]reemption
is the fiercest battle in products liability litigation today.” As fate would
have it, the Supreme Court provided its “watershed” case that thrust
preemption into the foreground of products liability in 1992 at about the
same time that the Products Liability Restatement was getting
underway. In that year the Court decided Cipollone v. Liggett Group,
Inc., a case that analyzed whether the Public Health Cigarette Smoking
Act of 1969 expressly preempted failure to warn tort claims. The Act’s
language that formed the basis of the Court’s express preemption
analysis was that “[n]o requirement or prohibition . . . shall be imposed

41 See Schwartz, supra note 27, at 1391-95.
42 The Bleeding Edge, THE ECONOMIST, Mar. 1, 2008, at 74 (discussing how
technological advances and an aging population encourage increased innovation in the medical
device technology industry and create heightened public demand for new devices).
43 128 S. Ct. 999 (2008). For a discussion of Riegel, see infra Part III.A.
44 See supra note 27 and accompanying text.
45 According to prominent plaintiffs’ lawyer Paul D. Rheingold, between 2003 and 2008
some 200 cases discuss section 402A, while only “a handful” discuss section 6. Paul D. Rheingold,
Remarks at the Brooklyn Law Review Symposium: The Products Liability Restatement (Nov. 13,
2008) (transcript on file with author).
46 Catherine M. Sharkey, Products Liability Preemption: An Institutional Approach, 76
47 Id. at 459 (describing Cipollone v. Liggett Group Inc., 505 U.S. 504 (1992), as “a
watershed case in products liability preemption jurisprudence”).
48 Cipollone, 505 U.S. at 508.
under State law with respect to the advertising or promotion of any cigarettes.\footnote{Id. at 515 (citing 15 U.S.C. § 1334(b)).} The Court ruled fairly broadly, holding that this preemption language applies to common law tort warning defect claims as well as to state statutes and regulations.\footnote{Id. at 524-31; see also \textit{Sharkey}, \textit{supra} note 46, at 460.}

Despite the significance of the \textit{Cipollone} decision and other cases to tobacco litigation and to other areas of products liability litigation where some federal regulation existed, the American Law Institute more or less punted on addressing preemption in the \textit{Products Liability Restatement}. In comment a to section 6, the Reporters assumed the issue under the rug as follows:

> The rules imposing liability on a manufacturer for inadequate warning or defective design of prescription drugs and medical devices assume that the federal regulatory standard has not preempted the imposition of tort liability under state law. When such preemption is found, liability cannot attach if the manufacturer has complied with the applicable federal standard. See §4, Comment e.\footnote{\textit{RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB.} § 6 cmt. b (1998). The comment went on to briefly note:}

> The doctrine of preemption based on the supremacy of federal law should be distinguished from the proposition that compliance with statutory and regulatory standards satisfies the state's requirements for product safety. Subsections (c) and (d) recognize common-law causes of action for defective drug design and for failure to provide reasonable instructions or warnings, even though the manufacturer complied with governmental standards. For the rules governing compliance with governmental standards generally, see § 4(b).}

The Court provided another major products liability preemption decision in 1996, shortly before the \textit{Products Liability Restatement} was completed. In \textit{Medtronic Inc., v. Lohr}, the Court addressed express preemption in the context of the Medical Device Act.\footnote{518 U.S. 470, 474 (1996).} In \textit{Lohr}, the plaintiff claimed that a pacemaker made by defendant had both design and manufacturing defects that injured the plaintiff.\footnote{Id. at 481; see also Mary J. Davis, \textit{The Battle Over Implied Preemption: Products Liability and the FDA}, 48 B.C. L. REV. 1089, 1121 (2007).} The Court split on the question of whether the plaintiff’s claims were preempted by the FDA, and the plurality decision authored by Justice Stevens seemed to retreat from \textit{Cipollone}’s stance that express preemption language addressing “requirements” applies equally to common law tort claims as well as it does to state statutes and regulations.\footnote{\textit{Medtronic}, 518 U.S. at 501-02; see also Davis, \textit{supra} note 53, at 1121; Sharkey, \textit{supra} note 46, at 466.}

Following \textit{Lohr}, the Court continued analyzing preemption in products liability cases on a fairly regular basis. For example, in 2000 the Court held that an airbag defect claim was impliedly preempted by the
National Traffic and Motor Vehicle Safety Act of 1966.55 In 2001 the Court used implied preemption to negate a lawsuit against a device manufacturer’s regulatory consultant.56 In 2002 the Court declined to find express or implied preemption by the Federal Boat Safety Act of 1971 for tort claims against a boat manufacturer for failing to equip the boat with propeller guards.57 And in 2005, the Court declined to apply preemption under the Federal Insecticide, Fungicide, and Rodenticide Act to farmers’ claims that a pesticide manufactured by defendant damaged their crops.58 However, despite the importance of these decisions, early 2008 through early 2009 may be remembered as the most significant period thus far for products liability preemption analysis. In that twelve month span the Court decided no fewer than three major preemption cases involving products liability.

A. Riegel v. Medtronic—Cutting Back on Liability for Prescription Medical Devices

Although preemption is presently the fiercest battle in products liability generally, two of the three products liability preemption cases that the Supreme Court decided between early 2008 and early 2009 made the issue particularly heated in prescription product litigation. The first of these cases, Riegel v. Medtronic,59 was a prescription product preemption case that generated broad interest among lawyers, products liability scholars, and the media.

Riegel addressed whether the Medical Device Amendments Act of 1976 (“MDA”) preempts products liability lawsuits for defects in prescription devices covered under the Act.60 Increasingly “complex [medical] devices proliferated” in the 1960s and 1970s,61 a trend that has continued to the present and that seems likely only to become stronger in the future as medical science progresses. The enactment of the MDA in 1976 was propelled by “[a] series of high-profile medical device failures that caused extensive injuries and loss of life.”62 The best known of these failures involved the Dalkon Shield intrauterine device, which was designed to provide birth control.63 Between 1970 and 1974, over two million women in the United States used the Dalkon Shield.64 By the middle of 1975 numerous deaths and miscarriages had been attributed to

60 Id. at 1002.
61 Id. at 1003.
62 Id. at 1014 (Ginsburg, J., dissenting).
63 Id. at 1014-15.
64 Id. at 1014-15.
the device, and “by early 1976 [over] 500 lawsuits . . . had been filed.”\textsuperscript{65} The lawsuits sought more than $400 million in compensatory and punitive damages.\textsuperscript{66} Eventually the “manufacturer . . . settled or litigated approximately 7,700 Dalkon Shield cases.”\textsuperscript{67}

In response to public concern generated by situations such as the Dalkon Shield fiasco, the MDA created differing levels of oversight for medical devices based on the devices’ risks.\textsuperscript{68} “Class III” devices receive the greatest degree of scrutiny, requiring premarket approval unless they are “substantially equivalent” to existing devices.\textsuperscript{69} Premarket approval is a “rigorous” process.\textsuperscript{70} Currently, it is only required for a small percentage of devices placed on the market because most devices are considered substantially equivalent to existing devices. For example, in 2005 only about one percent—thirty-two out of 3,148 devices—entering the market had been subjected to the premarket approval process.\textsuperscript{71}

In \textit{Riegel}, the plaintiff Charles Riegel suffered from a “diseased and heavily calcified coronary artery.”\textsuperscript{72} The plaintiff’s doctor surgically implanted an Evergreen Balloon Catheter manufactured by Medtronic into the plaintiff’s artery to dilate it even though the device’s label warned against using it for calcified stenoses.\textsuperscript{73} The doctor also inflated the catheter more than the instructions allowed.\textsuperscript{74} The fifth time the doctor inflated the catheter it ruptured.\textsuperscript{75} The plaintiff then “developed a heart block,” requiring emergency surgery.\textsuperscript{76} The plaintiff sued in the Northern District of New York, alleging design, warning, and manufacturing defects under negligence, strict liability in tort, and implied warranty of merchantability theories.\textsuperscript{77}

Medtronic asserted that the plaintiff’s design, warning, and manufacturing claims were preempted by the MDA, and the district court agreed, dismissing the claims.\textsuperscript{78} The United States Court of Appeals for the Second Circuit affirmed, holding that the plaintiff’s claims “would, if

\textsuperscript{65} Id. at 1015 (citing H.R. Rep. No. 94-853, at 8 (1976)) (quotation marks omitted).
\textsuperscript{66} Id.
\textsuperscript{67} Id. at 1015 n.6 (citing R. SOBOL, BENDING THE LAW: THE STORY OF THE DALKON SHIELD BANKRUPTCY 23 (1991)).
\textsuperscript{68} Id. at 1003.
\textsuperscript{69} Id. at 1004 (citing 21 U.S.C. § 360c(f)(1)(A) (2006)).
\textsuperscript{70} Id.
\textsuperscript{71} Id.
\textsuperscript{72} Id. at 1005. By the time the Supreme Court addressed the case Charles Riegel had died, and his widow Donna Riegel was petitioner “on her own behalf and as administrator of her husband’s estate.” Id. at 1006 n.3.
\textsuperscript{73} Id. at 1005.
\textsuperscript{74} Id.
\textsuperscript{75} Id.
\textsuperscript{76} Id.
\textsuperscript{77} Id. at 1005-06.
\textsuperscript{78} Id. The district court held that the MDA did not preempt claims based on violation of federal law. Id. at 1006. The district court also found the MDA preempted the loss of consortium claim brought by Donna Riegel, Charles’ widow, “to the extent it was derivative of the pre-empted claims.” Id.
successful, impose state requirements that differed from, or added to” the requirements of the MDA.  

The Supreme Court also affirmed in an 8-1 decision authored by Justice Scalia. Justice Stevens joined the decision except for Parts III-A and III-B, and Justice Ginsburg dissented. Justice Scalia noted that the MDA includes an express preemption clause at 21 U.S.C. § 360k(a).80 It states that:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.81

Justice Scalia portrayed the case as presenting two questions. The first was “whether the Federal Government ha[d] established requirements applicable to Medtronic’s catheter.”82 In addressing this question Justice Scalia contrasted Riegel’s facts with the facts of Lohr,83 the previously mentioned 1996 Supreme Court case that addressed whether federal manufacturing and labeling requirements applicable to medical devices generally preempted common law claims of negligence and strict liability.84 In Lohr, the Court rejected finding preemption based on broad federal labeling requirements applicable to medical devices that reflected “entirely generic concerns about device regulation generally.”85 Justice Scalia emphasized that Riegel, unlike Lohr, involved a federal requirement that is “specific to individual devices.”86 Under Riegel’s facts, each and every medical device that is not substantially equivalent to existing devices must undergo the federal premarket approval process. The MDA, rather than exempting federal safety review, “is federal safety review.”87 Thus, Justice Scalia concluded that the federal government has established requirements applicable to Medtronic’s catheter.88

Justice Scalia presented the second question in Riegel as whether the plaintiff’s claims rely on any “requirement” of New York law that is

79 Riegel v. Medtronic, Inc., 451 F.3d 104, 121, 127 (2d Cir. 2006).
80 Riegel, 128 S. Ct. at 1003.
82 Riegel, 128. S. Ct. at 1006.
84 Riegel, 128. S. Ct. at 1006; see supra text accompanying notes 52-54.
85 Lohr, 518 U.S. at 501.
86 Riegel, 128. S. Ct. at 1007.
87 Id.
88 See id.
different from or in addition to federal requirements.\textsuperscript{89} He again cited \textit{Lohr} for guidance, noting that in that case five Justices held that state negligence and strict liability causes of action constitute “‘requirement[s]’ and would be preempted by federal requirements specific to a medical device.”\textsuperscript{90} Justice Scalia asserted that under normal circumstances “‘requirements’ include [state] common-law duties.”\textsuperscript{91} Further, under \textit{Riegel}’s facts, “there is nothing to contradict this normal meaning.”\textsuperscript{92} This is because “[s]tate tort law that requires a manufacturer’s catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.”\textsuperscript{93}

The tone of Justice Scalia’s analysis suggests that skepticism regarding American tort law may be an important factor in preemption’s rise. Indeed, the decision is surprisingly derisive regarding the tort system in products liability cases. Perhaps even more surprisingly, the majority opinion may reflect a fundamental misunderstanding of important aspects of products liability law.

Justice Scalia’s majority opinion argues that tort liability under negligence or strict liability is “less deserving of preservation” in the presence of federal regulation than are state statutes or state regulations.\textsuperscript{94} He views state statutes or regulations related to prescription products as at least similar to FDA regulations, in that they can “be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA.”\textsuperscript{95} In Justice Scalia’s view, this cost-benefit analysis by state regulators and FDA regulators asks: “How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm?”\textsuperscript{96}

Juries in torts cases, Justice Scalia seemingly asserts, are simply not to be trusted to balance these interests. In what appears to represent a significant misunderstanding of design defect analysis, he insists that “[a] jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.”\textsuperscript{97}

Apparently Justice Scalia is not familiar with the Restatement (Third)’s design defect standard nor the numerous decisions by state courts setting forth a risk/utility test for liability.\textsuperscript{98} Under this dominant

\textsuperscript{89} Id. (citing 21 U.S.C. § 360k(a) (2006)).
\textsuperscript{90} Id.
\textsuperscript{91} Id. at 1008.
\textsuperscript{92} Id.
\textsuperscript{93} Id.
\textsuperscript{94} See id.
\textsuperscript{95} Id.
\textsuperscript{96} Id.
\textsuperscript{97} Id.
\textsuperscript{98} According to the Restatement (Third), a product
approach to design defects, jurors are of course instructed to consider a design’s benefits as well as its risks.\textsuperscript{99} True, the patients who reaped a design’s benefits are not themselves represented in court, but the defendant-seller most certainly is, and it will communicate as much as possible to the jury about these patients’ reaping benefits (at least in general terms). In addition to minimizing the design’s risks (often in comparison to what the plaintiff asserts is a reasonable alternative design),\textsuperscript{100} the defendant manufacturer or other seller of course focuses on evidence highlighting the design’s benefits and, at least in general terms, its ability to achieve good results for other patients.

Even if a court rejects the risk/utility approach in favor of its most common alternative, the reasonable consumer expectations test,\textsuperscript{101} the product’s benefits as well as its risks are relevant to a jury’s analysis of reasonable expectations.\textsuperscript{102} Consumers might expect that

\textit{is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe.}
manufacturers would market a product that features high risk if the product also offers correspondingly high benefits, thus making the dangerous product arguably non-defective under a consumer expectations analysis. Arguing, as did Justice Scalia, that a jury is “not concerned with [a design’s] benefits” is only tenable if one assumes that juries completely disregard the defendant’s evidence and arguments.103 Judging from manufacturers’ frequent success in products liability litigation, this is simply not accurate.104 Jurors in products liability cases as a matter of course consider designs’ benefits, and very frequently they find that because of those benefits an injured plaintiff must lose.105

Another potential signal that perhaps drug regulation and tort law were not considered carefully enough is found in Justice Scalia’s somewhat dramatic pronouncement that the cost-benefit analysis used by FDA and by state drug regulators focuses on “how many more lives will be saved by a device which . . . brings a greater risk of harm.”106 In reality, many Class III medical devices have nothing to do with saving lives. Class III medical devices, subject to MDA regulation, entail a wide range of utilities and purposes. Breast implants, to pick an easy example, are Class III medical devices but are rarely thought of as saving lives.107 Some Class III medical devices save lives, but many or perhaps most have an honorable but less compelling use. Stating the cost-benefit analysis as one of “saving lives” is at best loose language and seems to equate Class III regulation with life or death matters across the board, thus making potential interference by the tort system seem to risk life or death across the board. Tort law that regulates a matter of life or death seems more grave than tort law that plays a role in regulation that is appropriate safety incentives whenever consumer expectations, for whatever reason, are lower than the level of safety that a risk-utility test would deem reasonable.”).
sometimes a matter of life or death, sometimes a matter of cosmetics, and probably most often somewhere between those two extremes.

The *Riegel* majority concluded that state tort lawsuits are only preempted “to the extent that they are different from, or in addition to” federal requirements.\(^{108}\) Under this reading, the court, again citing *Lohr*, held that damages remedies are not preempted if they run “parallel” to federal requirements rather than adding to them.\(^{109}\) A claim would parallel the MDA regulations if the defendant’s medical product ran afoul of both the MDA and state tort law.

Justice Stevens concurred in part and concurred with the judgment. He disagreed with the majority’s assertion that Congress decided when enacting the MDA that costs of injuries caused by medical devices falling within the Act’s scope would be outweighed by concern that some medical devices would not be available if juries were permitted to apply the tort law of all fifty states.\(^{110}\) To the contrary, Justice Stevens asserted that “[t]here is nothing in the preenactment history of the MDA suggesting that Congress thought state tort remedies had impeded the development of medical devices.”\(^{111}\) He agreed with Justice Ginsburg’s dissent that “the overriding purpose of the legislation was to provide additional protection to consumers, not to withdraw existing protections.”\(^{112}\) However, despite his disagreement over Congress’ intent in enacting the MDA, Justice Stevens agreed with the majority that the plaintiff’s tort claims must be preempted. Regardless of Congress’ intent when the MDA became law, Justice Stevens believed that allowing plaintiff’s tort claims would “constitute requirements with respect to the device at issue that differ from federal requirements relating to safety and effectiveness.”\(^{113}\)

Justice Ginsburg provided the sole dissent. In doing so she focused heavily on the history and background of the MDA. She described the majority’s position as a “radical curtailment” of tort claims that was not intended by Congress when it enacted the MDA.\(^{114}\) In Justice Ginsburg view, the reason Congress enacted the MDA “is evident.”\(^{115}\) As addressed above, prior to 1976 the federal government did not regulate medical devices before they entered the market.\(^{116}\) However, the Dalkon Shield tragedy and other problems with prescription devices created political pressure for some form of regulation.\(^{117}\) Several “states acted to

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\(^{108}\) *Riegel*, 128 S. Ct. at 1011.
\(^{109}\) Id.
\(^{110}\) Id. at 1012 (Stevens, J., concurring in part and concurring in the judgment).
\(^{111}\) Id.
\(^{112}\) Id.
\(^{113}\) Id. at 1012-13.
\(^{114}\) Id. at 1013 (Ginsburg, J., dissenting).
\(^{115}\) Id.
\(^{116}\) Id.; see *supra* notes 60-68 and accompanying text.
\(^{117}\) *Riegel*, 128 S. Ct. at 1014-15.
By the time of the MDA’s enactment in 1976, thirteen states had already created statutes governing medical devices.118 Needing to comply with these states’ explicit regulations as well as the federal government’s new regulations in 1976 was considered overly burdensome to prescription product manufacturers. Thus, Justice Ginsburg explained, the MDA’s preemption clause was drafted to eliminate these state regulatory systems rather than to preempt state tort claims.120 Since Congress’ intent is the “ultimate touchstone” of preemption analysis, Justice Ginsburg could not agree with the majority’s decision.121

Justice Ginsburg’s dissent briefly noted a point widely discussed among scholars and in the media: that during the litigation, the FDA announced a new position favoring preemption in premarket approval MDA claims.122 Justice Ginsburg emphasized that previously, under the Clinton administration, the FDA had taken the position that “FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection.”123 She asserted that inconsistency in an agency’s position regarding whether preemption should apply is a factor to consider in deciding how much weight the agency’s position is due and summarily rejected the FDA’s new pro-preemption position as “entitled to little weight.”124

In late 2008, after Riegel had been decided and shortly before the Supreme Court heard oral arguments in the later preemption case of Levine v. Wyeth, controversy related to the FDA’s shift in position made headlines. On October 29th, United States House of Representatives member Henry Waxman released documents detailing a rift in the FDA’s management between top staff regulators and Bush administration political appointees regarding whether to shift the FDA’s position on preemption.125

During his administration, President George W. Bush expressed concerns regarding tort liability for prescription products.126 Perhaps not

118 Id. at 1013.
119 Id. at 1003 (majority opinion) (citing Robert B. Leflar & Robert S. Adler, The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic, 64 TENN. L. REV. 691, 703 (1997)).
120 Id. at 1018 (Ginsburg, J., dissenting).
121 Id. at 1013.
122 Id. at 1016 n.8.
123 Id. at 1015 (quoting Margaret Jane Porter, The Lohr Decision: FDA Perspective and Position, 52 FOOD & DRUG L.J. 7, 11 (1997)).
124 Id. at 1016 n.8.
126 For example, President Bush backed a 2005 medical malpractice bill that shielded pharmaceutical companies from liability for punitive damages, as long as their drugs meet the Food and Drug Administration’s (“FDA”) approval standards. Jim VandeHei, Malpractice Bill Shields
surprisingly, he appointed officials who favored expanding preemption to limit tort liability for prescription products. According to the documents released by Representative Waxman, the struggle between the Bush administration and senior FDA staff members developed early in the Bush administration. Critics of the FDA’s shift in position to support preemption hailed the Waxman report as evidence that the Bush administration was playing politics with the FDA rather than acting in the best interests of consumers. One consumer activist described the documents as showing “that the nonpolitical people—the actual experts in the drug-approval process—didn’t agree with the approach of deferring to the companies.”

Another interesting sidebar to Justice Ginsburg’s dissent is her emphasis that the majority decision does not address an “important issue” whether the MDA’s express preemption language preempts tort lawsuits “where evidence of a medical device’s defect comes to light only after the device receives premarket approval.” Assuming that a defect for which the manufacturer is responsible exists, finding no preemption in such cases may be consistent with the reasoning of Riegel’s majority opinion; in such cases the FDA has not made a fully informed decision that a product’s benefits as marketed outweigh its costs.

Justice Ginsburg’s dissent addresses at least two additional matters of interest. First, she noted that the FDA’s premarket approval of Medtronic’s medical device would remain relevant even under her position. Although she would have rejected express preemption under section 360k(a), implied conflict preemption would still remain a possibility in appropriate cases. Thus, “a medical device manufacturer

Drugmakers, WASH. POST, Jan. 5, 2005, at A3. The Bush administration also supported pharmaceutical companies that seek to avoid liability in products defect lawsuits by claiming that federal law preempts state tort law. See Jerry Markon, High Court Case Looms Large for Drugmakers, WASH. POST, Nov. 4, 2008, at D1. The Bush administration supported the drug-maker involved in the latest Supreme Court case in which the defendants argued federal preemption, Wyeth v. Levine, after “[h]aving failed to persuade Congress or the states to limit” suits against prescription drug-makers. David G. Savage, Drug Makers Seek Shield From Suits, L.A. TIMES, Sept. 7, 2008, at A16.

127 See Stephen Labaton, ‘Silent Tort Reform’ is Overriding States’ Powers, N.Y. TIMES, Mar. 10, 2006, at C5; Savage, supra note 125.
128 According to Congressman Waxman’s report, “[i]nternal FDA documents indicate that in at least 138 cases involving drugs or biological products” between 2000 and 2005, the “FDA failed to take enforcement actions recommended by the agency’s own field inspectors.” SPECIAL INVESTIGATIONS DIV., H. COMM. ON GOV’T REFORM, PRESCRIPTION FOR HARM: THE DECLINE IN FDA ENFORCEMENT ACTIVITY 10 (2006), available at http://oversight.house.gov/documents/2006-0627101434-98349.pdf. According to the report, “[i]n many of the cases, FDA officials in Washington undermined the efforts of field officials through extended delays in acting on the enforcement recommendations.” Id. at 11. These actions were far from harmless: “[i]n multiple cases, enforcement recommendations were rejected where actual harm, including death, resulted from the violations.” Id. at 12.
129 Savage, supra note 125.
131 See id. at 1019-20.
may have a dispositive defense if it can identify an actual conflict between the plaintiff’s theory of the case and the FDA’s premarket approval of the device in question.\footnote{Id.} Justice Ginsburg noted that Medtronic did not argue implied conflict preemption in this case.\footnote{Id. at 1020.}

Second, Justice Ginsburg pointed out that medical device manufacturers also can make regulatory compliance defenses based on the FDA’s premarket approval of their product.\footnote{Id.} Although in most states the fact that a manufacturer has complied with regulations does not automatically clear him or her of liability, it is nevertheless “regarded as one factor to be considered by the jury.”\footnote{Id. at 1018.}

Near the end of her dissent, Justice Ginsburg indicated that she found Medtronic’s preemption argument wanting on policy grounds in addition to grounds of conflicting with congressional intent. Although Medtronic’s product underwent a premarket approval process, “the process for approving new drugs is at least as rigorous as the premarket approval process for medical devices.”\footnote{Id. at 1018-19.} However, “[c]ourts that have considered the question have overwhelmingly held that FDA approval of a new drug application does not preempt state tort law suits.”\footnote{Id. at 1019 n.16.} If rigorous premarket approval for prescription drugs does not preempt tort claims, Justice Ginsburg reasoned, on policy grounds neither should premarket approval for prescription medical devices.\footnote{Id.} She noted: “This court will soon address the issue in Levine v. Wyeth.”\footnote{944 A.2d 179, 182 (Vt. 2006), aff’d, 129 S. Ct. 1187 (2009).}

\section*{B. Levine v. Wyeth—Seeking to Extend Preemption to Drug Failure to Warn Claims}

The second prescription product case considered by the Supreme Court in 2008—and decided in 2009—featured even higher stakes for the future of tort liability for prescription products. In \textit{Levine v. Wyeth}, plaintiff Diana Levine sued over harm related to defendant Wyeth’s drug Phenageran.\footnote{Id.} In April 2000, Levine went to the Northeast Washington County Community Health, Inc. in Vermont complaining of nausea related to a migraine headache.\footnote{Id. at 1018.} To treat the nausea she was given two injections of Phenageran.\footnote{Id. at 1018-19.} The first injection was given intramuscularly.\footnote{Id. at 1019 n.16.} However, because the nausea continued, later in the
day she was given another injection by an intravenous injection directly into her arm. The intravenous injection was performed through a procedure called “IV push,” during which the Phenageran was accidentally injected into one of Levine’s arteries. This caused severe damage to the artery, leading to gangrene and eventually to amputation of Levine’s hand and forearm. Levine sued Wyeth for failure to provide adequate warnings related to accidental intra-arterial injections with Phenageran. Levine’s attorneys argued that Wyeth should have warned against ever injecting the drug.

Wyeth’s label for Phenageran did provide warnings for health care providers about the dangers of inadvertent intra-arterial injection. The warnings stated that “extreme care should be exercised to avoid perivascular extravasation or inadvertent intra-arterial injection.” The label also stated that “[w]hen administering any irritant drug intravenously it is usually preferable to inject it through the tubing of an intravenous infusion set that is known to be functioning satisfactorily.”

The FDA had approved this warning used by Wyeth. Levine argued that “the label should not have allowed IV push as a means of administration, as it was safer to use other available options, such as intramuscular injection or administration through the tubing of a hanging IV bag.” The trial court instructed jurors that they could consider the label’s compliance with FDA requirements, but that regulatory compliance was not dispositive as a defense. The jury found for Levine, awarding her $7.4 million in compensatory damages. The Vermont Supreme Court affirmed the jury verdict, and Wyeth appealed to the United States Supreme Court, which granted certiorari.

1. *Wyeth* in the Vermont Supreme Court

The Vermont Supreme Court’s decision in *Wyeth* set forth many of the issues to be considered by the United States Supreme Court.

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144 Id.
145 Id.
146 Id.
147 Id.
148 Id.
149 Id.; see also David G. Savage, *High Court Looks Split on Suits Against Drug Makers*, L.A. TIMES, Nov. 4, 2008, at A5.
150 *Wyeth*, 944 A.2d at 183 n.1.
151 Id.
152 Id.
153 Id. at 182.
154 Id.
155 Id.
156 Id. at 184.
157 The award affirmed by the Vermont Supreme Court was actually for $6,744,000, the reduction accounting for prejudgment interest and “plaintiff’s recovery in a settlement of a separate action she had filed against the Health Center.” Id.
Wyeth argued to the Vermont Supreme Court that “any state common law duty to provide a stronger warning about the dangers of administering Phenergan by IV push conflicts with the FDA’s approval of the drug’s label.” Thus, Wyeth argued, preemption should disallow Levine’s tort claims. Wyeth conceded that Congress did not expressly preempt claims such as Levine’s in the Food, Drug and Cosmetics Act, and instead asserted implied preemption. According to Wyeth, it was impossible to comply both with federal requirements and the regulation of Vermont tort law. Wyeth alternatively argued that Levine’s tort claim presented an obstacle to compliance with federal regulations by penalizing drug companies for compliance with FDA standards.

In rejecting these arguments, the Vermont Supreme Court summarized its position with the familiar refrain that the FDA’s requirements create “a floor, not a ceiling, for state regulation.” The court focused its analysis on the existence of “[a] key FDA regulation” that permits drug manufacturers to alter their labeling without prior approval by the FDA when necessary. The regulation, found at 21 C.F.R. § 314.70(c), allows manufacturers, among other things, “[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction” and to “add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product.” The court held that this regulation not only permits, but also “arguably encourages” manufacturers to add warnings when the FDA warnings are not enough to provide adequate safety. Tort lawsuits “simply give these manufacturers a concrete incentive to take this action as quickly as possible.”

2. Wyeth in the United States Supreme Court

After being granted certiorari by the United States Supreme Court, Wyeth garnered significant media attention. It was perceived as potentially becoming an extremely important case, in that it offered the possibility of a broad preemption ruling that could virtually destroy prescription product warning litigation. In analyzing the case before oral arguments were heard by the Supreme Court, Professors Anthony Sebok

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158 Id.
159 Id.
160 Id. at 185.
161 Id.
162 Id. at 188.
163 Id. at 186.
164 21 C.F.R. § 314.70(c) (1999).
165 Wyeth, 944 A.2d at 186.
166 Id.
and Benjamin Zipursky opined that “it is no exaggeration to say that the case presents the Roberts Court with the opportunity to eliminate most of pharmaceutical liability under state tort law in one fell swoop, if it so chooses.”

Both consumer groups and drug industry supporters seemed to agree, as numerous amicus briefs were filed on both sides of the issue. In July 2008, the New England Journal of Medicine published an editorial warning that drug companies “could effectively be immunized” from tort lawsuits involving warnings approved by the FDA if the court ruled for the manufacturer. Praising the impact of products liability litigation on drug safety, the editorial argued that “[p]reemption will thus result in drugs and devices that are less safe and will thereby undermine a national effort to improve patient safety.”

The editorial urged Congress to legislatively reverse Riegel and to consider doing the same with Wyeth if the Court chose to apply preemption to that case. Numerous other editorials and op-ed articles appeared in other publications both supporting and opposing the possibility of a broad preemption ruling in Wyeth. As noted above, Representative Waxman’s report on the conflict between the Bush administration and FDA staff members regarding preemption made headlines shortly before the Court heard oral arguments. By the time the Court heard oral arguments, Wyeth had become “the highest profile business case of the

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169 In total, thirty-three amicus briefs were filed with the Supreme Court in connection with the case before oral arguments took place on November 3, 2008. Levine v. Wyeth, 129 S. Ct. 1187 (2009).
171 Id. at 2.
172 Id. at 3.
173 For examples of arguments in favor of preemption, see Steve Huntley, Editorial, Firms That Follow Rules Deserve Protection, CHI. SUN-TIMES, Sept. 23, 2008, at 21 (“Preemption would not prevent suits for shoddy drug production or other wrongdoing. . . . Finding new drugs is expensive enough—and consumers end up paying those costs—without pharmaceutical companies facing the prospect of using dry scientific data to counter the raw emotional appeals of the injured to juries.”); Editorial, Wyeth Should Win: Otherwise, a Bad Case Will Make Bad Law, SAN DIEGO UNION TRIB., Nov. 17, 2008, at B6 (arguing in favor of preemption: “Why have the Food and Drug Administration? To have uniform, scientific, nationwide standards to prevent unsafe drugs. . . . Allowing lawsuits based on inconsistent mandates will cause the confusion and vulnerability the FDA exists to prevent.”). For examples of arguments against preemption, see Editorial, No Haven for Dangerous Drugs, BOSTON GLOBE, Sept. 27, 2008, at A14 (arguing against preemption: “The Supreme Court has no business depriving patients of their recourse to courts.”); Editorial, The Court Confronts a Grievous Injury, N.Y. TIMES, Nov. 7, 2008, at A26 (arguing against preemption: “For the court to broadly endorse the concept of ‘implied pre-emption’ in this case would show disrespect for the considered decisions of Congress and could foreclose injury suits involving not only drugs, but also motor vehicles, household products and other things. The ultimate effect would be to undermine consumer safety.”).
174 See supra notes 125-129 and accompanying text.
and one of the most intensely debated cases related to products liability in many years. The National Chamber of Commerce described it, perhaps a bit too breathlessly, as “the business case of the century.”

Reactions to oral arguments on November 3, 2008, were mixed, although the Justices’ questions and comments seemed to lower many observers’ expectations regarding a potentially sweeping decision that might virtually eliminate prescription product warnings defect litigation. The Los Angeles Times reported that “the justices appeared to be closely split” on whether to follow the Bush administration’s approach to preemption. The Houston Chronicle was less equivocal, with the headline of its article covering the oral argument reading in part: “Justices appear poised to side with drugmakers.” The New York Times reported that what “was supposed to be the term’s blockbuster business case . . . quickly turned into a search for limiting principles.” Although several of the Justices asked questions or made comments that may have reflected openness to some form of preemption in warning cases involving FDA approval, several of them also may have hinted at an interest in restricting preemption in some cases involving FDA-approved labels; for example, cases in which drug companies learn of new risks after the FDA has approved their labeling. Many of the Justices’ questions, particularly those directed at the plaintiff’s counsel, seemed to focus on when a risk is “new,” and on which party might have the burden of persuasion that a risk was discovered after FDA approval.

When the Supreme Court delivered its decision in Wyeth in March 2009, many were surprised. In a six-to-three decision the court held that Levine’s claims against Wyeth were not preempted by the FDA’s approval of Phenergan’s warning label. The New York Times described this ruling as “a major setback for business groups that had hoped to build a barrier against injury lawsuits seeking billions of dollars.”

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176 Alicia Mundy & Shirley S. Wang, In Drug Case, Justices to Weigh Right to Sue, WALL ST. J., Oct. 27, 2008, at B1. Depending on how it is decided, Wyeth could indeed be one of the most important business cases of the 21st century thus far, but we have ninety-two years remaining in the century.
177 Savage, supra note 149.
178 Doyle, supra note 175.
181 See generally Oral Argument Transcript, supra note 180.
In its decision, the Court rejected Wyeth’s impossibility defense and its argument that failing to find preemption would obstruct the purposes and objectives of FDA regulations. Regarding impossibility, the Court held that FDA regulations allow manufacturers to add to or strengthen warnings based on “newly acquired information,” and that newly acquired information may include new analyses of previously submitted data.\(^{183}\) In this case, the Court held that the plaintiff had provided evidence “of at least 20 incidents prior to her injury in which a Phenergan injection resulted in gangrene and an amputation,”\(^{184}\) and that on the basis of this information Wyeth could have added a stronger warning regarding use of the IV-push method.\(^{185}\) Noting that “impossibility pre-emption is a demanding defense,” the Court found Wyeth’s argument for it lacking.\(^{186}\)

Regarding Wyeth’s argument that allowing liability would obstruct the FDA regulatory scheme’s purposes and objectives, the Court agreed with the Vermont Supreme Court that FDA requirements provide merely a floor for drug regulation, rather than “both a floor and a ceiling” as contended by Wyeth.\(^{187}\) State tort lawsuits, the Court held, are an important aspect of drug regulation that builds up from the floor of FDA requirements.\(^{188}\) The Court emphasized that the FDA has only limited resources to monitor the thousands of drugs on the market, and that the tort system may be especially helpful in regulating new risks that may emerge in drugs’ postmarketing phase.\(^{189}\) The Court also found it significant that Congress had never chosen to insert an express preemption provision into the Federal Drug and Cosmetic Act in its seventy-year history; if Congress thought state tort claims interfered with its objectives, the Court reasoned that Congress would have at some point enacted an express preemption provision.\(^{190}\)

Significantly, the Court found that the FDA’s 2006 preamble supporting preemption “does not merit deference.”\(^{191}\) In language that may reflect consciousness of the political controversy surrounding the FDA’s new pro-preemption stance under the George W. Bush administration, the Court described the FDA’s 2006 preamble as “inherently suspect.”\(^{192}\) This is because the FDA articulated a new “sweeping position” in the preamble without offering states or other

\(^{184}\) Id. at 1197.
\(^{185}\) Id.
\(^{186}\) Id. at 1199.
\(^{187}\) Id.
\(^{188}\) Id. at 1202.
\(^{189}\) Id.
\(^{190}\) Id. at 1200.
\(^{191}\) Id. at 1190.
\(^{192}\) Id.
interested parties notice or opportunity to comment.\textsuperscript{193} Further, the Court found the preamble “at odds” with other evidence of Congress’ purposes, criticizing it for failing to provide any discussion of how state tort law has interfered with Congress’ purposes.\textsuperscript{194} The Court also found the George W. Bush administration’s amicus brief “similarly undeserving of deference,” because its “explanation of federal drug regulation departs markedly from the FDA’s understanding at all times relevant to this case.”\textsuperscript{195}

Justice Breyer wrote a separate concurring opinion seeking to emphasize that state tort law sometimes is an obstacle to the FDA’s objectives, and thus may be in some instances preempted, but that preemption is not applicable to this case.\textsuperscript{196} Justice Thomas also wrote a separate concurring opinion to express that he has become “increasingly skeptical” of the Court’s “‘purposes and objectives’ preemption jurisprudence,” and that he cannot join the majority’s “implicit endorsement of far-reaching implied preemption doctrines.”\textsuperscript{197}

Justice Alito, joined by Justice Scalia and Chief Justice Roberts, dissented. The dissent argued that the majority’s decision was inconsistent with prior preemption decisions, and that in its decision the majority effectively allows state tort juries to countermand considered decisions by the FDA.\textsuperscript{198} The dissent expressed concern that this “has potentially far-reaching consequences.”\textsuperscript{199}

An especially interesting aspect of the dissent is its repetition of Justice Scalia’s attack on the civil jury system in drug cases set forth in \textit{Riegel}.\textsuperscript{200} Justice Alito argued that “[b]y their very nature, juries are ill-equipped to perform the FDA’s cost-benefit-balancing function.” This is because, according to the dissenters, juries only see the injured plaintiff and do not see the patients who reaped the benefits of a drug. As noted above, this criticism seems to reflect misunderstanding of what information juries consider in prescription drug litigation.\textsuperscript{201} Further, drug cases are not unique with respect to jurors only seeing the injured party and not seeing those who benefited from a products design or warning. Rather, this would be typical in all forms of product liability litigation based on design or warning defect claims where the defendant manufacturer argues that other consumers were benefited by the design or warning chosen. Only the injured plaintiff is before the jury’s eyes, and the defendant is permitted to present evidence to the jury of the

\textsuperscript{193} Id.
\textsuperscript{194} Id.
\textsuperscript{195} Id. at 1203 n.13.
\textsuperscript{196} Id. at 1204 (Breyer, J., concurring).
\textsuperscript{197} Id. at 1205 (Thomas, J., concurring).
\textsuperscript{198} Id. at 1217-18 (Alito, J., dissenting).
\textsuperscript{199} Id. at 1229.
\textsuperscript{200} See supra notes 94-105 and accompanying text.
\textsuperscript{201} See supra notes 94-105 and accompanying text.
design or warning’s benefits to other consumers even though those consumers are not present in the courtroom. Casting out prescription product litigation on this basis as being ill-suited to determination by juries would seemingly implicate most other types of design or warning litigation.

C. Altria Group, Inc. v. Good—If at First You Don’t Preempt, Try, Try Again

A third products liability preemption case analyzed by the Supreme Court between early 2008 and early 2009 was Altria Group, Inc. v. Good.202 Although Altria did not involve prescription products, it merits a brief discussion in this analysis. Altria involved an assertion by a cigarette manufacturer that the Federal Cigarette Labeling and Advertising Act preempted a lawsuit based on state unfair practices statute.203 The lawsuit centered on allegations that the defendant engaged in fraud (which allegedly violated the Maine Unfair Trade Practices Act) by conveying the message that its “light” cigarettes “deliver less tar and nicotine to consumers.”204 In reality, the lawsuit alleged, the cigarette company knew that “[b]y covering filter ventilation holes with their lips or fingers, taking larger or more frequent puffs, and holding the smoke in their lungs for a longer period of time, smokers of ‘light’ cigarettes unknowingly inhale as much tar and nicotine as do smokers of regular cigarettes.”205

The Federal Cigarette Labeling and Advertising Act “establish[ed] a comprehensive federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health.”206 A narrow five-to-four majority held that the state law claim was not expressly preempted because a state-imposed duty not to engage in fraud “has nothing to do with smoking and health.”207 Rather, it has to do with not engaging in fraud.

The majority relied heavily on Cipollone, the 1992 cigarette warning case that arguably started the Court’s evolution toward increased preemption in products liability claims.208 As noted above, Cipollone held that the Public Health Cigarette Smoking Act of 1969 expressly preempted failure to warn tort claims.209 However, a plurality in Cipollone declined to preempt fraud claims under the Act, holding that

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203 Id. at 541.
204 Id.
205 Id.
206 Id. at 544 (quoting 15 U.S.C. § 1331 (2006)).
207 Id. at 545.
209 See supra notes 48-50 and accompanying text.
fraud claims “rely only on a single, uniform standard: falsity.” 210 Such fraud claims, the Cipollone plurality held, are not “based on” smoking and health. 211 The majority in Altria agreed with this holding in addressing the fraud-related claim before it.

Perhaps the most interesting aspect of Altria for our purposes is how close it came to cutting off many fraud-related claims against cigarette manufacturers. Four Justices—Justice Alito, Chief Justice Roberts, Justice Scalia, and Justice Thomas (the dissent’s author) — dissented from the majority’s holding, and would have preempted the fraud-related claim. Expressly disagreeing with the plurality in Cipollone, the dissenters argued that the majority’s decision in Altria “will thus result in a ‘requirement’ that petitioners represent the effects of smoking on health in a particular way in their advertising and promotion of light cigarettes.” 212 This position, which would have provided yet another significant expansion of preemption’s scope in cigarette litigation, came within one vote of prevailing.

IV. CONCLUSION: HEARING THE TUNE IF NOT THE WORDS: THE RESTATEMENT (THIRD)’S PRESCRIPTION PRODUCT STANDARD AND COURTS’ TREND TOWARD RESTRICTIVENESS

As noted above in Part II, the Restatement (Third)’s prescription product design standard set forth in section 6(c)—the no-reasonable-health-care-provider-would-prescribe-to-any-class-of-patients test—has not experienced great success on its own terms. The standard did not have strong support in case law when it was adopted, 213 and relatively few appellate courts have expressly applied the standard in the years that have followed the Restatement (Third)’s completion. 214 Further, much, although not all, of the scholarly commentary addressing the standard has been critical. 215

However, if one looks from a wider angle at the tone of section 6(c) and its comments and Reporters’ notes, more grounds for optimism arise in assessing its general consistency with judicial trends. Section 6(c)’s restrictive tone may have to some extent caught the broad mood of courts in assessing prescription product design liability, even if the specific details of the unfamiliar standard have not found much traction.

From this broad perspective, section 6(c)’s near-immunity standard is one of the most dramatic examples of the Restatement (Third)’s generally conservative approach to products liability, and courts have on the whole become increasingly conservative regarding

211 Id. at 530.
212 Altria, 129 S. Ct. at 552 (Thomas, J., dissenting).
213 See supra text accompanying notes 44-45.
214 See supra note 32 and accompanying text.
215 See supra note 27 and accompanying text.
products liability in general, and specifically regarding liability for prescription products. The Supreme Court’s decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* in 1993, and, even more importantly, the enthusiasm with which many state and federal courts embraced *Daubert’s* restrictive tone, provides a helpful illustration. *Daubert* was a products liability case; it involved expert testimony regarding Bendectin. As I noted in an earlier article, “[w]ithout products liability, there would have been no *Daubert,* and there may have been relatively little perceived need for a decision like *Daubert.*”

The *Daubert* decision, one of the most influential evidence cases of the twentieth century, was neither pro-plaintiff nor pro-defendant in its specific holding. However, the concerns with “junk science” that spawned the case were widely perceived as primarily problems with plaintiffs’ experts, and many products liability cases such as Bendectin litigation are particularly reliant upon experts. Thus, not surprisingly, *Daubert’s* application in federal and state courts is generally viewed as pro-defendant and anti-liability.

Indeed, in practice *Daubert’s* evidentiary restrictions, when viewed broadly, may be thought of as a form of judicial tort reform. Most courts’ and commentators’ general perception from at least the 1990s to the present has seemed to be, on the whole, that torts and products liability needed to be reigned in, as is reflected in the *Restatement (Third)*’s leanings. By significantly increasing the cost of expert testimony to meet its reliability standards, *Daubert* and its progeny (particularly its progeny) made thousands of products liability cases much more expensive to litigate, thus rendering many medium-value claims financially unviable for plaintiffs and their attorneys.

Preemption’s rise also reflects a judicial outlook that may be, on the whole, increasingly attracted to limiting products liability. *Riegel v. Medtronic, Inc.*, addressed at some length above, provides an illustration with prescription medical device design. Through its expansive preemption holding, the Supreme Court moved us closer to the *Restatement (Third)*’s goal of being quite restrictive in this area.

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217 Id. at 582.
219 Id. at 528.
220 Because of the expense of litigation, small products liability claims requiring expert testimony were, of course, already rare even before *Daubert.*
221 Cupp, *supra* note 218, at 528-29. Because of the expense of litigation, small products liability claims requiring expert testimony were, of course, already rare even before *Daubert.*
223 See *supra* Part III.A.
Riegel specifically focused on prescription medical devices that have undergone premarket FDA approval. Although most new Class III devices do not undergo the premarket approval process (according to Riegel, only thirty-two out of 3,148 in 2005), the ruling eliminates lawsuits for a category of new medical devices that might most likely be the subject of litigation—since they are entirely new rather than “substantially equivalent” to already existing devices. Thus, Riegel will have a substantial restrictive effect on prescription product design defect claims. Particularly when one considers Justice Scalia’s derisive tone in addressing the jury system in prescription product claims (“A jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court”), it does not seem a stretch to speculate that the case’s expansive preemption ruling may have been influenced in part by a more general concern that products liability claims for prescription products need to be restricted as a matter of general public policy. Although it focuses on preemption rather than doctrinal limitations, Riegel presents a tone of restrictiveness consistent with the Restatement (Third)’s tone.

Further, some of section 6(c)’s reasons for being restrictive overlap with some of the arguments for preemption in drug design cases. For example, in supporting the Restatement’s restrictive standard for prescription drug design, comment b notes that “[c]ourts have also recognized that the regulatory system governing prescription drugs is a legitimate mechanism for setting the standards for drug design.” The comment notes that this deference results in part from concerns over increased cost and decreased availability related to liability, and in part from assumptions that health care providers can ensure that “the right drugs and medical devices reach the right patients.” However, the comment also notes that the deference is based in part on an assumption “that governmental regulatory agencies adequately review new prescription drugs and devices, keeping unreasonably dangerous designs off the market.” Additionally, comment f asserts that section 6(c) “shows appropriate deference to the regulated market.”

The full impact of the Wyeth decision in 2009 will only be known over time. Professor Catherine Sharkey is probably correct in asserting that now, in light of Wyeth, “there is certainly a thumb on the scale against the more aggressive arguments for implied preemption.” This seems especially true in light of Barak Obama’s election as
President in late 2008. President Obama seems unlikely to appoint Supreme Court justices that would empower the Wyeth dissenters (Justices Alito, Roberts, and Scalia) to effectively reverse the decision in the coming several years. Also important, President Obama seems unlikely to staff the FDA with officials who would equal the George W. Bush administration’s appointees in disdain for tort law involving prescription product warnings.

Although Wyeth provides some boundaries for preemption’s growth, it is a case involving prescription product warning claims, not prescription product design claims. Riegel, decided only a short time before Wyeth, addressed prescription design claims in the context of prescription medical devices and applied preemption fairly aggressively.232

Thus, perhaps, when viewed broadly, the Riegel and Wyeth preemption decisions may to some extent parallel the Restatement (Third)’s disdain for prescription product design liability but acceptance of prescription product warning liability. Maybe section 6(c) missed the song’s words but heard its tune when developing a standard with a tone of deference to federal regulation in prescription product design defect claims that is in line with courts’ evolution, even though the section’s explicit standard is not. Section 6(c) has increasingly seemed to capture courts’ general pulse on prescription design defects despite failing to attain traction with its doctrinal analysis.

232 In the aftermath of Wyeth, congressional critics of Riegel’s preemption holding indicated that they would present a bill seeking to legislatively overrule Riegel. Barry Meier & Natasha Singer, Drug Ruling Puts Devices in Spotlight, N.Y. TIMES, Mar. 5, 2009, at B1. An expert speculated that the Wyeth decision “might have energized members of Congress who were already eager to nullify last year’s device ruling.” Id.
On Restating Products Liability Preemption

Mary J. Davis

The opportunity to reflect on the impact of the Restatement (Third) of Torts: Products Liability since its adoption by the American Law Institute in 1998 and its interaction with the ever-changing preemption landscape is a fascinating one. Many have written on the subject of federal preemption of products liability actions generally and on the narrower subject of preemption by particular federal regulatory action, whether by Congress directly or by an administrative agency. As a way of framing the discussion at the symposium celebrating the 10th Anniversary of the Restatement (Third) of Torts: Products Liability, (“Products Liability Restatement”), our organizers asked the following question: “Now that the Supreme Court has manifested a strong interest in federal preemption of common law personal-injury doctrine, should

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3 Most recently, the subject of preemption by the Federal Food and Drug Administration’s actions has been a popular subject because it involves not express preemption but implied preemption, which the Supreme Court has only addressed occasionally in recent years. The Court has decided an implied preemption case this term in Wyeth v. Levine, 129 S. Ct. 1187 (2009), involving preemption of state common law failure-to-warn claims based on FDA-approved pharmaceutical labeling. The Wyeth case and preemption by the FDA was the subject of lively debate at the Products Liability Restatement 10th Anniversary Symposium. I thank the other panel participants, Professor Robert Rabin, Malcolm Wheeler, and Sheila Birnbaum for the engaging discussion. For my position on that issue, see Mary J. Davis, The Battle Over Implied Preemption: Products Liability and the FDA, 48 B.C. L. Rev. 1089 (2007) [hereinafter Davis, The Battle Over Implied Preemption]. For other writing on that subject, see Richard A. Epstein, Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda, 1 J. Tort Law art. 5 (2006); Richard A. Nagareda, FDA Preemption: When Tort Law Meets the Administrative State, 1 J. Tort Law art. 4 (2006); Peter H. Schuck, FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot, 13 Roger Williams Univ. L. Rev. 73 (2008).
this topic (omitted in 1998) join the Restatement?” The Reporters of the Products Liability Restatement correctly concluded, in section 4, comment e, dealing with the effect of statutes and regulations on liability, that, “The complex set of rules and standards for resolving questions of federal preemption are beyond the scope of this Restatement.” After almost two decades of struggle in the Supreme Court over products liability preemption, the subject is still beyond the scope of the Products Liability Restatement, or any Restatement project, and is likely to be so for a while.

Many reasons exist for the continuing state of uncertainty in preemption doctrine. Even though the Supreme Court has regularly decided cases involving preemption of products liability actions since its initial foray into the subject in 1992 in Cipollone v. Liggett Group, Inc., the Court’s keen interest in the subject has not resulted in a predictable doctrinal approach. In addition, some have questioned the Supreme Court’s motives in addressing the subject so frequently, causing many observers to opine about the “politics of preemption,” which includes concerns about the doctrine’s relationship to tort reform movements and the tension, even among pro-preemption advocates, about unwarranted federal intrusion into spheres of traditional state regulation as a matter of respecting principles of federalism. Before Cipollone, the Supreme Court had not decided a products liability preemption case and had only rarely decided any case pitting state common law damages actions against a federal regulatory scheme. Since Cipollone, the Court has decided nine products liability preemption cases, the most recent the

6 See infra notes 49-72 and accompanying text.
9 See, e.g., Davis, Unmasking the Presumption, supra note 2, at 969 (“[P]reemption is about power and politics because it involves the fundamental balance of Congress’s power in relation to the states. . . . To the extent that the Supreme Court has something to say about the power struggle of federalism, it speaks, partially at least, through its preemption decisions.”); Nelson, supra note 7, at 229; Jeffrey Rosen, Supreme Court Inc., N.Y. Times, Mar. 16, 2008, § MM (Magazine), at 38; see also Catherine M. Sharkey, What Riegel Portends for FDA Preemption of State Law Products Liability Claims, 102 Nw. U. L. Rev. Coll. 415, 417 & n.12 (2008) (noting that preemption decisions regularly involve policy decisions and describing the policy preference model of Supreme Court decision-making noted by political scientists).
10 See Davis, Unmasking the Presumption, supra note 2, at 998.
highly anticipated _Wyeth v. Levine_, involving implied preemption of state law-based pharmaceutical failure-to-warn claims by the Federal Food and Drug Administration’s (FDA’s) product labeling approval decisions. The number of preemption decisions decided by the Court in the last two decades that involved common law damages actions is extraordinary, a record pace by any measure for a subject that had received only scant attention during the prior century. Given the Supreme Court’s continuing interest in the subject of preemption, the relentless pursuit of preemption by regulated industries as a way to limit liability exposure, and the variety of issues presented by the cases, the continuing substantial uncertainty about the state of the doctrine counsels against any attempt to restate it.

To state the black-letter law of federal preemption would, in truth, be a fairly simple task. Preemption of state law stems from the Supremacy Clause of the United States Constitution which the Court has long held requires an assessment of Congressional purpose. To that end, the Court has defined express and implied preemption doctrines. Express preemption exists when a statutory provision provides the scope of Congress’ intent to preempt, and its scope must be evaluated through an assessment of the statutory language, its structure, and, there is disagreement here, its purpose as discerned through the legislative history. Implied preemption doctrines substitute for Congress’ express intent to preempt a judicial determination that Congress would have wanted federal laws to govern when state laws create an actual conflict with federal objectives or make it impossible to comply with both federal laws.


See Davis, _Unmasking the Presumption, supra_ note 2, at 998.

From whether state consumer trade regulations are preempted by express preemption provisions, _see Altria Group, Inc._, 129 S. Ct. 538, to whether product-specific labeling decisions impliedly preempt common law claims, _see Wyeth_, 129 S. Ct. 1187, it is clear that aggressive preemption arguments can continue to be expected.
Implementing implied preemption doctrines often requires judges to cut at the joint between overlapping federal objectives and important state prerogatives and, therefore, is a sensitive inquiry. A variety of factors has been important to the Court’s implied preemption doctrine over the years and it might be possible to “restate” those in a catalogue-type way if one were so inclined.

Our symposium organizers likely asked the framing question rhetorically, however, understanding that the debate over preemption of products liability personal injury actions is about much more than the doctrine itself. It provides a much broader canvas than that. Rather, it provides the opportunity to examine a number of considerations that are not directly related to the details of preemption doctrine or whether that doctrine is ready to be “restated” in the American Law Institute way. That is why this opportunity is such a fascinating one.

The considerations to which I refer are both doctrinal and normative. They relate to the way preemption doctrine has evolved in the past two decades and to the question of whether the current trend in preemption doctrine, toward increased preemption of state common law personal injury actions, strikes the right balance between federal interests in certainty and uniformity of regulation and the interests of those harmed by the unrelenting risks produced by some regulated industries. The Supreme Court’s own struggle over this balance supports a narrow vision of preemption doctrine. I also suggest that to restate preemption doctrine that codifies a rule that places the risk of uncertainty on the future victim of that risk, absent unquestionable congressional intent to do so, or clear, focused analysis that openly takes those victims’ interests into account, does not strike that balance appropriately.

This Article provides a brief explanation of the state of preemption doctrine and explains how the Court altered, quite dramatically, its treatment of preemption of common law tort actions in the last two decades. The Court’s almost exclusive focus on the interpretation of express preemption provisions, which never specifically address common law tort claims one way or the other, turned “traditional” preemption analysis of common law tort claims on its head. The Court then, almost as suddenly, signaled a retreat from the emphasis on express preemption analysis and returned, awkwardly, to implied preemption doctrine. The Court has only recently begun meaningful

20 See Cipollone, 505 U.S. at 516-17.
21 See Davis, Unmasking the Presumption, supra note 2, at 1013-14.
22 See, e.g., Davis, The Battle Over Implied Preemption, supra note 3, at 1138-51 (applying identified factors in implied conflict preemption to failure-to-warn claims involving pharmaceuticals).
modern analysis of implied preemption, particularly with its decisions Geier v. American Honda Motor Co. and Wyeth v. Levine, and that doctrine will require years of fleshing out by the Court’s current members. After describing the current, uneasy state of preemption doctrine, this Article will provide a few observations about the normative inquiry regarding what preemption doctrine should, and should not, be accomplishing.

The effort to identify congressional intent to preempt has always been central to the preemption inquiry. As mentioned earlier, under the command of the Supremacy Clause of the Constitution, the Court has obligated itself to identify and follow the “clear and manifest purpose of Congress” to assess the preemptive scope of federal legislation. It must be remembered that before Cipollone in 1992, the Court had only rarely found common law tort claims to be contained within the scope of any express preemption provision, much less had it found such claims impliedly preempted. With its opinion in Cipollone, the Court began in earnest to shift the focus on determining congressional intent by inquiring into the plain or ordinary meaning of the terms of express preemption provisions.

Cipollone is an example of the difficulty of that inquiry as it applies to common law tort claims. The case involved the question of whether the preemption provision of the federal cigarette labeling laws, the Federal Cigarette Labeling Act of 1965, as amended by the Public Health Cigarette Smoking Act of 1969, preempted tort claims arising out of cigarette smoking-related health problems. Neither statute

24 Geier, 529 U.S. 861, and Sprietsma v. Mercury Marine, 537 U.S. 51 (2002), both involved express preemption provisions that the Court concluded did not preempt the claims in issue and implied conflict preemption analyses which supported preemption in Geier but not in Sprietsma. See infra notes 55-59, 69-71 and accompanying text; see also Davis, The Battle Over Implied Preemption, supra note 3, at 1124-27, 1129-30.


27 Indeed, watching how the Justices line up on the preemption scorecard has been somewhat of a pastime for many observers of preemption jurisprudence. See, e.g., Sharkey, supra note 9, at 419, 428-29 (discussing the unusual 8-to-1 decision in Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008), involving Medical Device Amendments preemption). After attempting to predict how the Court would answer the Federal Boat Safety Act preemption question in Sprietsma v. Mercury Marine, I have given up on prognosticating where preemption is concerned. See Davis, Unmasking the Presumption, supra note 2, at 1025-28.

28 U.S. CONST. art. VI, cl. 2. For a thorough analysis of the history of this provision and its meaning in historical context, see Nelson, supra note 7, at 232-64.


30 See Davis, Unmasking the Presumption, supra note 2, at 998.

31 Cipollone v. Liggett Group, Inc., 505 U.S. 504, 517 (1992) (stating that express preemption controls when it provides “reliable indicum of congressional intent” to be discerned by interpretation of statutory language (quoting Malone, 435 U.S. at 505)).


33 Cipollone, 505 U.S. at 508-09.
specifically mentioned common law damages claims, but rather stated, respectively, that the states may not impose any “statement” or “requirement or prohibition” “relating to smoking and health” in cigarette packaging or advertising. 34 All the Justices in Cipollone agreed that the preemption analysis should proceed by an interpretation of the scope of the express preemption provision, 35 but that is where the agreement ended.

The majority opinion, authored by Justice Stevens, 36 summarized the state of preemption doctrine and then engaged in a “fair[] but . . . narrow[]” interpretation of the provisions in issue with sensitivity to the presumption against preemption where matters historically within the police powers of the state are involved. 37 The majority concluded, therefore, that the 1965 Act did not preempt any common law tort actions. 38 A plurality of Justices then concluded that the 1969 Act’s language, preempts state law “requirements or prohibitions,” preempted some but not all of the claims. 39 Even the plurality was not entirely true to the task of fair but narrow statutory interpretation based on the presumption against preemption: the plurality found that the 1969 Act preempted some claims because of the change in the preemption provision’s language, even though Congress specifically stated in the legislative history of the 1969 Act that it did not intend to alter the scope of the preemption provision from its previous version. 40

Three concurring Justices found no express preemption at all, resting on the premise that common law damages actions have at most an indirect regulatory effect and, therefore, do not impose either requirements or prohibitions inconsistent with Congress’ intent. 41 Justice Blackmun, speaking for this group, recognized the Court’s long tradition of declining “to find the regulatory effects of state tort law direct or

35 See id. at 516; id. at 531 (Blackmun, J., concurring in part and dissenting in part); id. at 545-46 (Scalia, J., concurring in part and dissenting in part).
36 Justice Stevens has authored many of the Court’s preemption opinions including, in addition to Cipollone, the opinions of the Court in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), Sprietsma v. Mercury Marine, 537 U.S. 51 (2002), Bates v. Dow Agrosciences LLC, 544 U.S. 431 (2005), and, most recently, Altria Group, Inc. v. Good, 129 S. Ct. 538 (2008), which confirms the viability of the plurality opinion’s analysis in Cipollone.
37 Cipollone, 505 U.S. at 518, 523 (plurality opinion).
38 Id. at 519-20.
39 Id. at 521.
40 Id. (“The phrase ‘[n]o requirement or prohibition’ sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules.”) (quoting Public Health Cigarette Smoking Act of 1969, 15 U.S.C. § 1334(b) (2006)). The plurality opinion found partial preemption of those damages actions whose predicate is a “requirement or prohibition based on smoking and health.” Id. at 524. The Court dismissed Congress’ statement in the legislative history regarding no intended change in scope of the preemption provision as inconsistent with the plain meaning of the statute’s language. Id. at 520-21 & n.19.
41 Id. at 535-36 (Blackmun, J., concurring in part and dissenting in part).
substantial enough to warrant pre-emption."

The two remaining Justices, Scalia and Thomas, found complete preemption based on the “apparent meaning” of the same words. So, the stage was set for decades of confusing express preemption analysis and relentless arguments that Congress intended words like “requirements” to include common law damages actions.

The Cipollone court also addressed the presumption against preemption of state law in areas involving the historic police powers of the state, including matters of public health and safety. The Court disagreed about the presumption then, and continues to disagree about it. The Cipollone plurality said that express preemption provisions should be fairly but narrowly interpreted, being informed by an understanding of the value of the long tradition of tort law that complemented federal regulation of public health and safety. That understanding reflected the federalism balance struck by historical preemption jurisprudence over the previous seventy years. Implied preemption played no role in Cipollone, though the Court had emphasized implied preemption analysis in its discussion of preemption of common law damages actions throughout history.

The Court’s post-Cipollone opinions have been similarly fractured, though in differing ways. First, the Court has continued to struggle with determining the scope of express preemption provisions. Medtronic, Inc. v. Lohr, involving the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, is another example of the Court’s struggle with express preemption principles. In Lohr, the

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42 Id. at 537.


44 Cipollone, 505 U.S. at 518. For a fuller discussion of the “presumption against preemption,” see Davis, Unmasking the Presumption, supra note 2.

45 See Davis, The Battle Over Implied Preemption, supra note 3, at 1132-34; Davis, Unmasking the Presumption, supra note 2, at 1013-14.

46 Cipollone, 505 U.S. at 516.

47 See Davis, Unmasking the Presumption, supra note 2, at 972-97.

48 See id.


50 The preemption provision of the MDA, added to the FDCA in 1976 and at issue in Lohr, stated that states may not impose “requirement[s] . . . different from or in addition to” any federal requirement “relate[d] to safety or effectiveness.” 21 U.S.C. § 360k(a) (2006). The three opinions in Lohr revisited the disagreement begun in Cipollone over whether “requirement” was intended to mean common law damages actions and how express preemption provisions were to be read, whether neutrally or with an understanding of the presumption against preemption in the case of historic state police powers. See Davis, Unmasking the Presumption, supra note 2, at 1002-04. Five justices found that the provision did not preempt any claims against the medical device manufacturer, with Justice Breyer’s concurrence being critical to the holding. Lohr, 518 U.S. at 503 (Breyer, J., concurring). He suggested that common law damages actions could be requirements, but they were not intended to be so based on the preemption provision’s language and the FDA’s regulation implementing the provision. Id. at 503-04. For additional discussion of Lohr and MDA preemption, see Richard C. Ausness, “After you, My Dear Alphonse!?: Should the Courts Defer to
manufacturers of a medical device that had been approved under a grandfathering method known as pre-market notification argued that the MDA’s preemption provision preempted common law tort claims based on alleged defects in the device’s design, warning, and manufacture.\footnote{Lohr, 518 U.S. at 480-83.} The Court was again divided on the meaning of the term “requirements,” with a plurality considering that it did not preempt the claims in issue under a narrow interpretation of the statute and its implementing regulations,\footnote{Id. at 492-94.} but a majority, four in dissent and one concurring in the result, disagreed.\footnote{Id. at 508 (Breyer, J., concurring in part and concurring in the judgment); id. at 509 (O'Connor, J. concurring in part and dissenting in part).}

With such disagreement, it is no wonder that commentators opined that Medtronic, Inc. v. Lohr was a “veiled implied preemption analysis”\footnote{See Davis, Unmasking the Presumption, supra note 2, at 1004.} in express preemption clothing, because the Justices continued to debate whether Congress intended to include common law damages actions within the meaning of the term “requirement.” Those commentators might be called prescient. Four years later in Geier v. American Honda Motor Co.,\footnote{529 U.S. 861 (2000).} the Court found that an express preemption provision, arguably clearer than that involved in Lohr, which prohibited state “standards” that were not identical to the statutorily-defined minimum federal standards in issue, did not expressly preempt a design defect claim based on failure to include an air bag, but that implied conflict preemption principles did bar the claim.\footnote{Id. at 865-87.} This result is even more remarkable given that the legislation in issue, the National Traffic and Motor Vehicle Safety Act (NTMVSA),\footnote{The NTVMSA of 1966, 15 U.S.C. §§ 1381-1431 (1988) (repealed 1994), is currently codified at 49 U.S.C. §§ 30101-30169 (2000).} contains a savings clause, which states that compliance with a federal standard “does not exempt a person from liability at common law.”\footnote{15 U.S.C. § 1397(k) (1988).} The majority opinion in Geier said nothing about the presumption against preemption nor did it engage in a particularly meaningful evaluation of the actual terms of the express preemption provision, as one would have expected after Cipollone and Lohr.\footnote{See Davis, Unmasking the Presumption, supra note 2, at 1006-07.}

\footnote{\textit{The FDA's New Interpretation of § 360k(a) of the Medical Device Amendments?}, 80 Tul. L. Rev. 727, 767-75 (2006); Davis, Unmasking the Presumption, supra note 2, at 1002-04.}
The implied preemption analysis from *Geier* is an important modern exploration by the Court of implied conflict preemption and for that reason is likely to be very influential going forward. The Court did not discuss the presumption against preemption *per se* but did identify features of the air bag regulatory scheme and its history that informed the assessment of actual conflict. The Court reviewed a wide range of factors in determining actual conflict: the history of the regulation, the views of the various Secretaries of Transportation on the objectives of the standard, as well as the published comments to the various versions of the standard. The obvious effort by Department of Transportation officials to balance the interests of the regulated industry and the consuming public during the evolution of the standard influenced the Court in its determination that state tort laws would have an impermissible impact on the implementation of those objectives. The Court also discussed the relevance of the Secretary’s position on preemption and how much weight to place on the Department of Transportation’s assessment of conflict. The lack of a formal statement on preemption was not determinative, though the Court seemed uneasy about how to treat less-than-formal expressions of agency position.

In the eight years between *Cipollone* and *Geier*, then, the Court’s preemption doctrine stood on shifting sand. With every new case, the Court resisted discussing the “presumption against preemption” and struggled with how to balance the historic role of state tort law in regulating product safety. Subsequent cases continued to reflect that conflict. In *Buckman Co. v. Plaintiffs Legal Committee*, the Court conducted an implied preemption analysis under the Medical Device Amendments, after quickly concluding that the plaintiff’s fraud-on-the-FDA claims were not expressly preempted. Because policing fraud on a federal agency was uniquely federal and not traditionally governed by the states, the Court concluded that the presumption against preemption

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60 See Davis, *The Battle Over Implied Preemption*, supra note 3, at 1124-27. The Court discussed *Geier* at length in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), in applying implied preemption principles to the pharmaceutical labeling claims involved there. The FDCA does not have an express preemption provision related to its pharmaceutical approval provisions. See *Wyeth*, 129 S. Ct. at 1195-96 (discussing history of FDCA and noting that Congress did not include an express preemption provision for pharmaceutical approvals when it added the express preemption provision in the Medical Device Amendments in 1976); see also *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1035 (S.D. Ill. 2001) (explaining that the portion of FDCA dealing with pharmaceuticals does not contain a preemption provision).

61 *Geier*, 529 U.S. at 869-72; see also *id.* at 894 (Stevens, J., dissenting).

62 *Id.* at 877-85.

63 *Id.* at 882-83. For a more elaborate discussion of the *Geier* implied conflict preemption analysis, see Davis, *The Battle Over Implied Preemption*, supra note 3, at 1124-27.

64 *Geier*, 529 U.S. at 883.

65 *Id.* at 884-85.


67 *Id.* at 347-48.
did not operate and that the state-law based claims were preempted. In Sprietsma v. Mercury Marine, the Court similarly concluded that the Federal Boat Safety Act of 1971 did not expressly preempt design defect claims based on a failure to equip a recreational vessel with a propeller guard even though the Coast Guard had studied the matter and declined to require the guards. The Court also found no implied preemption because the Coast Guard regulations preserved state authority in the absence of federal action, and the Coast Guard previously had been in favor of permitting state common law claims. The Court in Sprietsma unanimously concluded that the more prominent safety objective in the federal statutory scheme justified maintaining complementary common law remedies. The unanimity was remarkable in itself for a subject about which the Court had been so fractured.

At this point, it would be well to highlight the importance of federal agency position on preemption analysis. One of the main issues in preemption analysis present in virtually every case, except Cipollone, is how much weight to give the relevant federal agency’s position on the matter. An agency position articulating the federal objectives at stake and assessing whether those objectives preempt state tort claims might properly inform the preemption analysis as a substitute for congressional intent when determining whether an actual conflict exists. The Court has recognized the need, in some cases, to defer to agency interpretations of statutes and administrative regulations, but whether to defer to agency position on preemption of state common law has proved more troublesome. Medtronic, Inc. v. Lohr, involved an FDA regulation implementing the statutory preemption provision; the majority opinion was “substantially informed” by that regulation because it had been formally adopted and because of the agency’s “unique role” enforcing the statute. Geier v. American Honda Motor Co., “place[d] some weight” on the position of the Department of Transportation, DOT, in favor of preemption, but did not defer to it. The Court in Sprietsma, as just mentioned, was heavily influenced by the Coast Guard’s position

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68 Id.
70 Id. at 59-60.
71 Id. at 64-66. Like the NTMVSA, the FBSA had both an express preemption provision and a savings clause. Id. at 62-63 (applying 46 U.S.C. §§ 4301-4311 (2000)).
72 Id. at 69-70.
73 Many have discussed the importance of agency position in preemption analysis. See generally Eskridge, supra note 14; Nina Mendelson, Chevron and Preemption, 102 Mich. L. Rev. 737 (2004); Catherine M. Sharkey, Preemption by Preamble: Federal Agencies and the Federalization of Tort Law, 56 DePaul L. Rev. 227 (2007); see also Ausness, supra note 50, at 767-75.
74 Medtronic, Inc. v. Lohr, 518 U.S. 470, 495-96 (1996). Justice Breyer concurred, agreeing that “the relevant administrative agency possess[ed] a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect.” Id. at 505-06 (Breyer, J., concurring).
against preemption. The importance of agency position on preemption, and the uncertainty regarding the Court’s position on the matter, has compounded the uneasiness of preemption analysis.

Bates v. Dow Agrosciences LLC\(^76\) offered hope that stability might have come to the Court’s express preemption analysis. The Court was presented with an express preemption provision, this time from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).\(^77\) The Court, speaking through Justice Stevens, made some important general observations about the delicate balance that must be achieved in determining the scope of such provisions, and about the effect of shifting agency position on preemption analysis. First, the Court gave an uncharacteristic endorsement of the longstanding value of tort law as a catalyst in the effort to enhance public safety.\(^78\) I say “uncharacteristic” because the Court’s opinions had most recently failed even to discuss the presumption against preemption, much less the value of tort law in enhancing public safety.\(^79\) The Court employed the narrow express preemption analysis it described in Cipollone, specifically rejecting the conclusion that common law jury verdicts are the equivalent of “requirements” simply because they may influence decision-making.\(^80\) The Court also rejected as irrelevant speculation over whether a jury verdict might affect a manufacturer’s conduct,\(^81\) and described the proper inquiry as an examination of the predicate “common-law dut[ies] in issue” to determine whether Congress intended that they be preempted.\(^82\)

The Court concluded that the express preemption provision preempted very few claims.\(^83\) The Court reiterated its adherence to the presumption against preemption because tort litigation “provid[es] an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items.”\(^84\) The Court also expressed a sense of frustration at the way the lower courts had broadly read the term

\(^78\) Bates, 544 U.S. at 449-51.
\(^79\) Id. at 441. The Court also observed that it was not until Cipollone that preemption arguments based on the notion that “requirements” includes common law tort claims began to flood the courts. Id.
\(^80\) Id. at 445.
\(^81\) Id. (“This effects-based test finds no support in the text of § 136v(b), which speaks only of requirements. A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.”) (internal quotation marks omitted).
\(^82\) Id. (“The inducement test is unquestionably overbroad . . . .”).
\(^83\) Id. at 451-52.
\(^84\) Id. at 449; see also id. at 459 (Thomas, J., concurring in part and dissenting in part) (“Today’s decision thus comports with this Court’s increasing reluctance to expand federal statutes beyond their terms through doctrines of implied preemption. This reluctance reflects that preemption analysis is not [a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives, . . . but an inquiry into whether the ordinary meanings of state and federal law conflict.”) (citations omitted) (also endorsing a narrow view of cases in which implied preemption is permitted).
“requirements” after Cipollone, and chastised the “too quick conclusion”85 that claims were also, therefore, preempted under FIFRA.

Bates also raised the importance of agency position on preemption. The regulating agency, the Environmental Protection Agency, had shifted its position on preemption in the previous five years from being against it to being for it.86 The Court was not influenced by that shift in position.87 Rather, the Court noted that “if Congress had intended to [prevent the operation] of a long available form of compensation, it surely would have expressed that intent more clearly.”88 The Court endorsed the notion that common law tort claims, enforced by private parties, “would seem to aid, rather than hinder, the functioning of FIFRA . . . [which] contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products’ performance in diverse settings . . . [T]ort suits can serve as a catalyst in this process.”89 The concern expressed by the defendant and the EPA that “tort suits led to a ‘crazy-quilt’ of FIFRA standards or otherwise created a real hardship for manufacturers” fell on deaf ears, as the Court observed that “for much of this period EPA appears to have welcomed these tort suits.”90 The Court’s skepticism about the sincerity of agency position on preemption after such a shift is palpable.

By 2005, one could fairly describe the Court’s preemption personality as a bit Jekyll-and-Hyde-like. Which analysis will apply, express or implied preemption? If express preemption analysis applies, will it be fair but narrow, or something else? Does a presumption against preemption exist or not? What is the role of agency position on preemption? Even with such open questions, I might have suggested that federal preemption doctrine was approaching stasis. After Bates, it looked as if express preemption analysis was taking a more certain shape, and, after Geier and Sprietsma, that implied preemption had the same potential. But in its 2007-08 term, in Riegel v. Medtronic, Inc.,91 by finding express preemption under the Medical Device Amendments for devices that satisfied the pre-market approval process, the Court again reflected an aggressive pro-preemption inclination in spite of Sprietsma and Bates.92 Some observers describe Riegel as a fairly narrow application of the MDA express preemption provision and a logical extension of Medtronic, Inc. v. Lohr.93 As to the application of the MDA preemption provision to the pre-market approval process, that may be so.

85 Bates, 544 U.S. at 446 (majority opinion).
86 Id. at 436-37 & n.7, 449.
87 Id. at 449.
88 Id.
89 Id. at 451.
90 Id. at 451-52.
92 Id. at 1006-11.
93 See Sharkey, supra note 9, at 415 nn.3-4.
The Court’s language, however, is gratuitous in its criticism of the role of common law tort claims and expansive in its description of the scope of express preemption where it had not been before.

There are several reasons that I consider Riegel to be an unwarranted extension of preemption doctrine, and these reasons support my position that the time has not come to “restate” products liability preemption doctrine. First, Riegel purports to be yet another statement on how to read express preemption provisions, but it is much broader than its predecessors. It is an example of the bankruptcy of the idea that express preemption analysis is a search for the clear and manifest intent of Congress. In interpreting, now for the second time, the MDA express preemption provision which preempts state “requirements” different from or in addition to those required by federal regulations, there is little discussion of Congress’ intent. The Court’s discussion of the issue in Lohr had been badly fractured and so Riegel provided an opportunity to explore and clarify the matter. Instead, the Court failed to continue the dialogue begun in Lohr about the regulatory effect of common law damages actions within the structure of the MDA. I realize that some members of the Court are reluctant to explore legislative purposes and history in statutory interpretation, but even under an “apparent” meaning analysis, the Court could have explored what Congress’ intent was in this regard, as it had in prior cases. The Court appears committed to the position that “requirements” includes common law tort claims, so I will not tarry too long expressing my disagreement with this conclusion. I will, however, direct all readers to Justice Ginsburg’s persuasive dissent in Riegel on this point.

In lieu of an analysis of congressional intent as the touchstone of preemption analysis, the Court states: “Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a State’s ‘requirements’ includes its common-law duties.” Of course, the MDA was written in 1976 long before the Court’s current dictionary of definitions was taking shape. Nevertheless, it is fair to say that the Court’s pronouncement, which was joined by eight Justices, stands in stark contrast to the decision in Bates, just three years earlier, that was significantly more circumspect on the meaning of the term “requirement.” One is left to wonder what meaning

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94 Riegel, 128 S. Ct. at 1007-08. Instead, the Court explains its conclusion about what “requirements” means from its own discussion of the term, in Bates involving a statute written in the 1940s, and in Cipollone involving statutes written in the 1960s. Id.
95 Id. at 1013 (Ginsburg, J., dissenting). Justice Stevens, the author of Cipollone, Medtronic, Inc., Sprietsma, and Bates, concurred on the scope of “requirements” because it is consistent with the result in Medtronic, Inc. See Riegel, 128 S. Ct. at 1011-13 (Stevens, J., concurring in part and dissenting in part). Prof. Rabin’s remarks on this topic at the symposium are relevant as well. See Robert L. Rabin, Territorial Claims in the Domain of Accidental Harm: Conflicting Conceptions of Tort Preemption, 74 BROOK. L. REV. 987 (2009).
96 Riegel, 128 S. Ct. at 1008.
words will have ten, twenty, or thirty years from now, shorn of their connection either to ordinary meaning or congressional intent.

Second, while defining the “normal meaning” of the term “requirement” for future congresses, the Court displayed its contempt for common law tort actions. According to the _Riegel_ court, tort law as applied by juries is simply unfit to regulate. It is “less deserving of preservation” than other state regulations.97 Juries are incapable of balancing costs and benefits adequately as they “see[] only the costs of a more dangerous design, and [are] not concerned with [the] benefits” consumers reap by the manufacturer’s design choices.98 It is “implausible,” according to the Court, that Congress would create the “perverse distinction” that grants greater power to a single state jury than to state officials.99 Whether one agrees or disagrees with these remarks, there is certainly little, if anything, left of the historic place that state tort law held in regulating public safety in them, and certainly little in common with Justice Stevens’ remarks on that score in _Bates_. Such comments also seem to have no place in an opinion analyzing the meaning of a term used by a Congress, writing in 1976, in response to the design and warning labeling failures of the medical device industry which had prompted enactment of the legislation.100 Remarks such as these also give credence to the criticism that the Court is taking a political and policy position in its preemption doctrine, rendering its opinions unnecessarily activist.

Third, the _Riegel_ court discusses, at some length, the effect of the FDA’s changing position on preemption, even though it acknowledged that the position was not relevant to the case because the statutory language was clear.101 The FDA had recently changed its position on the scope of the MDA preemption provision as it applied to the pre-market approval process.102 It has also done so in a high-profile way in the pharmaceutical labeling implied preemption cases.103 While largely dicta, the Court’s statements displayed some sympathy for the proposition that recent agency position may be relevant to an assessment of current preemptive scope, despite longstanding contrary agency position.104 Some of the Court’s earlier pronouncements on this matter differ from its

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97 Id.
98 Id.
99 Id.
100 Id. at 1003; see also id. at 1014-15 (Ginsburg, J., dissenting) (chronicling the history of the MDA and the Dalkon Shield intrauterine device litigation which prompted it).
101 Id. at 1009 (majority opinion).
102 Id.
103 See Davis, _The Battle Over Implied Preemption_, supra note 3, at 1108-11.
104 _Riegel_, 128 S. Ct. at 1009 (“But of course, the agency’s earlier position . . . is even more compromised, indeed deprived of all claim to deference, by the fact that it is no longer the agency’s position.”).
discussion in Riegel. Riegel does not display the search for balance in preemption doctrine reflected in the Court’s other opinions. The respect for the traditional longstanding role of the common law is absent. Express preemption doctrine has some semblance of predictability and stability though that predictability is not sufficiently connected to congressional intent as it is supposed to be. An example of this disconnect in express preemption analysis may be found in Altria Group, Inc. v. Good, decided after Riegel and which involved whether the plurality opinion in Cipollone, defining the claims that survived express preemption under the cigarette labeling laws, had continuing validity after the ensuing sixteen years of preemption doctrine. I would have expected, after Riegel and its 8-to-1 opinion in favor (in dicta, at least) of a more expansive reading of express preemption provisions, that Justice Stevens’ plurality opinion in Cipollone was destined for extinction, but I would have been wrong. In what can only be described as a stunning turn of events in preemption doctrine, Justice Stevens, joined by Justices Breyer, Ginsburg, Kennedy, and Souter, held that the plurality opinion of Cipollone does, indeed, control the express preemption analysis of that statute. The majority opinion rejected the broader scope of preemption analysis proposed by Justice Scalia in Cipollone, and advocated in Altria Group by Justice Thomas for the dissent, stating, “Justice Scalia’s approach was rejected by seven Members of the Court, and in the almost 17 years since Cipollone was decided Congress has done nothing to indicate its approval of that approach.” Justice Stevens returned in Altria Group to his opinion in Bates and endorsed the presumption against preemption and a fair but narrow reading of the scope of express preemption. One is also left to wonder what to make of the continuing validity of the definition of the term “requirements,” fashioned by the majority opinion in Riegel.

As if the Court’s recent flurry of preemption decisions was not enough to digest, the Court agreed to decide in its 2008-09 term an implied preemption case involving claims challenging the adequacy of

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105 See discussion of Bates v. Dow Agrosciences LLC, supra notes 76-88 and accompanying text; see also Sharkey, supra note 9, at 423.
106 Riegel, 128 S. Ct. at 1009; id. at 1017-19 (Ginsburg, J., dissenting).
108 Id. at 541-42.
109 Id. at 549 (“In sum, we conclude now, as the plurality did in Cipollone, that ‘the phrase “based on smoking and health” fairly but narrowly construed does not encompass the more general duty not to make fraudulent statements.’” (quoting Cipollone v. Liggett Group, 505 U.S. 504, 529 (1992))).
110 Id. at 545 n.7; see id. at 552-54 (Thomas, J., dissenting).
111 Id. at 545 n.7 (majority opinion).
112 See id. at 543.
federally approved pharmaceutical labeling, *Wyeth v. Levine.* The FDA’s high profile change in position in favor of preemption of common law tort claims based on its labeling approval decisions began to make its way into briefs on the issue in 2004. Many lower courts had struggled with implied preemption doctrine in these cases, and what to make of the FDA’s recent position shift in that analysis. The FDA also described that shift in a very controversial discussion in the preamble to a 2006 pharmaceutical labeling regulation. After *Riegel* and the open debate between Justice Scalia in the majority and Justice Ginsburg in dissent over the scope of implied preemption in pharmaceutical labeling cases and the relevance of agency position on preemption, many observers, including several at the symposium, expected the Court to find a narrow ground on which to preempt the claims in issue in *Wyeth.* But, again, the Court’s preemption decisions defy prediction. The Court, speaking through Justice Stevens with a six-to-three majority, found that the FDA’s product labeling approvals did not impliedly preempt Levine’s tort claims.

*Wyeth* involved the anti-nausea drug Phenergan which was approved in 1955. Ms. Levine had been injected with the drug to alleviate symptoms from a migraine headache and, through inadvertent injection into an artery, gangrene, a known side effect, resulted and her arm eventually had to be amputated. *Wyeth* knew about the risk of intra-arterial injection, had warned about it in a section of the labeling, and that labeling had been approved over the years by the FDA. Ms. Levine claimed that the labeling inadequately warned of the risk of gangrene, and the jury agreed. The Vermont Supreme Court affirmed a lower court ruling that Ms. Levine’s claims were not impliedly preempted by the FDA’s labeling approvals. *Wyeth* made two separate preemption arguments: first that it would have been impossible for it to comply with the state law duty to warn without violating federal law. *Wyeth* argued that it would have been a violation of federal regulations to alter the Phenergan label

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114 *See* *Davis, The Battle Over Implied Preemption,* supra note 2, at 1090.
117 *Wyeth,* 129 S. Ct. at 1191.
118 *Id.* at 1192.
119 *Id.* at 1191.
120 *Id.* at 1192.
121 *Id.* at 1192-93.
123 *Wyeth,* 129 S. Ct. at 1193, 1196.
without first obtaining FDA approval. The Court disagreed after a thorough exploration of the labeling approval regulations which permitted pharmaceutical manufacturers to alter product labels to add or strengthen a warning. Implied conflict preemption based on the impossibility of complying with both federal and state law has only rarely been applied, and the Court rejected it in this instance, too. The Court noted that impossibility preemption is “a demanding defense” and that it would require “clear evidence” of impossibility to succeed. This guidance on implied conflict preemption involving arguments of impossibility will be a welcome addition to the Court’s jurisprudence in this area.

Of greater importance, however, is the Court’s discussion of general implied preemption principles relating to obstacle conflict preemption. Borrowing from the analysis in Geier which supported implied conflict preemption, Wyeth had argued that plaintiff’s tort claims are preempted because “they interfere with ‘Congress’s purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives,’” and that set both a floor and a ceiling for drug regulation. The Court emphatically rejected these arguments, noting they rely on an “untenable interpretation” of congressional intent and “an overbroad view” of an agency’s power to preempt state law.

After Riegel, the Court could not have been expected to so boldly embrace the regulatory value of state tort law, but it did, reiterating adherence to the presumption against preemption. It explored congressional purposes behind the labeling provisions by reviewing how the history of those provisions illuminated Congress’ attitude toward complementary state tort litigation. The Court concluded that, “If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA’s 70-year history.” Adding to its conclusion that Congress did not consider state tort law to be an obstacle

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124 See id. at 1197.
125 Id. at 1196-97.
126 Id. at 1196-99.
127 Id. at 1199.
128 Id. at 1198 (“But absent clear evidence that the FDA would not have approved a change to Phenergan’s label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirement.”)
129 Id. at 1199 (quoting Brief for Petitioner at 46, Wyeth v. Levine, 129 S. Ct. 1187 (2009) (No. 06-1249)).
130 Id.
131 Id.
132 Id. at 1194-95; see also id. at 1195 n.3 (“We rely on the presumption because respect for the States as ‘independent sovereigns in our federal system’ leads us to assume that ‘Congress does not cavalierly preempt state-law causes of action.’” (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996))).
133 Id. at 1200.
to achieving federal objectives in the area of pharmaceutical labeling, the Court rejected as irrelevant the FDA’s “mere assertion” that state law poses an obstacle.\textsuperscript{134} Finding this position at odds with the available evidence of Congress’ purposes, the Court explored the many ways that tort law acts as a complementary form of drug regulation.\textsuperscript{135}

After the discussion in \textit{Riegel} about the negative impact that tort verdicts have on regulated industries, the discussion in \textit{Wyeth} seems to be coming from an entirely different court. Compare the following language from \textit{Wyeth} with earlier remarks from \textit{Riegel}:

State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular lend force to the FDCA’s premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times.\textsuperscript{136}

These comments sound like those of Justice Stevens in \textit{Bates} and are a welcome return to greater balance between the role of state tort law and the need to give federal regulation the breathing room that Congress intended, but no more.

Finally, because Wyeth had relied on \textit{Geier} for many of its implied preemption arguments, the Court distinguished \textit{Geier} by noting the significant differences in the two regulatory schemes.\textsuperscript{137} \textit{Geier} involved a formal agency rule-making with a contemporaneous plan to implement the defined objectives.\textsuperscript{138} \textit{Wyeth} did not. On this point, Justice Breyer noted in concurrence that “it is also possible that state tort law will sometimes interfere with the FDA’s desire to create a drug label containing a specific set of cautions and instructions”\textsuperscript{139} similar to the regulation in \textit{Geier}, an opinion authored by Justice Breyer. The future of implied obstacle preemption will likely be defined, therefore, by the thoroughness of federal agency assessment of “lawful specific regulations” and not on hindsight case specific evaluations.

So where does that leave us? Trying to make sense of preemption opinions reminds one of being on a roller coaster and, while enjoying the ride, getting off is a welcome relief. The uncertainty of where the coaster will go, while exhilarating for the time, is also exhausting and frustrating. This coaster ride is over for the time being though much work is left to be done after \textit{Wyeth} in deciphering labeling approval decisions to identify those that may preempt state tort claims.

\textsuperscript{134} \textit{Id}. at 1201. The Court discussed the FDA’s 2006 drug regulation preamble in which the preemption position was most recently articulated and found it did not deserve deference under an assessment of its “thoroughness, consistency, and persuasiveness.” \textit{Id}.

\textsuperscript{135} \textit{Id}. at 1202-03.

\textsuperscript{136} \textit{Id}.

\textsuperscript{137} \textit{Id}. at 1203.

\textsuperscript{138} \textit{Id}.

\textsuperscript{139} \textit{Id}. at 1204 (Breyer, J. concurring).
Two cases were remanded by the Court for further ruling in light of *Wyeth* and many others are likely to be reconsidered in its wake. For the time being, it is important to point out that under *Geier* and *Wyeth* opportunities remain to argue for implied preemption in the pharmaceutical labeling context, and under other regulatory regimes.

Building on this assessment of the current, uncertain state of the doctrine of preemption, this Article will now identify some of the normative concerns that counsel against endorsing preemption doctrine in the current preemption climate. First, the Court’s express preemption doctrine continues to raise questions about the defining congressional intent to preempt. After *Riegel*’s diatribe against tort law as implemented by juries, preemption doctrine would have been fairly criticized as being more concerned about reducing the role that tort law will play in the world of regulated products than about fairly assessing congressional intent to preempt. Whether the historic respect for the role of a robust state tort law in enhancing product safety continues or not remains an important open question in express preemption cases. *Bates* and *Riegel* provide inconsistent answers, but they at least openly engage the debate.

I am in the camp of those who believe that state tort law has an important role to play in regulating product safety and that it does not create perverse incentives in doing so. Tort law is not of a piece and the Court’s suggestion to the contrary in *Riegel* dismisses the reality that the measured evolution of tort doctrines has already incorporated many limits to address its alleged excesses. Many states have adopted regulatory compliance defenses, causation-limiting doctrines and apportionment mechanisms, limits on non-economic damages, and other doctrines that limit the potential for excess liability. It also bears repeating, as the Court noted in *Wyeth*, that tort law fundamentally serves goals other than regulating conduct: compensation, enhancing the availability of risk information, and corrective justice concerns are also fundamental to tort law. These important objectives should not be blithely ignored.

Second, as confirmed in *Wyeth*, the presence of a parallel tort law regime fulfills the constant and critical need for oversight of the

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143 See *DAN B. DOBIS, THE LAW OF TORTS § 384 (2000).*
regulatory process.145 Many have expressed the concern that our federal agencies are simply ill-equipped to act as the “one-stop shop” for insuring product safety.146 One need only look at the failures of weak regulatory regimes in recent months to recognize the value of shining a light on the dark recesses of our regulatory systems. Those recesses result from a host of problems in the way our federal agencies operate: from a lack of staffing and funding to insure regulatory compliance to an inability to produce complete risk information (either pre- or post-regulatory decision-making) because the regulated industry is largely in charge of that information, to the influence of shifting political winds on agency positions.147 These are concerns that stem from the inherent limits of the regulatory process. While faith in the expertise and good judgment of our regulators is certainly justified, that faith should not be blinded by the limitations that the process imposes on them.

Finally, as a policy matter, a choice has to be made about where the risk of uncertainty in the regulatory decision-making process should be placed: on the future victim of that uncertainty or the creator of it. Reasonable, rational, good faith decisions will be made that will produce real and significant harms alongside the benefits of those decisions. Inherent uncertainty exists in the current regulatory system because of, among other things, information-gathering and enforcement limitations. That uncertainty may or may not produce unreasonable risks from conduct that leads to common law products liability. If it does, however, the traditional tort system should not be prohibited from operating in its traditional way without the unquestionably clear intent of our federal legislators and regulators that such a result was, in fact, consciously considered, contemplated, and desired.

Much has been written on the effect of limitations on information gathering, and that ignoring those limitations can lead to analyses that “diverge in significant ways from reality.”148 Questions about the character of scientific knowledge and its relationship to the law

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145 For a discussion of the need for regulatory oversight regarding the FDA and its effect on implied conflict preemption, see Davis, The Battle Over Implied Preemption, supra note 3, at 1148-51.
146 See Wendy Wagner, When All Else Fails: Regulating Risky Products Through Tort Litigation, 95 GEO. L.J. 693, 695 (2007). Wagner explains:

[Pro]tective regulation is plagued by a variety of important information costs that slow and even halt regulatory progress. . . In some settings, the tort system can be more effective than the regulatory system in accessing the various types of information needed to inform regulatory decisions. Thus, in addition to its critical role in compensating victims, the tort system plays an indispensable role in supplementing agency regulation of risky products and activities.

Id.; see also Carter, supra note 8, at 42 (“The FDA is claiming total responsibility for drug and medical device safety. Some think it’s a bad idea.”).
147 See id. at 44-45.
148 Wagner, supra note 146, at 695.
Scientific certainty and legal certainty are often in conflict; it has been said that “[s]cience aims at truth without ever being certain.” Regulatory action based on scientific inquiry suffers from the same problem. The limits of human knowledge belie the certainty with which the Court tends to view regulatory action. The tort system places the risk of uncertainty on the creator of that risk, providing a necessary incentive for regulated industries to reduce reasonably the risk of uncertainty by understanding, acknowledging, managing, and disclosing that risk.

Many scholars have weighed in recently on the debate over whether tort law or administrative law should govern the risk inherent in the discovery of products and processes that benefit a large percentage of the population but, nevertheless, have inherent risks that will inevitably burden a smaller percentage of that population. These discussions include a variety of institutional comparisons and competency assessments, noting the differing goals served by the different regimes including uniformity, application of technical expertise, the viability of optimal safety regulation, the desirability of compensatory remedies and the need for oversight and accountability, among others. This larger debate over the role of federal agency regulatory action as it relates to traditional, state law-based private rights and responsibilities must continue. The Court’s preemption doctrine is only one part of this debate.

The evolution of preemption doctrine since *Cipollone* in 1992 is marked by aggressive efforts to expand its applicability to limit the operation of tort laws and to further the reach of uniform federal regulation. The relentless pursuit of preemption in the last two decades strikes me more as an effort to overcome dissatisfaction with the tort liability system than a sincere attempt at discerning congressional intent under a particular legislative scheme. The object of modern preemption doctrine seems to vacillate between discerning the scope of congressional intent, and creating it.

No Congress writing in the last seventy years can rationally be found to have intended to displace the central role that common law tort doctrines have held in the goal of enhancing public safety yet such arguments are often made. If state product liability and tort doctrines are to be re-evaluated because of the perceived limitations they place on

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149 The use of scientific expert testimony in litigation and the uneasy relationship between that testimony and proof of legal facts has made a cottage industry out of testifying as an expert. For the seminal case discussing the relationship between science and the law, see Daubert v. Merrell Dow Pharm. Inc., 509 U.S. 579 (1993).


innovation or some generalized notion of societal welfare, expanding preemption doctrine is not the way to accomplish it. That debate should be held in the full light of day and not hidden behind the cloud of preemption.

Preemption doctrine is out of balance, uncertain, and unwieldy in application. Though the result in *Wyeth* is consistent with my own position on the application of implied preemption doctrine to pharmaceutical labeling cases, many questions remain about implied preemption analysis generally. Now is certainly not the time to restate products liability preemption; perhaps by the time we have a Restatement (Fourth) of Products Liability.

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152 See Davis, *The Battle Over Implied Preemption*, supra note 3, at 1151-54.
The Value of Consumer Choice in Products Liability

*Mark A. Geistfeld*

**INTRODUCTION**

Tort law has always recognized the principle expressed by the Latin maxim *volenti non fit injuria*, or “a person is not wronged by that to which he or she consents.” The absence of consent is part of the prima facie case for tort liability, distinguishing tortious behavior from socially acceptable behavior. “For example, consent turns trespass into a dinner party; a battery into a handshake; [or] a theft into a gift.”

By removing informed choices from the ambit of liability, tort law allows individuals to structure their relationships in the manner that promotes their welfare as per the requirements of allocative efficiency. More fundamentally, “[t]o have the ability to create and dispel rights and duties [as a matter of informed, voluntary consent] is what it means to be an autonomous moral agent.” The role of consent within tort law derives from the value of individual autonomy or self-determination.

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1 Black’s Law Dictionary 1605 (8th ed. 2004). Modern tort law originated with the writ of trespass, and allegations of wrongdoing under that writ “were thought to be inappropriate where the defendant had acted with the consent of the plaintiff.” D.J. Ibbetson, A Historical Introduction to the Law of Obligations 41-42 (1999). Thus, “[i]t is a fundamental principle of the common law that *volenti non fit injuria*—to one who is willing, no wrong is done.” W. Page Keeton et al., Prosser and Keeton on the Law of Torts § 18, at 112 (5th ed. 1984).

2 See Keeton et al., supra note 1, § 18, at 112 (explaining why *volenti non fit injuria* “goes to negative the existence of any tort in the first instance”); see also Dan B. Dobbs, The Law of Torts § 95, at 218 (2000) (“In many cases, consent is not a true affirmative defense [to an intentional tort] but instead marks a deficiency in the plaintiff’s prima facie case.”); id. § 212 (explaining why the prima facie case for negligence liability depends on the absence of consent).


4 Cf. R.H. Coase, The Problem of Social Cost, 3 J.L. & Econ. 1, 9-11, 13, 15 (1960) (showing that when individuals have full information of all the relevant factors and do not incur any other costs in bargaining with others, voluntary agreements among right holders and duty holders will produce allocatively efficient outcomes).

5 Hurd, supra note 3, at 124. For purposes of legal analysis, a normative value such as individual autonomy is necessarily more fundamental than the instrumental objective of allocative efficiency. The computation of costs and benefits depends on how the legal system has specified the underlying legal entitlements. Consequently, neither allocative efficiency nor cost-benefit analysis can determine initial entitlements, making the substantive content of any legal rule dependent on normative justification in the first instance. See Mark A. Geistfeld, Efficiency.
Enabling individuals to make their own safety choices as a matter of self-determination is a value that tort law presumably also recognizes in product cases. In the typical product case, the individual right holder is a consumer, making the value of individual choice equivalent to the value of consumer choice. In light of the consumerist orientation of contemporary society, it would be astonishing to find that products liability does not fundamentally value consumer choice.

Nevertheless, the value of consumer choice in strict products liability is surprisingly unclear. Consider the liability rules governing defects of product design or warning, the most important categories of product defect. According to the Restatement (Third) of Torts: Products Liability, “[t]he emphasis is on creating incentives for manufacturers to achieve optimal levels of safety in designing and marketing products.”

The optimal level of safety has no evident connection to the amount of safety that would be chosen by consumers, because “consumer expectations do not play a determinative role in determining defectiveness.” Whether a product is defective in these cases instead depends on “[a] broad range of factors,” including “the nature and strength of consumer expectations regarding the product.” In some cases, consumer expectations can be “ultimately determinative” of the liability question, but it is not apparent why the liability rules exclusively rely on consumer choice in only these cases but not others.

The value of consumer choice in strict products liability becomes even harder to discern when considered in relation to assumption of risk, one of the liability-limiting doctrines based on the autonomy principle. According to this doctrine, an individual right holder who voluntarily
chooses to face a known risk bears responsibility for her ensuing injuries, thereby reducing or eliminating the liability that others might incur with respect to the identical safety decision. In the ordinary tort case, the doctrine can eliminate liability under the distinctive rules of express and primary assumption of risk, while at least reducing liability under the rule of secondary assumption of risk. By contrast, the Restatement (Third), like most jurisdictions, only recognizes secondary assumption of risk in product cases, and then treats such conduct as a form of contributory negligence that merely reduces the plaintiff’s recovery within a system of comparative responsibility. Assumption of risk has no evident role in products liability, deepening the impression that this body of tort law undervalues individual choice.

The impression is misleading. Strict products liability appropriately values consumer choice. The value of consumer choice, however, is obscured by the way in which the Restatement (Third) has de-emphasized the importance of consumer expectations. Properly understood, the value of consumer choice not only justifies the liability rules in the Restatement (Third), it also provides the key to understanding the important limitations of strict products liability, including those based on assumed risks.

As explained in Part I, a product seller typically incurs a tort duty only with respect to product attributes that frustrate the actual safety expectations of the ordinary consumer. Courts have long recognized that contractual remedies do not adequately protect uninformed consumers from the risk of product-caused physical harms, creating a safety problem that implicates the core concern of tort law. The rule of strict products liability accordingly addresses the safety problems stemming from consumers’ uninformed product decisions. An exclusive focus on cases involving the absence of informed consumer choice creates the misleading appearance that consumer choice is largely irrelevant for products liability.

Part II then shows how strict products liability instantiates the value of consumer choice. A liability rule that is supposed to address the safety problems created by uninformed consumer choice should require

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13 See Geistfeld, supra note 6, at 307-09 (explaining why assumption of risk only applies to the same safety choice implicated by the plaintiff’s prima facie case for liability). See generally Kenneth W. Simons, Assumption of Risk and Consent in the Law of Torts: A Theory of Full Preference, 67 B.U. L. REV. 213, 238 (1987) (explaining that assumption of risk should only apply when the plaintiff’s “chosen course of action was based on a full and true preference, i.e., made with knowledge of all the alternatives that defendant had a duty to offer, including that alternative which plaintiff claims defendant tortiously failed to offer”).


15 See Restatement (Third) of Torts: Prods. Liab. § 17(a), cmt. a (1998) (recognizing an affirmative defense only when “the plaintiff’s conduct fails to conform to generally applicable rules establishing appropriate standards of care,” which encompasses assumption of risk only insofar as the plaintiff’s choice to face the risk was unreasonable); id. § 18 (refusing to enforce oral or written contractual limitations of liability).
the amount of safety that would be chosen by consumers if they were 
fully informed. A fully informed consumer chooses the amount of 
product safety satisfying the risk-utility test. Consequently, the 
reasonable safety expectations of the ordinary consumer can be defined 
by the risk-utility test, a formulation of the liability rule that has been 
adopted by an increasing number of jurisdictions. This formulation does 
not simply convert consumer expectations into the risk-utility test, but 
instead relies on the value of consumer choice to justify the liability rule.

Part III concludes by showing how the value of consumer choice 
can explain the important limitations of strict products liability, including 
the affirmative defenses. Like the other rules of strict products liability, 
the limitations of liability can be squared with the old maxim that “No 
injury or wrong is done to one who consents.”

I. UNINFORMED CONSUMER CHOICE AS THE PREDICATE FOR 
STRICT PRODUCTS LIABILITY

The widely adopted rule of strict products liability law in section 
402A of the Restatement (Second) of Torts is based on the tort doctrine 
of the implied warranty. “In its inception, breach of warranty was a tort. 
The . . . wrong was conceived to be a form of misrepresentation, in the 
nature of deceit . . . .” The misrepresentation stemmed from the manner 
in which the product frustrated the reasonable safety expectations of the 
purchaser; liability was strict in the sense that it did not require any 
culpable wrongdoing on the seller’s part. The rule of strict liability was 
instead justified by the purchaser’s lack of knowledge about the product 
attributes in question, creating a mismatch between the product’s actual 
qualities and the purchaser’s expectation of quality.

The paradigmatic example involves the sale of contaminated 
food, which for centuries has subjected sellers to liability under implied 
warranty. As the Texas Supreme Court has explained:

Liability in such case is not based on negligence, nor on a breach of the usual 
implied contractual warranty, but on the broad principle of the public policy to 
protect human health and life. It is a well-known fact that articles of food are 
manufactured and placed in the channels of commerce, with the intention that 
they shall pass from hand to hand until they are finally used by some remote 
consumer. It is usually impracticable, if not impossible, for the ultimate 
consumer to analyze the food and ascertain whether or not it is suitable for 
human consumption. Since it has been packed and placed on the market as a

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17 RESTATEMENT (SECOND) OF TORTS § 402A cmt. m (1965) (“There is nothing in this 
Section which would prevent any court from treating the rule stated as a matter of ‘warranty’ to the 
user or consumer.”).
18 William L. Prosser, The Implied Warranty of Merchantable Quality, 27 MINN. L. REV. 
117, 118 (1943).
food for human consumption, and marked as such, the purchaser usually eats it or causes it to be served to his family without the precaution of having it analyzed by a technician to ascertain whether or not it is suitable for human consumption. In fact, in most instances the only satisfactory examination that could be made would be only at the time and place of the processing of the food. It seems to be the rule that where food products sold for human consumption are unfit for that purpose, there is such an utter failure of the purpose for which the food is sold, and the consequences of eating unsound food are so disastrous to human health and life, that the law imposes a warranty of purity in favor of the ultimate consumer as a matter of public policy.20

The rule of strict liability governing the sale of contaminated food was extended by courts in the twentieth century to encompass other products.21 In adopting the rule of strict products liability, courts often relied on opinions authored by Justice Roger Traynor of the California Supreme Court.22 In his influential concurring opinion in Escola v. Coca Cola Bottling Co., Traynor addressed the problem of uninformed consumer choice:

As handicrafts have been replaced by mass production with its great markets and transportation facilities, the close relationship between the producer and consumer of a product has been altered. Manufacturing processes, frequently valuable secrets, are ordinarily either inaccessible or beyond the ken of the general public. The consumer no longer has means or skill enough to investigate for himself the soundness of a product, even when it is not contained in a sealed package, and his erstwhile vigilance has been lulled by the steady efforts of manufacturers to build up confidence by advertising and marketing devices such as trade-marks. Consumers no longer approach products warily but accept them on faith, relying on the reputation of the manufacturer or the trade mark.23

By emphasizing how consumers are unable to make informed product choices, Traynor adopted a rationale for tort liability that had been invoked by others. As one commentator had observed a few years earlier, “[e]mphasis upon the inability of the unspecialized consumer adequately to inspect or test merchandise is becoming increasingly common and seems to have recently influenced rapid developments in the scope of liability to the consumer.”24

When interpreting the rule of strict products liability, courts have continued to recognize the problem of uninformed consumer choice:

In today’s world, it is often only the manufacturer who can fairly be said to know and to understand when an article is suitably designed and safely made for its intended purpose. Once floated on the market, many articles in a very

20 Jacob E. Decker & Sons v. Capps, 164 S.W.2d 828, 829 (Tex. 1942).
real practical sense defy detection of defect, except possibly in the hands of an expert after laborious and perhaps even destructive disassembly.25

The rule of strict products liability governs the designs of automobiles, for example, because “manufacturers of such complex products as motor vehicles invariably have greater access than do ordinary consumers to the information necessary to reach informed decisions concerning the efficacy of potential safety measures.”26 Thus, one of the public policy rationales for the rule of strict products liability is that “the consumer does not have the ability to investigate for himself the soundness of the product.”27

Tort liability can be justified in these terms because of the safety problems that are created when product sellers rationally respond to the safety decisions made by uninformed consumers. Consider a manufacturer’s decision about whether to install a costly safety device to eliminate an unreasonable product risk of which the ordinary consumer is unaware. By installing the safety device, the manufacturer increases the cost and the price of the product. Without the device, the product would expose consumers to the associated risk of injury. Unless consumers know about the risk, they will not be willing to pay for the safety device, leading them to purchase the lower priced product without the device. Why spend money on safety if one is unaware of the need to do so? Manufacturers will not tell consumers about these risks, as doing so would only increase consumer estimates of product cost and decrease sales. What is the point of advertising negative product attributes to the consumer? The process of price competition predictably forces manufacturers to forego these types of safety investments, resulting in unreasonably dangerous products. The ensuing safety problem both justifies the tort duty and explains why customary product safety practices can be unreasonably dangerous.28

During the 1920s, for example, the president of the automobile manufacturer General Motors “insisted that the company could not make windshields with safety glass because doing so would harm the bottom line.”29 The automobile manufacturers were simply responding to misinformed consumer demand. “G.M. believed that consumers weren’t prepared to pay more for cars with safety glass . . . .”30 The same dynamic has occurred throughout the history of automotive safety. During the 1950s, “auto executives told Congress that making seat belts

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28 For a more complete analysis, including other economic rationales for the tort duty, see Mark A. Geistfeld, Principles of Products Liability 34-50 (2006).
30 Id.
compulsory would slash industry profits.”\textsuperscript{31} The industry had the same response to airbags. As the president of the Chrysler Motors lamented, “safety has really killed all our business.”\textsuperscript{32} Without the intervention of tort law or other forms of safety regulation, the market would have adopted customary practices (no safety glass, no seat belts, no airbags) that were unreasonably dangerous.

The growth of the economy and proliferation of products have also made it increasingly difficult for consumers to acquire information about product risk. Consumers now face a bewildering array of product choices. Over thirty thousand items are available in the typical supermarket.\textsuperscript{33} Experience with a brand may provide the consumer with some knowledge, but even that is short-lived. For U.S. manufacturing firms that remain in operation over a manufacturing census period (every five years), almost two-thirds of the firms change their product mixes, with the product switches involving almost half of existing products.\textsuperscript{34} The consumer’s ability to evaluate risk is then made even more difficult by the increased complexity of products. Who has the time, energy and desire to evaluate each and every one of these product risks, particularly given the range of other decisions we face on a daily basis?\textsuperscript{35}

Recognizing that consumers are simply unable to evaluate all product risks, courts and legislatures have adopted the rule of strict products liability. The associated tort duty places responsibility for the safety decision on the party most capable of making that decision on an informed basis—the manufacturer.\textsuperscript{36}

\begin{itemize}
\item \textsuperscript{31} Id.
\item \textsuperscript{32} Id.
\item \textsuperscript{33} Gary Cross, An All-Consuming Century: Why Commercialism Won in Modern America 214 (2000).
\item \textsuperscript{34} See Andrew B. Bernard et al., Product Choice and Product Switching 5-6 (Nat’l Bureau of Econ. Research, Working Paper No. 9789, 2003).
\item \textsuperscript{36} The manufacturer has greater technical expertise and can make one thorough investigation of the product, spreading that information cost among all consumers via a price increase. The associated cost per consumer will often be less than the average amount that each consumer would otherwise incur to investigate product safety on her own. Because information acquisition depends on a comparison of costs and benefits incurred by the decision maker, a reduction in costs should increase the total amount of information acquired, assuming there is no change in the benefits of the information.
\end{itemize}

A tort duty, moreover, is likely to increase the benefits of information for the decision maker. A seller owing a duty to all consumers considers the benefit of added information in terms of that group, whereas the individual consumer acquiring information only considers her private benefit. The benefit for the group will typically exceed the benefit for the individual consumer. Because information acquisition depends on the decision maker’s comparison of costs with benefits, an increase in benefits should increase the amount of information acquired, all else being equal.
II. STRICT PRODUCTS LIABILITY AS THE INSTANTIATION OF INFORMED CONSUMER CHOICE

As we have found, the tort duty is predicated on the conclusion that the ordinary consumer does not have sufficient information about product risks, causing her to undervalue product safety. Due to the process of price competition, these uninformed consumer choices give manufacturers an incentive to supply unreasonably dangerous products. These products are more dangerous than expected by the ordinary (misinformed) consumer, and so the resultant product-caused injuries frustrate consumer safety expectations. To address this safety problem, tort law overrides these misguided contractual choices (and customary product-safety practices more generally) by subjecting product sellers to a tort duty.

The Restatement (Second) rule of strict products liability applies to “[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property.” 37 To be “unreasonably dangerous,” the product attribute “must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.” 38 Such a product attribute frustrates the ordinary consumer’s actual expectations of product safety, the condition required for tort law to supplement the seller’s contractual obligations with a tort duty.

Because the tort duty is based on the product attribute frustrating the actual (misinformed) safety expectations of the ordinary consumer, the separate element of defect must be defined in some other manner. Otherwise, the existence of duty would necessarily establish the existence of defect, conflating the two elements into a single requirement.

The frustration of the ordinary consumer’s actual (misinformed) safety expectations creates the tort duty, and so the element of defect becomes a separate requirement when defined in terms of the ordinary consumer’s reasonable (well-informed) safety expectations. Having received a product with the amount of safety that she would have chosen if adequately informed of the relevant factors, the ordinary consumer could not reasonably expect some other amount of product safety. A product satisfying the well-informed or reasonable safety expectations of the ordinary consumer is not defective.39

For other reasons why a tort duty would improve safety decisions in situations of high information costs, see Steven P. Croley & Jon D. Hanson, Rescuing the Revolution: The Revived Case for Enterprise Liability, 91 Mich. L. Rev. 683, 770-92 (1993).

38 Id. § 402A cmt. i.
39 See, e.g., Potter v. Chi. Pneumatic Tool Co., 694 A.2d 1319, 1333 (Conn. 1997) (holding that for safety attributes that are not well understood by the ordinary consumer, “the inquiry
This definition of defect has a straightforward rationale. A liability rule formulated to address the safety problems created by uninformed consumer choice should require the amount of safety that would be chosen by consumers if they were fully informed. Fully informed consumers understand that products cannot always be made entirely safe for all uses. Perfection typically is either not possible or unduly expensive. Some product risk is usually inevitable, and so the mere fact that a product causes an accident does not frustrate the consumer’s reasonable safety expectations. The accident must instead be caused by a defect in the product, making the definition of defect dependent on the reason why the product attribute frustrates the safety expectations of the ordinary consumer.

According to the Restatement (Third), “[p]roducts that malfunction due to manufacturing defects disappoint reasonable expectations of product performance,” thereby justifying strict liability. A manufacturing or construction defect departs from the product’s intended design. In an effort to eliminate such defects, sellers adopt procedures or systems of quality control. Perfect quality control is not reasonably expected by the ordinary consumer for the same reason that perfect product safety is not a reasonable expectation. The complete elimination of product risk typically is not feasible or desirable. Consequently, the ordinary consumer only reasonably expects that the product has passed the appropriate tests of quality control. To enforce such an implied guarantee of product quality, the consumer can reasonably expect the seller to provide a guaranteed remedy for malfunctioning products. This guarantee makes the seller (strictly) liable for malfunctioning products, thereby creating the requisite financial incentive for reducing the incidence of these defects in a cost-effective manner.

In contrast to the rule governing construction or manufacturing defects, the Restatement (Third) eschews consumer expectations in favor of the risk-utility test to determine whether the product is defective

\[\text{See, e.g., Green v. Smith & Nephew AHP, Inc., 629 N.W.2d 727, 753 (Wis. 2001) ("Virtually no product is entirely safe for all consumers under all conditions, even when being used as intended. We presume that the ordinary consumer recognizes as much. Thus, when the ordinary consumer purchases or uses a product, we must assume that consumer contemplates there is at least some danger involved.").}\]

\[\text{41 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. a (1998).}\]

\[\text{\textit{See} GEISTFELD, supra note 28, at 30-31; \textit{see also} RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. a (1998) ("[I]mposing strict liability on manufacturers for harm caused by manufacturing defects encourages greater investment in product safety than does a regime of fault-based liability under which, as a practical matter, sellers may escape their appropriate share of responsibility.").}\]
because of design or an inadequate warning. Doing so is unnecessary, if not counterproductive.

Excluding instances of bystander injuries (discussed in Part III.A), product cases only implicate consumer interests. Any tort burdens incurred by the manufacturer or other product sellers, including the cost of safety investments and liability for injury compensation, are passed on to the consumer in the form of higher prices. Consequently, the risk-utility test in the Restatement (Third) is formulated entirely in terms of consumer interests: “[I]t is not a factor . . . that the imposition of liability would have a negative effect on corporate earnings or would reduce employment in a given industry.” Why would a risk-utility test that is limited to consumer interests ever require product designs or warnings that are not reasonably expected by the ordinary consumer?

Indeed, the consumer’s full set of interests is best protected by safety investments satisfying the cost-benefit version of the risk-utility test. For example, the risk of a car design without an airbag refers to the increased risk the consumer will suffer injury due to the absence of the airbag, a measure corresponding to the consumer’s injury costs that would be reduced or eliminated by the airbag. The utility of the design without an airbag involves any savings the consumer experiences by not having the airbag, an amount equal to the total cost of the airbag. Under the cost-benefit version of the risk-utility test, the car is defective for not having an airbag if the utility of the existing design is less than the increased risk posed by the design:

\[
\text{added utility of design without airbag} < \text{added risk of design without airbag}
\]
\[
\text{total cost of airbag} < \text{injury costs eliminated by airbag}
\]

For safety investments satisfying this condition, consumer right holders incur a cost or burden that is less than the associated benefit they derive from the enhanced product safety (the reduction of expected injury costs). A product containing the cost-benefit amount of product safety promotes consumer welfare as reasonably expected by the ordinary consumer, thereby satisfying the seller’s tort obligation.

Proof that a product is defectively designed usually involves a comparison of the existing design to a proposed alternative. “While a manufacturer has a duty to design a product that is reasonably safe for its foreseeable use, it is not required to design the ‘best possible product,’

44 See Geistfeld, supra note 28, at 38 n.7 (providing more rigorous support for this claim).
46 Cf. 63 Am. Jur. 2d Products Liability § 583 (2d ed. 1997) ("The reasonable expectation of the user or consumer is to be determined through consideration of a number of factors, including the relative cost of the product, the gravity of potential harm from a claimed defect, and the cost and feasibility of eliminating or minimizing risk.")
and ‘proof that technology existed, which if implemented could feasibly have avoided a dangerous condition, does not alone establish a defect.’”47 Increased product safety typically increases product costs for the consumer due to increased price or decreased functionality. The safest possible product is not preferred by a well-informed consumer whenever the benefits of such safety for the consumer are outweighed by the resultant costs borne by the consumer. A design defect, therefore, is defined by reference to a reasonable alternative design.48 By proving that there is a reasonable alternative to the existing product design—one that passes the risk-utility test in the usual case—the plaintiff in effect proves that the manufacturer failed to provide the design that would be chosen by well-informed consumers.49

To further foster informed consumer choice, strict products liability obligates the seller to warn consumers of any unknown product risks that would be material to their decisions concerning the purchase or safe use of the product.50 Insofar as the average or ordinary consumer is unaware of a risk, a warning to that effect allows her to make an informed risk-utility decision. The duty to warn is the most obvious instance in which strict products liability is formulated in terms of consumer choice, further confirming that this body of tort law strives to create outcomes that instantiate the value of informed consumer choice.

III. CONSUMER CHOICE AS A LIMITATION OF STRICT PRODUCTS LIABILITY

The value of consumer choice provides a compelling justification for strict products liability, and yet many reject this rationale on the ground that consumer choice places too great of a limit on tort liability. As a leading treatise explains:

The utility of the consumer expectations test is severely compromised when design dangers are obvious. Because consumers acquire their safety and danger expectations most directly from a product’s appearance, obvious dangers—such as the risk to human limbs from an unguarded power mower or industrial machine—are virtually always contemplated or expected by the user or consumer who thereby is necessarily unprotected by the consumer expectations

47 Robinson v. Brandtjen & Kluge, Inc., 500 F.3d 691, 696 (8th Cir. 2007) (applying South Dakota law) (citing Sexton ex rel. Sexton v. Bell Helmets, Inc., 926 F.2d 331, 336 (4th Cir. 1991)) (internal citation omitted).
49 For cases in which the design prevents the product from performing its intended function, the plaintiff does not need to establish defect by reference to a reasonable alternative design. See id. § 3 cmt. b. By purchasing or using the product, the ordinary consumer reasonably expects that there is some design that would enable the product to perform its intended function. The proof of malfunction accordingly establishes the frustration of reasonable expectations, regardless of whether the plaintiff can identify a reasonable alternative design.
50 See GEISTFELD, supra note 28, at 134-59 (explaining the duty to warn and showing how it fosters informed consumer decision making).
test, no matter how probable or severe the likely danger nor how easy or cheap the means of avoiding it. . . . And a pure consumer expectations test perniciously rewards manufacturers for failing to adopt cost-effective measures to remedy obviously unnecessary dangers to human life and limb. The failure of the consumer expectations test to deal adequately with the obvious danger problem profoundly weakens the usefulness of this test and effectively disqualifies it for principled use as the sole basis for determining defects in design.\footnote{David G. Owen, \textit{Products Liability Law} § 8.3, at 490-91 (2d ed. 2008) (footnotes omitted).}

This characterization of consumer expectations mistakenly assumes that a consumer who is aware of a danger has necessarily made an informed safety choice about the matter. Awareness of risk is only one factor in the consumer’s safety decision, and so consumer expectations are not satisfied simply because the danger is open or obvious. For an important class of safety decisions, however, consumer expectations are satisfied with respect to apparent risks, thereby explaining otherwise puzzling rules concerning important limitations of strict products liability. Rather than providing a reason to reject consumer expectations, the problem of known or obvious dangers further supports the conclusion that strict products liability appropriately values consumer choice.

\subsection*{A. Open or Obvious Dangers}

The problem of open or obvious dangers is addressed by the patent-danger rule, which originated in cases involving a product malfunction that allegedly breached the implied warranty. According to this rule,

if the buyer has examined the goods and their defects are discovered, or so obvious that he could avoid discovery only by shutting his eyes as to what was evident, the warranty is ineffective. The reason is that he must understand that the seller is offering for sale what is before him, as it appears to be; and even express language, at least in any form other than an explicit reference to the defect itself, will not entitle him to expect anything different.\footnote{Prosser, \textit{supra} note 18, at 153 (footnotes omitted).}

When the consumer knows of an open or obvious danger that the product might malfunction, the occurrence of such a malfunction does not frustrate consumer expectations of performance. Products breach the implied warranty “if they cannot be used.”\footnote{\textit{Id.} at 132.} Thus, “any latent condition, such as a pin inside of a loaf of bread, which would prevent purchase if it were known, is enough” to breach the warranty.\footnote{\textit{Id.} at 137 (footnote omitted).} Having decided to purchase and then use the particular product despite its open or obvious danger of malfunction, the plaintiff cannot claim that the associated

defect would prevent purchase or use of that product as required by the allegation of liability, thereby barring recovery.

In these cases, the plaintiff made an informed safety decision that is identical to the decision implicated by the allegation of liability. In deciding to purchase the product, the plaintiff presumably figured out how much utility she would derive from the product use after subtracting the purchase price and other costs. She also knew of the defect that could cause the product to malfunction. Her purchase of the product, therefore, involved an informed decision that the total net utility of using the product exceeded the risk of malfunction. That risk-utility decision is inconsistent with the plaintiff’s allegation that the product breached the implied warranty. According to the allegation of breach, this particular product should not have been sold, a condition that is satisfied only if the risk of malfunction exceeds the total net utility of product use. Because the plaintiff had already made an informed decision that the risk of malfunction is less than the total net utility of product use, a court that respects the value of consumer choice will bar the plaintiff’s recovery.55

This rationale for the patent-danger rule does not apply to most allegations of defective design involving open or obvious dangers. A consumer’s decision of whether to purchase a product in light of a known danger of malfunction is fundamentally different from most safety decisions involving product design. Product malfunctions implicate the consumer’s decision of whether to purchase or use the product at all. By contrast, the issue of defective design normally implicates a different decision. For example, if there were no automobiles equipped with airbags, consumers would still use these products. In deciding to use a car, the consumer presumably concluded that the total benefits of using the automobile outweigh its total costs. An informed risk-utility decision concerning an airbag, by contrast, compares the cost (or disutility) of the airbag with its safety benefit (or reduced risk of injury). The consumer’s decision to use the automobile differs from the risk-utility decision implicated by the allegation of defective design. The court can value the

55 Even if the plaintiff only used the product and did not purchase it, the value of consumer choice would still bar recovery. In products liability, the “consumer” includes both the purchaser and other expected users of the product. See, e.g., Henningsen v. Bloomfield Motors, Inc., 161 A.2d 69, 80-81 (N.J. 1960) (“[T]he connotation of ‘consumer’ is broader than that of ‘buyer.’ He signifies[es] such a person, who, in the reasonable contemplation of the parties to the sale, might be expected to use the product.”). Similarly, welfare economists typically evaluate consumer behavior in terms of households rather than individuals. See, e.g., Robin Boadway & Neil Bruce, Welfare Economics 8 (1984). The consumer can be conceptualized in this manner because the interests of such a product user are indistinguishable from those of the buyer. One who purchases a product presumably gives equal consideration to the welfare of those whom she expects to use the product, such as family members, friends, or employees. As a product user whose interests were adequately accounted for by the purchaser, the plaintiff only reasonably expects the amount of product safety that is acceptable to the buyer. See Geistfeld, supra note 28, at 39 nn.9-10 (illustrating the point in the context of employer-employee relationships and analogizing the issue to the duty a landowner owes to licensees). Consequently, even if the plaintiff did not actually purchase the product, her role as consumer makes it appropriate to analyze the case as if she were the purchaser.
plaintiff’s choice to use the product without barring her claim that this open or obvious danger constitutes a design defect.

The obvious absence of a safety device like an airbag also does not imply that the plaintiff or any other consumer had adequate knowledge of the risk-utility features of the device. Prior to the widespread adoption of airbags, how many consumers actually knew that they could be installed in cars or how they work? Even today, how many consumers truly know about the cost of an airbag, which includes not only the price of an airbag but also replacement costs and any increased injury costs created by the airbag, such as the risk posed to children? Indeed, “the ordinary consumer of an automobile simply has ‘no idea’ of how it should perform in all foreseeable situations, or how safe it should be made against all foreseeable hazards.”56 Without such knowledge, the consumer cannot make an informed risk-utility decision about the airbag or any other safety device that would eliminate an open or obvious danger posed by the automobile design.

The cost of acquiring and processing all of the risk-utility information can also induce the consumer to forego the evaluation altogether. Given the multitude of apparent risks that an individual confronts on a daily basis, does it make sense to evaluate each one with a full-blown risk-utility or cost-benefit analysis? At most, consumers will engage in a limited number of risk-utility decisions, even for open or obvious product risks.57

Consistent with this reasoning, courts have long recognized that an open or obvious danger can frustrate consumer expectations in breach of the implied warranty:

The offer to sell “what you see” cannot charge the buyer with acceptance of what is not visible; and the question becomes one of whether the understanding that goods of merchantable quality are to be sold is destroyed merely by the fact that the buyer has inspected at all. . . . It is entirely possible that the seller may say, in effect, “Here are merchantable goods, of the kind and quality sold on the market; if you have doubts, you are free to examine them;” and after examination the buyer may say, in return, “They look alright; I will take them for what they appear to be, but for the rest I will rely upon your undertaking as to quality.” Under such conditions, the warranty may of course still be implied, even where the buyer has made the fullest examination open to him, and certainly all the more readily where his inspection is only a hasty or partial one, or where he declines the opportunity and does not inspect at all.58

To satisfy the implied warranty, products “must be marketable with their true character known.”59 Products have become increasingly complex, making it increasingly difficult for consumers to discern the

57 See supra note 35 and accompanying text.
58 Prosser, supra note 18, at 154-55 (footnotes omitted).
59 Id. at 128-29.
true character of apparent product risks. Are they inherent in the product or could they be eliminated by cost-effective changes in product design? “Whether a danger is open and obvious depends not just on what people can see with their eyes but also on what they know and believe about what they see.”60 A consumer who is aware of an open or obvious danger can expect that such a risk is inherent in the product and cannot be eliminated by cost-effective safety investments. If such a risk could be eliminated in this manner and the seller failed to do so, the product design frustrates consumer expectations and subjects the seller to tort liability for the ensuing physical harms.

In the years leading up to the adoption of strict products liability, courts were increasingly willing to find that the implied warranty governed apparent dangers that had been inspected by the purchaser, turning these otherwise open or obvious dangers into latent defects not subject to the patent-danger rule:

[T]he emphasis has been shifted to the actual understanding of the parties, with the result that there has been a strong tendency to find a warranty as to latent defects even in the face of inspection. This has proved to be all the more necessary as goods have become more highly specialized, marketing processes more complex, and buyers more helpless to form any intelligent estimate of the character of the goods on the basis of their own examination or tests.61

These cases establish the important principle that if the consumer cannot make an “intelligent estimate” of all the relevant risk-utility factors, consumer expectations can be frustrated by risks that are otherwise open or obvious, subjecting the seller to tort liability. This principle was established by warranty cases that were all decided before the 1960s, making them part of the doctrinal foundation for the rule of strict products liability.62 This principle accordingly justifies the rule adopted by most courts that the plaintiff is not barred from recovery under strict products liability merely because the danger was apparent.63

In order for consumer expectations to be satisfied, the consumer must have made the safety decision on the basis of good information about all of the risk-utility factors. As we have found, a well-informed consumer will choose to face only those risks that cannot be eliminated by cost-effective safety investments.64 Consequently, consumer expectations are satisfied by risks that are “inherent in the product,

61 Prosser, supra note 18, at 156 (footnotes omitted).
62 Compare RESTATEMENT (SECOND) OF TORTS § 402A cmt. m (1965) (“There is nothing in this Section which would prevent any court from treating the rule stated as a matter of ‘warranty’ to the user or consumer.”), with Prosser, supra note 18, at 155-56 & nn.218-19 (explaining this principle and providing citations to warranty cases decided prior to 1943).
64 See supra notes 45-46 and accompanying text.
completely within the cognition of a reasonable user, and incapable of being economically alleviated."65

Once the patent-danger rule has been formulated in these terms, it explains the otherwise puzzling line of cases in which the plaintiff claims that a product is defective no matter how it is designed. Such a claim effectively asserts that for the general category of comparable or substitute products, the design of each one is defective. Because any product within the category is alleged to be defectively designed and unreasonably dangerous, the product at issue in the suit is also defective and unreasonably dangerous, regardless of its particular design features. “American courts have avoided product category [liability] like the plague,”66 although tort scholars have continued to question the rationale for doing so.67 “After all, if strict liability attaches to products with unreasonably dangerous features how can it not reasonably attach to unreasonably dangerous products?”68 The answer is supplied by consumer expectations. Categorical risks are inherent in the product, completely within the cognition of an ordinary user, and incapable of being economically alleviated, thereby satisfying the (properly formulated) patent-danger rule and explaining why courts routinely reject claims of categorical liability.

To see why, recall that the tort duty makes it reasonable for the consumer to assume that the product contains no manufacturing or construction flaws. By relying on the tort duty, the consumer can also assume that each product design within the category is reasonably safe. In effect, the tort duty guarantees the reasonable safety of all products within each category, enabling the ordinary consumer to focus on the risk-utility comparisons across product categories, such as that involved in comparing a standard automobile to a subcompact car. In making choices across product categories, the ordinary consumer also benefits from the duty to warn, which guarantees that the product warning provides the ordinary consumer with the material information required for informed safety decisions.69 Once the information already held by the ordinary consumer is supplemented by the information provided by the product warning, she presumably is able to make an informed categorical

66 James A. Henderson, Jr. & Aaron D. Twerski, A Fictional Tale of Unintended Consequences: A Response to Professor Wertheimer, 70 BROOK. L. REV. 939, 945 (2005); see also James A. Henderson, Jr. & Aaron D. Twerski, Closing the American Products Liability Frontier: The Rejection of Liability Without Defect, 66 N.Y.U. L. REV. 1263, 1329 (1991) (“Most courts that have considered product-category liability claims have rejected them out of hand. And of the very few decisions that have embraced the notion, each has been reversed by its respective state legislature.”).
69 See supra note 50 and accompanying text.
choice. The ordinary consumer presumably then makes such a
categorical risk-utility assessment in deciding whether to choose one
product category over another (such as the subcompact over the
standard-sized automobile), even if she forgoes more limited risk-utility
evaluations involving particular safety devices (like an airbag, the
steering mechanism, the braking system, and so on). Having made an
informed categorical risk-utility decision, the ordinary consumer’s actual
expectations of safety are satisfied in that regard, thereby eliminating the
seller’s design duty with respect to any risk that is inherent in the product
category.

The plaintiff, for example, cannot claim that a microbus is
defectively designed for not having the safety features characteristic of a
standard passenger vehicle.70 Similarly, the plaintiff cannot claim that a
bullet-proof vest is defectively designed merely because it does not
provide the more extensive protection afforded by other styles that were
available on the market.71 Having chosen a less safe alternative, the
consumer does not expect the greater safety offered by a product
configuration she decided not to purchase.

For the same reason, the consumer’s informed choice of an
optional safety feature can bar a claim of strict products liability:
The product is not defective where the evidence and reasonable inferences
therefrom show that: (1) the buyer is thoroughly knowledgeable regarding the
product and its use and is actually aware that the safety feature is available; (2)
there exist normal circumstances of use in which the product is not
unreasonably dangerous without the optional equipment; and (3) the buyer is in
a position, given the range of uses of the product, to balance the benefits and
the risks of not having the safety device in the specifically contemplated
circumstances of the buyer’s use of the product. In such a case, the buyer, not
the manufacturer, is in the superior position to make the risk-utility assessment,
and a well-considered decision by the buyer to dispense with the optional safety
equipment will excuse the manufacturer from liability.72

Liability is limited in this manner in order to further the value of
consumer choice. “Consumers are entitled to consider the risks and
benefits of the different designs and choose among them.”73 These
choices satisfy the actual safety expectations of the ordinary consumer,
so the product is not “unreasonably dangerous” under the Restatement (Second)
rule of strict products liability.74

When applied in this manner,

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70 Dreisonstok v. Volkswagenwerk, A.G., 489 F.2d 1066, 1069, 1073-75 (4th Cir. 1974)
(applying Virginia law).
71 Linegar v. Armour of Am., Inc., 909 F.2d 1150, 1151-54 (8th Cir. 1990) (applying
Missouri law).
omitted).
74 See supra notes 37-39 and accompanying text.
the “unreasonably dangerous” requirement serves the useful function of balancing safety considerations against a policy which favors product diversity and consumer choice. Automobiles, and numerous other types of products, vary considerably in their safety features and characteristics. However, the law does not require that manufacturers produce only the safest product feasible in order to avoid being exposed to liability. Rather it requires them to avoid placing on the market products that are rendered “unreasonably dangerous” because of a defect in design or manufacture.75

So construed, the “unreasonably dangerous” requirement serves its intended purpose of ensuring that product sellers are not subject to liability merely because the consumer was injured by a known risk that inheres in the product.76 When the ordinary consumer has knowledge of those risks that are inherent in the product category—an informational requirement addressed by the seller’s duty to warn—then she is capable of making an informed categorical risk-utility decision, thereby precluding a claim of categorical liability.

The value of informed consumer choice justifies the widespread rejection of categorical liability, and yet the Restatement (Third) acknowledges the possibility of categorical liability for “manifestly unreasonable design” of products with “low social utility and [a] high degree of danger.”77 How could any application of categorical liability be squared with consumer expectations? After all, if the ordinary consumer has made an informed categorical risk-utility decision, why should the seller be obliged to make the contrary decision? The answer involves an alternative rationale for categorical liability, one that shows why the value of consumer choice is not always a defensible reason for limiting liability.

76 In discussing the “unreasonably dangerous” requirement in section 402A of the Restatement (Second), the California Supreme Court has observed that:
The analysis so far has been confined to the consumer, a concept including the buyer and other users of the product. Excluded are third parties or bystanders. When consumers face low information costs and have a choice among safety options, they are able to make informed safety choices that best promote their interests. In these cases, the rejection of categorical liability appropriately defers to consumer choice. Deference to consumer choice is not compelling, though, when third-party interests are at stake. Consumers who make safety decisions by reference to their own interests can make product choices that are unreasonably dangerous for bystanders. In these cases, the value of consumer choice does not justify a limitation of liability, explaining why the Restatement (Third) and many courts could defensibly recognize that categorical liability is appropriate if the product has “low social utility” (for the consumer) that is outweighed by the “high degree of danger” (faced by the consumer and bystanders).

Except for these circumstances, the risk-utility decision is limited to consumer interests, and the value of consumer choice justifies the widespread rejection of categorical liability. The ordinary consumer can make an informed categorical risk-utility decision, with the satisfaction of consumer expectations negating categorical liability or otherwise being “ultimately determinative” of the risk-utility inquiry in the Restatement (Third). In contrast to the categorical risk-utility decision, consumers usually do not make informed risk-utility decisions about every other apparent risk posed by a product. Consumer expectations are not satisfied simply because a danger is open or obvious. When properly formulated in terms of consumer expectations, the patent-danger rule does not bar recovery for every apparent danger, but instead limits strict products liability only when doing so furthers the value of informed consumer choice.

B. Assumed Risks

The value of individual choice in tort law traditionally has been associated with the doctrine of assumed risks:

The assumed risk rule was sometimes expressed in terms of the maxim, volenti non fit injuria or under the name of incurred risk. However formulated, the essential idea was that the plaintiff assumed the risk whenever she expressly agreed to do so by contract or otherwise, and also when she impliedly did so by words or conduct. Courts began to think that conduct implied consent whenever the plaintiff had specific knowledge of the risk posed by the defendant’s negligence, appreciated its nature, and proceeded voluntarily to encounter it nonetheless. The Restatement and more modern theory added that the risk was

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78 See supra note 55.
79 See GEISTFELD, supra note 28, at 252-59.
80 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. g (1998).
assumed only if the plaintiff’s conduct in encountering the risk manifested the plaintiff’s willingness to accept responsibility for the risk.\(^\text{81}\)

In product cases, plaintiffs cannot assume the risk expressly by contract. According to the Restatement (Third), courts do not enforce contractual or express waivers of strict products liability because “[i]t is presumed that the ordinary product user or consumer lacks sufficient information and bargaining power to execute a fair contractual limitation of rights to recover.”\(^\text{82}\) A disclaimer operates against a tort duty, which in turn exists only when the ordinary consumer is unable to make an informed risk-utility decision about the safety matter in question.\(^\text{83}\) An individual consumer like the plaintiff presumably has the characteristics of the ordinary consumer, and so the waiver question only arises when the plaintiff presumably lacks sufficient information about the risks. Insofar as there is no reliable way to determine whether the plaintiff differs from the ordinary (uninformed) consumer in this respect, the presumption cannot be rebutted; the court must conclude that the plaintiff did not have enough information to execute a fair contractual limitation of her right to recover.\(^\text{84}\) Evidential limitations can explain why courts do not recognize contractual or express assumption of risk in product cases.

Courts can also refuse to enforce disclaimers for policy reasons. At the time of purchase, the consumer knows that the seller has completed its investments in product safety. Liability could not induce the seller to make any further safety investments, giving each consumer at the point of sale an incentive to waive liability in exchange for a reduction in product price. But because consumers will predictably act in this way, the resultant lack of liability would remove the financial incentive for product sellers to comply with the tort obligation in the first instance. Waivers, therefore, can yield unreasonably dangerous products when courts permit all consumers to waive liability.\(^\text{85}\) A rule that permits only some consumers to waive liability, in turn, would then be unfair to those consumers who are foreclosed from that opportunity. These consumers would incur the full cost of ensuring that the seller complies with the tort duty, whereas those consumers who could waive liability would still be effectively protected by the tort duty—their products would be reasonably safe as required by the tort duty—but they would not have to incur the costs of enforcing that duty. To ensure that each consumer pays a fair share of the tort burden, courts can refuse to enforce

\(^{81}\) Dobbs, \textit{supra} note 2, § 210 at 535 (footnotes omitted).

\(^{82}\) Restatement (Third) of Torts: Prods. Liab. § 18 cmt. a (1998).

\(^{83}\) See supra notes 37-39 and accompanying text.

\(^{84}\) Cf. Geistfeld, \textit{supra} note 28, at 236-37 (explaining why the plaintiff’s experience with or expertise about the product does not reliably prove that she made an informed risk-utility decision to use the defective product).

\(^{85}\) See generally Abraham L. Wickelgren, \textit{The Inefficiency of Contractually-Based Liability With Rational Consumers}, 22 J. L. Econ. & Org. 168 (2006).
contractual or express disclaimers of liability without denying the value of consumer choice.

Courts in product cases also do not explicitly recognize another formulation of the assumed risk rule, known as primary assumption of risk. Under this doctrine, a right holder’s choice to engage in a risky activity, such as downhill skiing, makes her responsible for the risks inherent in the activity. In these cases, the ordinary right holder (skier) has enough information to make an informed decision that the benefits of engaging in the activity (skiing) outweigh the inherent risks, thereby relieving the duty holder (a ski resort) of responsibility for those risks. This defense does not have to be explicitly recognized in product cases because the identical principle justifies the rule against categorical liability. Rather than conclude that the consumer has primarily assumed the risk inherent in the activity (or the use of any product within the category), courts instead conclude that the product design satisfies consumer expectations and is not defective. As in the case of primary assumption of risk, the ordinary right holder (consumer) can make an informed decision that the benefits of engaging in the activity (or the utility of using the product) outweigh its inherent risks, relieving the duty holder (product seller) of responsibility for that particular safety decision. Strict products liability further the value of informed consumer choice in the manner required by the doctrine of primary assumption of risk, even though that formulation of the assumed risk rule is not expressly recognized as an affirmative defense.

The only remaining cases that implicate the assumed risk rule are those in which the defendant imposed a tortious risk on the plaintiff, who then had a choice of whether to continue to face the risk. To breach the duty under strict products liability, the defendant must have sold a defective product that was unreasonably dangerous. Even though the buyer did not know of the defect at the time of purchase (rendering the product “unreasonably dangerous” as per the Restatement (Second) rule of strict products liability), the plaintiff could subsequently gain knowledge of the defect. If the plaintiff then decided to use the product despite the known defect and was injured as a result, her tort claim against the seller would be governed by the doctrine known as secondary assumption of risk.

86 E.g., Morgan v. State, 685 N.E.2d 202, 207 (N.Y. 1997) (“[B]y engaging in a sport or recreational activity, a participant consents to those commonly appreciated risks which are inherent in and arise out of the nature of the sport generally and flow from such participation.”).

87 See, e.g., Sajkowski v. Young Men’s Christian Ass’n of Greater New York, 702 N.Y.S.2d 66, 67 (N.Y. App. Div. 2000) (“[I]f the risks of an activity are fully comprehended or perfectly obvious, one who participates in the activity is deemed to have consented to the risks. Furthermore, where the risk is open and obvious, the mere fact that the defendant could have provided safer conditions is irrelevant.”) (citations omitted).

88 See, e.g., Knight v. Jewett, 834 P.2d 696, 703, 707-08 (Cal. 1992) (distinguishing primary and secondary assumption of risk in terms of whether the defendant breached a duty owed to the plaintiff).
These claims are barred by the value of informed consumer choice only when the plaintiff’s choice to use the defective product was based on a risk-utility decision identical to the one implicated by the allegation of liability. This condition is not satisfied for the class of claims in question.

For example, assume the plaintiff discovers that an automobile is defectively designed for not containing an airbag. As previously discussed, the plaintiff’s risk-utility decision to use the automobile fundamentally differs from the risk-utility decision implicated by her allegation that the design is defective for not including airbags.89 A plaintiff who knows about a design defect and still uses the product has not made a risk-utility decision that is inconsistent with her allegation of liability, enabling the court to value the plaintiff’s safety decision while still recognizing her liability claim.

Indeed, the plaintiff’s decision to use the automobile without an airbag would be reasonable—the net benefits of using the car clearly outweigh the added risk posed by the absence of airbags. Under the assumed risk rule, “the plaintiff’s acceptance of a risk is not voluntary if the defendant’s tortious conduct has left him no reasonable alternative course of conduct in order to . . . exercise or protect a right or privilege of which the defendant has no right to deprive him.”90 A product seller has no right to deprive a consumer of the right to use the product in a reasonable manner, and the only way the plaintiff can use the automobile requires him to face the risk posed by the absence of an airbag. The plaintiff’s reasonable choice to use such a product with a known defect is not “voluntary” for purposes of the assumed risk rule, nor does the plaintiff’s reasonable product use provide any other ground for reducing the seller’s liability.

The same outcome occurs with respect to construction or manufacturing defects. This allegation of strict products liability implies that the defect renders the product unfit for sale, and so the allegation can be barred by the consumer’s informed risk-utility choice to purchase the product with a known risk of malfunction.91 Unlike these cases, the present inquiry is limited to defects that the consumer discovered only after purchase. In deciding whether to use a product that has already been purchased, the consumer presumably compares the net utility of the particular use with the risk posed by that use. The decision to use the defective product does not incorporate the sunk cost of the purchase price, an obvious difference with the earlier purchase decision (made without knowledge of the defect) that is implicated by the allegation of liability. Once again, the plaintiff’s informed choice to use the allegedly

89 See supra notes 54-56 and accompanying text.
90 RESTATEMENT (SECOND) OF TORTS § 496E(2)(b) (1965).
91 See supra notes 52-56 and accompanying text.
defective product can be fully valued by a court that recognizes the plaintiff’s allegation of liability.

For these reasons, the *Restatement (Second)* defensibly reduces the plaintiff’s recovery for secondary assumption of risk only when the plaintiff “voluntarily and unreasonably proceed[s] to encounter a known danger.”92 The plaintiff’s choice does not bar recovery—the choice to use the product on a particular occasion is not inconsistent with the allegation of liability—and so the only reason for reducing the plaintiff’s recovery involves instances in which her decision to use the product was unreasonable. Such a decision is merely a form of unreasonable conduct indistinguishable from other forms of contributory negligence. Secondary assumption of risk is also limited to cases of contributory negligence in the *Restatement (Third)*, which allows for a reduction of the plaintiff’s damages only when “the plaintiff’s conduct fails to conform to generally applicable rules establishing appropriate standards of care.”93 The plaintiff’s choice regarding product use can provide a ground for reducing the seller’s liability, but the reason does not stem from the value of informed consumer choice, thereby explaining why the plaintiff is not entirely barred from recovery.94

**CONCLUSION**

The growth of products liability has been astounding, particularly when compared to the slowly evolving tort rules of the common law. In 1965, the rule of strict products liability was adopted by the American Law Institute in section 402A of the *Restatement (Second) of Torts*, and was then adopted by most states shortly thereafter. The dozen or so pages devoted to the problem of product defects in the *Restatement (Second)* subsequently led to a body of law requiring over three hundred pages of exposition in the *Restatement (Third) of Torts: Products Liability*, which was adopted by the American Law Institute in 1997.95

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92 *Restatement (Second) of Torts* § 402A cmt. n (1965).
94 Product misuse instead implicates an issue of fairness across consumers. The individual plaintiff’s vindication of the tort right can also protect other consumers with respect to defects, like product design, that threaten other consumers in the market. The elimination of such defects works to the benefit of all right holders, but the damages award also increases the product price for all other consumers, including those who do not misuse the product. Whether the plaintiff’s recovery should be reduced for product misuse, therefore, depends on how this benefit and burden should be fairly distributed across consumers. Consistent with this reasoning, “[a] major policy reason which courts articulate for accepting comparative responsibility is that allowing a victim’s negligence to be irrelevant to her recovery is unduly unfair because it makes careful product users bear the costs created by the careless users of products.” William J. McNichols, *The Relevance of the Plaintiff’s Misconduct in Strict Tort Products Liability, the Advent of Comparative Responsibility, and the Proposed Restatement (Third) of Torts*, 47 Okla. L. Rev. 201, 242 (1994).
A rapidly developing body of law cannot be simply restated, and the ongoing interplay between consumer expectations and the risk-utility test has proven to be a particularly hard problem. A number of courts have rejected the Restatement (Third)'s risk-utility test for defective product designs because it “fundamentally alter[s] the law of product liability in this state.”\footnote{Mikolajczyk v. Ford Motor Co., No. 104983, 2008 WL 4603565, at *15 (Ill. Oct. 17, 2008); see also Potter v. Chi. Pneumatic Tool Co., 694 A.2d 1319, 1334 (Conn. 1997) (describing controversy and rejecting the risk-utility test in the Restatement (Third)).} As the Maryland Court of Appeals explained, “[g]iven the controversy that continues to surround the risk-utility standard articulated for design defect cases in . . . the Restatement (Third), we are reluctant at this point to cast aside our existing jurisprudence in favor of such an approach on any broad, general basis.”\footnote{Halliday v. Sturm, Ruger & Co., 792 A.2d 1145, 1159 (Md. 2002).} Although these decisions cast doubt on the overall approach adopted by the Restatement (Third), they also provide important support for the Restatement (Third). Having forcefully rejected the risk-utility test in the Restatement (Third), most of these courts have then incorporated the risk-utility test into their existing jurisprudence based on the Restatement (Second).\footnote{See, e.g., Mikolajczyk, 2008 WL 4603565, at *22.} Typically, the resultant liability rule is “in actuality, perfectly consistent with” the Restatement (Third).\footnote{RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 Reporters’ n. cmt. d at 72 (1998) (discussing Potter, 694 A.2d 1319).} Why do courts flatly reject the risk-utility test in the Restatement (Third) and then immediately incorporate that test into the Restatement (Second) liability rule?

Perhaps these courts have become entangled in “rhetorical confusion [that] is largely unnecessary.”\footnote{See James A. Henderson, Jr. & Aaron D. Twerski, Achieving Consensus on Defective Product Design, 83 CORNELL L. REV. 867, 867 (1998).} For reasons articulated here, courts could defensibly reject the basic approach of the Restatement (Third) while also adopting its liability rules. The Restatement (Third) has obscured the essential way in which strict products liability depends on consumer expectations, thereby creating the misleading impression that this body of law does not adequately value consumer choice.\footnote{See supra notes 7-16 and accompanying text.} Rather than being confused about the liability rules, courts could rightly reject any approach that does not appropriately recognize the value of consumer choice in products liability.

The value of consumer choice is recognized by the Restatement (Second) rule of strict products liability—the textual source of contemporary products liability law. The rule has considerably evolved over a short period of time. Courts have applied it to different sets of circumstances, producing a larger number of distinct doctrines that are addressed by the Restatement (Third). As the common origin of these varied doctrines, the Restatement (Second) rule of strict products liability...
ought to be substantively compatible with the liability rules in the Restatement (Third). Case law that adopts the risk-utility test in the Restatement (Third), for example, has often evolved from earlier decisions that defined consumer expectations in risk-utility terms. Like the risk-utility test, other important liability rules in the Restatement (Third) can be justified by the value of consumer choice. The two Restatements can be squared in this fundamental respect, and so the de-emphasis of consumer expectations in the Restatement (Third) should not prevent courts from adopting its liability rules. The liability rules in the Restatement (Third) can be deemed a success, regardless of what one thinks about its rationale for products liability.

102 Compare Aller v. Rodgers Mach. Mfg. Co., 268 N.W.2d 830, 834-35 (Iowa 1978) (“The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer . . . .” . . . Proof of unreasonableness involves a balancing process. On one side of the scale is the utility of the product and on the other is the risk of its use.”) (quoting RESTATEMENT (SECOND) OF TORTS § 402A cmt. i (1965)) (citation omitted), with Wright v. Brooke Group Ltd., 652 N.W.2d 159, 169 (Iowa 2002) (adopting the Restatement (Third)’s risk-utility test).

103 See supra Part II (explaining why the value of informed consumer choice justifies the liability rules in the Restatement (Third) governing construction, design and warning defects); supra Part III (explaining why the value of informed consumer choice justifies the rules in the Restatement (Third) concerning categorical liability and the affirmative defenses).
The Unappreciated Congruity of the Second and Third Torts Restatements on Design Defects

Michael D. Green

I. INTRODUCTION

Teaching products liability for the first time in 1980, I was baffled at how the California Supreme Court could have refused to provide more elaboration on the concept of defect. While its resistance to adopting the *Restatement (Second)*’s “defective condition unreasonably dangerous” language was understandable, even perhaps preferable, how could the court not have appreciated that the idea of a “defect” required elaboration in order for the fact finder to determine whether a product was sufficiently safe? Of course, eventually the California Supreme Court saw the light. In *Barker v. Lull Engineering Co.*, it relented on its refusal to provide further specification for the concept of defect and provided a two-pronged test for determining if a product was defective in design.

I think now I understand the court’s reluctance to provide more, reflected in its early post-section 402A products liability jurisprudence. I also appreciate now why I failed to comprehend the court’s reticence. And the explanation for that appreciation sheds light on the *Restatement (Third)* and its treatment of design defects, a matter that has generated much controversy and significant criticism. That is the subject that I would like to pursue in this symposium’s reflection on the tenth anniversary of the *Products Liability Restatement*.

† Williams Professor of Law, Wake Forest University School of Law. The author thanks Brandon Barnes and Meredith Green for their diligent research assistance. The author is also indebted to Oscar Gray, who explained a central point in this Article in a taxicab in Philadelphia after an Advisers meeting for the *Restatement (Third) of Torts: Products Liability*. I am grateful as well for helpful comments at a faculty colloquium at Washington University School of Law and students in Professor Kim Norwood’s products liability class at Washington University.

3 573 P.2d 443, 455-56 (Cal. 1978).
4 I refer to the *Restatement (Third) of Torts: Products Liability* alternatively as either *Restatement (Third)* or *Products Liability Restatement* in this Article. By contrast, I use *Restatement (Third) of Torts* to refer to the compendium of individual pieces, including the *Products Liability Restatement*, that will comprise the entirety of the third iteration of the torts Restatement.

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This Article is not intended as an all-encompassing defense of the Restatement (Third)’s treatment of design defects. Rather its goal is more modest. What I hope to demonstrate, contrary to contending critics of the Restatement (Third), is the congruity between the law adopted in the Restatement (Third) and the law in the Restatement (Second). To do that, though, I will have to spend more time than I would have thought when I began this Article on the scope of the Restatement (Second) with regard to manufacturing defects and design defects.

I begin in Part II of this Article by setting forth contending and conflicting claims about the scope of section 402A and its treatment of design defects. While one of those claims was made twenty years ago, well before the Restatement (Third) process began, it contends that section 402A was not about design defects. The conflicting claim, one raised vociferously during the drafting of the Restatement (Third), is that it fails to continue the strict liability reform of section 402A by abandoning consumer expectations as the basis for a design defect. Part III delves into the former claim, by Professor George Priest, that section 402A was meant to apply only to manufacturing defects, leaving alleged design and warnings defects to be decided under a negligence standard. I reanalyze the evidence that Professor Priest amassed in support of his claim, both in the scholarship leading up to the adoption and approval of section 402A and in the structure of that section and its comments. Having found Priest’s claim wanting, Part IV proceeds to explain the consistency of the Restatement (Second) and Restatement (Third) in their treatment of design defects, a consistency that escapes critics on both sides of the claims identified in Part II.

II. THE CRITIQUE OF DESIGN DEFECTS IN THE PRODUCTS LIABILITY RESTATEMENT

I do not attempt to address all of the criticism of the Products Liability Restatement’s treatment of design defects, but there are two competing themes that I pursue. One was first raised by George Priest, before we even knew that Products Liability would be the first piece of the Restatement (Third) of Torts. In 1989, Priest claimed that courts had strayed from what the founders intended and from what section 402A

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5 For example, one might reasonably have thought that the design defect standard in section 2(b) of the Restatement (Third) of Torts: Products Liability could have been more transparent about adopting a risk-utility standard. One might also have preferred placing the burden of proof on the foreseeability of risk on the defendant, on the grounds that it almost always exists in the case of durable goods. Actually, comment m to section 2 comes close to adopting such a placement in the burden of proof, despite black letter language that ignores the matter. See Restatement (Third) of Torts: Prods. Liab. § 2 cmt. m (1998). And for those committed to compensation and loss spreading, there is no doubt that the Restatement (Third) represents a retreat from the apogee of the strict liability movement when courts struggled to define a regime for strict liability different from the reasonableness-balancing of negligence.
was intended to address.\textsuperscript{6} According to Priest, section 402A was limited to manufacturing defects and in extending strict liability beyond those kinds of defects to include design and warnings, courts had strayed from the original intent.\textsuperscript{7} Priest’s claim has more widespread contemporary acceptance than I had appreciated. At the symposium where the papers in this issue of the \textit{Brooklyn Law Review} were presented, both Aaron Twerski and Hildy Bowbeer, the former a co-Reporter for the \textit{Products Liability Restatement} and the latter a prominent products liability lawyer, repeated the claim that section 402A was meant to apply only to manufacturing defects. Professor Twerski has since disavowed that claim.\textsuperscript{8} In Priest’s view, design and warnings issues were to be left to


\textsuperscript{7} Id. at 2303-04.


Douglas Kysar claims that the consumer expectations test in section 402A was not intended to address design defect litigation and cites Priest in support. See Douglas A. Kysar, \textit{The Expectations of Consumers}, 103 \textit{COLUM. L. REV.} 1700, 1713 & n.53 (2003). I do not disagree with Kysar on that point, although his suggestion that all of the product failure cases were manufacturing defect cases is not supportable. See \textit{id.} at 1714. By contrast, Richard Wright asserts that section 402A “clearly was meant to encompass design and warning defects,” which is a tad misleading given the lack of attention by the founders to the source of the defect, a matter that Wright acknowledges and appreciates. See Richard W. Wright, \textit{The Principles of Product Liability}, 26 \textit{REV. LITIG.} 1067, 1068-69 (2007).

negligence. While Priest was not speaking to the next-generation Restatement, the implications of his critique would be an important consideration for any effort to draft the next Restatement treatment of products liability.

The second critique is of the design defect standard in section 2(b) of the Restatement (Third). That subsection mandates that a reasonable alternative design be demonstrated in order to prove a design defect exists. Once the plaintiff identifies an alternative design, the jury must compare the additional risks that the alternative design can eliminate from the existing design with the additional costs entailed in adopting the alternative design. This risk-utility standard is, frankly, one that reflects a negligence balancing.

Although many commentators have raised criticisms about the Restatement (Third)’s treatment of design defects, I focus here on those that decry the Restatement (Third) for abandoning the strict liability adopted in section 402A and its use of consumer expectations as the basis for determining defectiveness. Ellen Wertheimer, a products liability scholar, has written extensively on the failed promise of the Restatement (Second) in the provisions of the Restatement (Third). She has argued that requiring proof of a reasonable alternative design and that the existing design fails a risk-utility test materially changes the standard for strict liability set out in the Restatement (Second). Similarly, Frank Vandall has charged that the reasonable alternative design requirement violates the core of what section 402A was about, especially cases like Greenman v. Yuba Power Products, Inc. Frequently, these critics have also asserted that the Reporters for the Restatement (Third) failed to follow the design defect jurisprudence that developed after widespread acceptance of strict products liability, which

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9 See Priest, supra note 6, at 2303.
10 See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) (1998).
11 See infra note 13.
12 Contrary to the implications of what Wertheimer wrote, these are not two independent requirements. One cannot assess risk-utility for a given design without an alternative design by which to frame the risk-utility analysis. See Michael D. Green, The Schizophrenia of Risk-Benefit Analysis in Design Defect Litigation, 48 VAND. L. REV. 609, 616-17 (1995).
13 See Ellen Wertheimer, The Third Restatement of Torts: An Unreasonably Dangerous Doctrine, 28 SUFFOLK U. L. REV. 1235, 1251-52, 1255 (1994); see also Ellen Wertheimer, The Smoke Gets in Their Eyes: Product Category Liability and Alternative Feasible Designs in the Third Restatement, 61 TENN. L. REV. 1429, 1431-32 (1994) (“The Restatement (Third), however, materially increases the plaintiff’s burden by requiring that the plaintiff show not only that the product fails a risk-utility test, but also that an alternative feasible design existed at the time of manufacture and that the manufacturer should have used that alternative design.”).
has not, for the most part, insisted on proof of a reasonable alternative design.  

Rather than engage now with this strain of criticism, I return to the conflicting Priest position. If Professor Priest is right, then criticism of the Restatement (Third) for adopting a negligence standard for design defects at least should appreciate that the Restatement (Third) remains true to the original reform exemplified in section 402A. Indeed, one might say that the Restatement (Third) returns us from a frolic and detour in which many courts engaged in the years after section 402A. During this period, courts struggled to find a form of “strict liability” to impose on products that was different from the extant negligence regime that operated before section 402A was adopted. If Priest’s hypothesis that section 402A limited strict liability to manufacturing defects is correct, then employing consumer expectations to determine how safe a product should be made, imputing knowledge of dangers that were unknown at the time of manufacture and sale, and similar steps were mistaken efforts that went beyond the more modest intentions of section 402A. In addition, the Restatement (Third) strays from its predecessor in permitting an inference of defect from the circumstances surrounding the product’s performance regardless of whether the source of the defect is one of design or manufacture.

III. THE PRIEST HYPOTHESIS

Professor Priest relies on two sources of evidence in support of his theory that section 402A was intended to be limited to manufacturing defects. The first is the academic literature leading up to the adoption of section 402A, which was published by Prosser, the Reporter for the Restatement (Second), 18 the Advisers for the Restatement (Second) of

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18 Prosser subsequently resigned as Reporter shortly before his death, and John Wade took over Reporter duties. Prosser was the Reporter at the time that section 402A was proposed and approved. See Herbert W. Titus, Restatement (Second) of Torts Section 402 and the Uniform Commercial Code, 22 STAN. L. REV. 713, 713 (1970).
Torts, and a small group of fellow travelers who were writing about products liability in the 1950s and early 1960s. The second source of evidence is the structure of section 402A and its commentary, which reflect, on Priest’s account, an assumption that the strict liability being described is limited to manufacturing defects (even if that terminology was not employed at the time).

A. The Founders’ Views

I understand Priest’s claim to be about the intent of the founders with regard to section 402A and not what the state of the law was in 1964 when section 402A was approved. As is well-known, section 402A was not a “restatement” of existing law. Rather, it reflected dissatisfaction with the existing state of the law that posed so many obstacles to establishing liability for dangerous products that caused harm. Prosser and the other founders conceived of section 402A as a means to transport the strict liability of implied warranty into tort law, stripping warranty of its contract impediments in the process. Relying on the slim foundation of contaminated food and riding the wave of a couple of late-breaking cases, Prosser forged section 402A as a progressive reform rather than a statement of existing law. Thus, the evidence relevant to Priest’s hypothesis is the normative positions of the founders—not their descriptive accounts of existing law.

Let me provide a contending theory of what was behind section 402A before proceeding to critique the Priest hypothesis. The strict liability proposed by section 402A was not limited to manufacturing defects. Indeed, that section, influenced by its warranty heritage—the then-existing source of strict liability in the law—employed a conceptual framework independent of specific types of defect. Rather than the familiar three-defect world in which we find ourselves today, section 402A contemplated a performance-based idea for defect. If a product performed in a way that revealed a defect—regardless of its source—then it was defective. Thus, if a gun went off when being held by its owner without the owner engaging its trigger, the gun was defective and we need not trace the source of that defect. It is this alternative to the Priest manufacturing-defect theory that better accounts, in my view, for the evidence relating to what was intended in section 402A.

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19 In addition to William Prosser, these commentators, all academics save for Justice Roger Traynor, include Dix Noel, Page Keeton, Fleming James, John Wade, and Traynor. These were all leading torts commentators in the middle of the twentieth century.
21 See Cupp & Polage, supra note 8, at 889-90; Rabin, supra note 8, at 202-03; Schwartz, supra note 8, at 947 & n.185.
Before proceeding, let me point out one aspect of agreement between my explanation and Priest’s. Section 402A was not about employing strict liability to determine how safe a product should be designed, the modern version of design defect litigation that emerged after courts accepted section 402A. I should explain that we can virtually always design a durable good to be marginally safer. A guard can be added to the pinch point of an industrial machine. If the guard is removable for maintenance purposes, then an interlock could be added to prevent use of the machine without the guard. We could extend this safety-for-cost tradeoff to extremes: cars, for example, could be designed like tanks and thereby eliminate almost all of the 40,000 traffic-related deaths and over two million personal injuries suffered each year by those riding on the nation’s highways. Nobody thought that section 402A would provide the metric for deciding how much safety should be built into industrial machinery or automobiles. At the same time, I do not think that section 402A was meant to be limited to manufacturing defects.

Priest explains his theory that section 402A was to be so limited and that negligence was to remain the regime for warnings and design defect cases, writing:

[T]he founders did not fully appreciate the distinctions among manufacturing defects, design defects, and defective warnings that would become the centerpiece of modern law. Section 402A represented only a limited change in the law because the founders intended the Section’s strict liability standard, with minor exceptions, to apply only to what we now call manufacturing defect cases.

The first notable matter about Priest’s claim is the logical inconsistency between the idea that the founders did not have a clear grasp of the three different kinds of defects and the claim that they intended to apply strict liability only to manufacturing defect cases. If the founders did not clearly know what a manufacturing defect is—not a difficult concept—or the ways in which it is different from a design or

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23 See Priest, supra note 6, at 2303.

24 Id. at 2303; see also id. at 2308 (“The cases for which the founders believed consumers deserved automatic recovery are what we now call manufacturing or production defect cases in which the injury to the consumer was caused by a deviation from the manufacturer’s own standards of production or quality control. We shall see in a moment that the Restatement and its Comments make sole reference to manufacturing defect cases.”).

Priest does not return to or explain the “minor exceptions” to which he adverts in the quoted language nor does he explain the discrepancy between the language quoted in the text and the language quoted in the prior paragraph, which is not qualified with any “exceptions.”

25 The Restatement (Third) explains a manufacturing defect as one that occurs when the product “departs from its intended design.” Restatement (Third) of Torts: Prods. Liab. § 2(a) (1998). That definition is similar to one provided by Page Keeton in the academic literature.
informational defect, how could they have intended to limit strict liability to a type of defect that they did not fully understand? A second aspect of Priest’s claim that requires careful attention is the difference between a type of defect—manufacturing defects—serving as the model for strict liability and the idea that strict liability was limited to those kinds of defects. There is no doubt, as explained below, that contaminated food was the ballast on which strict products liability was developed. Whether that means it was so limited to that kind of defect is a different question, a distinction that Professor Priest tends to ignore.26

But there is not much to Priest’s claim that the founders did not understand the idea of a design or warning defect—putting aside for the moment whether they intended strict liability to apply to it.27 As Priest’s own research revealed, academics of the day discussed liability for negligent design, so they were cognizant of the notion that defects might have different sources, including the manner in which products were designed.28 Indeed, Dix Noel wrote an article, published in the Yale Law Journal, that assessed manufacturers’ liability for design and warnings defects.29 That article reveals a thriving trade in cases confronting the question under negligence law of how safe a product should be designed. The idea of liability for a manufacturer whose design is negligent is even enshrined in a black letter section of the first Restatement of Torts.30 And Prosser had already prepared a draft of the Restatement (Second) of Torts that contained a similar provision.31 Dillard and Hart wrote an early important article on inadequate warnings as the basis for a seller’s liability.32 Others, who may not have used the term “manufacturing defect,” nevertheless described the concept.33

preceding the adoption of section 402A: “The product was not in all respects as it was intended to be or as the purchaser or user expected it to be.” Page Keeton, Products Liability—Liability Without Fault and the Requirement of a Defect, 41 TEX. L. REV. 855, 859 (1963).

26 Thus, for example, Priest claims that Roger Traynor believed that strict liability in section 402A was limited to manufacturing defects. Priest, supra note 6, at 2314. But his evidence for that proposition is that Traynor was thinking about such defects when he wrote about strict liability in a 1965 article. Id.; see also infra text accompanying notes 60-67.

27 Another error concerns Priest’s claim that “none of the founders at the time had focused clearly on design problems as ‘defects,’” Priest, supra note 6, at 2315 n.60, yet John Wade did exactly that in an article that Priest discusses. Id. at 2313 (“Wade believes that more difficult problems [than with manufacturing defects] arise where the product . . . incorporates a dangerous design.”).


29 Dix W. Noel, Manufacturer’s Negligence of Design or Directions for Use of a Product, 71 YALE L.J. 816, 816-17 (1962).

30 See RESTATEMENT (FIRST) OF TORTS § 398 (1934).

31 Section 398 in the Restatement (Second) broadened the first Restatement’s treatment modestly by extending its protection to all who might be expected to be endangered by the product instead of the first Restatement’s limitation to those expected to be “in the vicinity.” RESTATEMENT (SECOND) OF TORTS § 398 (Prelim. Draft No. 6, 1958).


33 See Keeton, supra note 25, at 859 (describing a situation where the “product was different from products of like kind” and “[t]here was a miscarriage in the manufacturing process”).
Yet, in a curious and oblique way, there is something to Priest’s claim: one does not readily find references to the different types of design defects in the Restatement or in the writings in the run-up to its adoption. However, my interpretation of that evidence is that rather than not appreciating these concepts, the Restatement and the founders did not consider them to be of importance.

Thus, most of the normative academic attention of the day was not about the standard for strict liability, as Priest explains. Instead, most academics were concerned with the various impediments to imposing liability—such as the privity barrier and other warranty law limitations—rather than the substantive standard by which products would be judged. Prosser, in his classic *Assault Upon the Citadel* article, in which he was working out the scope of section 402A, spent a great deal of time addressing which products and defendants would be subject to strict liability, which plaintiffs could recover, and what defenses might be available, but barely adverted to the standard by which defectiveness would be determined.

34 Priest, supra note 6, at 2305-08.

35 William L. Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1110-11, 1114-20 (1960). By the time he first revised his torts treatise after the publication of section 402A (and after cases had been decided on the matter), Prosser wrote that section 402A applied as well to design defect cases. See William L. Prosser, *Handbook of the Law of Torts* § 99, at 659 (4th ed. 1971) [hereinafter Prosser, HANDBOOK (4th ed.)]. But *Greenman v. Yuba Power Products, Inc.*, 377 P.2d 897 (Cal. 1963), one of the cases on which this statement was based, was pre-section 402A. Friedrich Kessler, another academic observer—one who Professor Priest credits as being among the three most influential scholars in the intellectual history of strict products liability—remarked two years after section 402A was published that it applied not only to manufacturing defects but to design defects as well as information deficiencies. See Friedrich Kessler, *Products Liability*, 76 YALE L.J. 887, 900 & n.71, 901 (1967); George L. Priest, *The Invention of Enterprise Liability: A Critical History of the Intellectual Foundations of Modern Tort Law*, 14 J. LEGAL STUD. 461, 492, 494-95 (1985). Priest does, however, explain that Kessler’s concern was with shifting influence away from contract law rather than with the question of defectiveness. See Priest, supra, at 493-94.

Professors Henderson and Twerski, in their effort to justify a risk-benefit standard for design defects in the Restatement (Third), accept Priest’s characterization of Prosser and cite Prosser’s discussion of negligent design in his 1971 treatise as support. See James A. Henderson, Jr. & Aaron D. Twerski, *Product Design Liability in Oregon and the New Restatement*, 78 OTR. L. REV. 1, 11 n.32, 24 & n.94 (1999) [hereinafter Henderson & Twerski, Product Design Liability in Oregon]; James A. Henderson, Jr. & Aaron D. Twerski, *Arriving at Reasonable Alternative Design: The Reporters’ Travelogue*, 30 U. MICH. J.L. REFORM 563, 569 & n.11, 572 & n.16 (1997) [hereinafter Henderson & Twerski, Arriving at a Reasonable Alternative Design]. If they had limited their claim to assert that Prosser did not address whether consumer expectations should be applied to modern design defect litigation that raises the issue of how safe a product should be designed, I think they would have been correct. However, they did not, instead asserting that Prosser “emphatically rejects” use of consumer expectations for design defect cases. See Henderson & Twerski, *Product Design Liability in Oregon*, supra, at 24. Prosser contributed to their reading of him with a slapdash and inconsistent revision of the third edition of his treatise, which was written before the adoption of section 402A, and the fourth edition, which was written after. Compare William L. Prosser, *Handbook of the Law of Torts* §§ 96, 99 (3d ed. 1964) [hereinafter Prosser, HANDBOOK (3d ed.)] with Prosser, HANDBOOK (4th ed.), supra, §§ 96, 99. In the midst of the discussion of negligent design carried forward from the third edition, Prosser inserted several paragraphs about strict liability and added that “the tort is essentially a matter of negligence,” before proceeding to explain the sort of balancing that would be relevant in a negligent design case. Prosser, HANDBOOK (4th ed.), supra, § 96, at 644-45. A dozen pages later, Prosser inserted a new section on “Strict
To be sure, most of the cases Prosser cited and discussed involved food contaminated with impurities. These are the edible equivalent of manufacturing defects, containing an aspect that is not intended by the preparer. Food was the first product subject to strict liability, and those cases contributed much of the precedential fodder on which Prosser and his fellow travelers relied. Yet nowhere does Prosser identify these contaminated-food cases as ones involving manufacturing defects or even as instances of deviation from the preparer’s intentions.

So, the fact that the predominant cases of the day were food and involved impurities supports the idea that strict liability would include manufacturing defects but it does not mean that other kinds of defects were meant to be excluded. Page Keeton, the academic of the day who seems to have thought most deeply and published the most about the substance of what a defect might encompass, identified, in a 1963 article, two classes of cases that might be subject to strict liability: 1) products having an aspect unintended by and unknown to the manufacturer; and 2) products that pose a danger because of essential characteristics of the product. Priest claims that Keeton’s first category is manufacturing defects, and the second category is not design defects, but a class of cases that have come to be known as “unavoidably unsafe products,” rather than design defect cases.

Priest is surely right that the second category does not reflect classic design defect cases. Yet it does involve defectiveness on a basis other than a manufacturing defect: these products are made precisely in the fashion intended by the manufacturer. Priest nevertheless finds Keeton’s discussion supportive because, “according to Keeton, strict liability is only appropriate for the first category of defects (manufacturing defects).” Instead, says Priest, Keeton contemplated that the second-category manufacturers would only be subject to liability for negligence. This, then, would limit strict liability to the first category, manufacturing defects. The problem with Priest’s claim is that Keeton did not conclude that strict liability should be inapplicable to the second category of products. Instead, he distinguished between socially valuable products, such as prescription drugs, and others, such as

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Liability in Tort,” that contains the assertion above that section 402A applies to design cases. See PROSSER, HANDBOOK (4th ed.), supra, § 96, at 659. In contrast to their acceptance of Prosser’s “emphatic rejection,” Professors Henderson and Twerski have acknowledged that section 402A was not drafted to exclude non-manufacturing defects. See James A. Henderson, Jr. & Aaron D. Twerski, Achieving Consensus on Defective Product Design, 83 CORNELL L. REV. 867, 879 (1998) [hereinafter Henderson & Twerski, Achieving Consensus]. They assert that section 402A failed, however, to confront the question of whether strict liability should be applied to the modern form of design defect litigation, which requires consideration of whether a marginally safer product should have been produced by changing its design in some fashion. See id. at 879-80.

Prosser, supra note 35, at 1103-10.
See Keeton, supra note 25, at 859.
Priest, supra note 6, at 2310-11.
Id. at 2311.
See id.
cosmetics, alcohol, and cigarettes for which Keeton allowed that it “may
be sound social policy”\textsuperscript{41} to extend the implied warranty to those who are
injured in using the product as a matter of loss distribution.\textsuperscript{42} Thus, the
founder who most deeply considered the standard for defectiveness
contemplated extending strict liability beyond manufacturing defects,
even if not in such terms nor in terms of modern-day design defects.\textsuperscript{43}

Keeton was not alone. In his article on liability for design
defects, Dix Noel briefly considered the notion of applying the emerging
strict liability standard for foodstuffs to durable goods.\textsuperscript{44} Priest writes of
Noel’s work that he “presumed that the negligence standard was the most
appropriate way of considering the design issue.”\textsuperscript{45} Yet, Noel’s 1962
article in the \textit{Yale Law Journal} was descriptive, not normative, and so, of
course, would explain liability for design in terms of negligence, the
applicable standard at the time. At the conclusion of his article, Noel
addresses strict liability for design defects.\textsuperscript{46} Priest finds this discussion
to be dismissive of the idea: Noel is “incredulous” that a jet plane whose
wing is torn off despite the best efforts of the manufacturer could be
defectively designed; he “sarcastically” asks about the strict liability of
cigarette manufacturers who produced cigarettes at a time no one knew
of their dangers and is “incredulous” about the possibility.\textsuperscript{47}

I do not read Noel in any such way. His discussion is
predominantly inquisitorial rather than normative. In referring to
cigarettes and state of the art jet airplanes, Noel sought to focus on the
issues that would have to be confronted if strict liability were employed
to address how safely products should be designed. In lawyerly fashion,
Noel tested the limits that would have to be addressed if strict liability
for design were employed. Far from being aghast at the possibility of

\textsuperscript{41} Keeton, \textit{supra} note 25, at 872.
\textsuperscript{42} Keeton wrote:

If the warranty does extend to each particular user that he will suffer no injury, then the
position in essence seems to be that the many who benefit from the use of cigarettes,
whiskey, cosmetics, and drugs are paying for the tragic injuries to the few. This may be
sound social policy if it be assumed that the industry will be able to do this without
impairing the normal incentive to bring out new products and without serious effect on
the economic well-being of an industry that is important to the economy and to society.
Whiskey, cigarettes, and cosmetics seem to be indistinguishable from the standpoint of
what the courts should do. On the other hand, drugs and medicines may well be put in a
different category.

\textit{Id.}

\textsuperscript{43} Even Keeton’s first category was not exclusively limited to products that did not
conform with the manufacturer’s intentions. Priest quotes Keeton, “[I]n this situation the product
was different from products of like kind,” but omits the first word of the sentence. Priest, \textit{supra} note
6, at 2310 (quoting Keeton, \textit{supra} note 25, 859) (internal quotation marks omitted). That word is
“generally.” Keeton, \textit{supra} note 25, at 859. Nowhere in the remainder of his article does Keeton
explain the reason for the “generally” qualification.

\textsuperscript{44} Noel, \textit{supra} note 29, at 877.
\textsuperscript{45} Priest, \textit{supra} note 6, at 2312.
\textsuperscript{46} Noel, \textit{supra} note 29, at 877.
\textsuperscript{47} Priest, \textit{supra} note 6, at 2312.
liability in that situation, Noel identified the conflicting tensions: “Perhaps liability even in this situation would be a useful means of spreading the loss; but that holding might unduly discourage the development of useful new products.”48 While Noel was cautious about the matter of strict liability for design, I do not read him as shrinking from the prospect but rather as identifying the issues that would have to be confronted if strict liability were so extended.

Priest cites two other articles by Noel.49 Priest finds in them Noel’s “insist[ence] on negligence as the appropriate standard for design-related injuries.”50 One of those articles reflects a presentation for lawyers sponsored by the Practising Law Institute and does not have a normative bone in its body.51 Far from stating his views on the proper role for strict liability, Noel took on the task of educating his audience on the expansion of negligence-based claims to product manufacturers. Much of the content was drawn from the second publication, also stemming from a presentation to lawyers, at an event sponsored by the Southwestern Legal Foundation.52 That article is a rehash of the Yale Law Journal article he had previously written and again has only descriptive goals. Noel presented the cases in which negligence had been applied to product design, after observing that while strict liability is the more spectacular development, the expansion of negligence in its application to products liability is worthy of attention in its own right.53 Nowhere in either of these articles can one find an expression of Noel’s views about strict liability being applied to design defects, Priest’s claims notwithstanding.

Priest’s treatment of Fleming James’s work is no more illuminating of James’s views than Priest’s characterization of Noel’s. Priest writes that James’s two-part article on products liability limited treatment of design defects to negligence.54 Yes, in a 1955 survey of products liability, James, in Part I, which was devoted to negligence liability, discussed manufacturers’ liability for negligent design.55 No, he did not say anything there about strict liability for design defects, but then he did not say anything about strict liability for any kind of defect defects.

48 Noel, supra note 29, at 877.
49 Priest, supra note 6, at 2313.
50 Id.
51 Dix Noel, Manufacturers’ Liability for Negligence, 33 Tenn. L. Rev. 444 (1966).
52 Dix Noel, Recent Trends in Manufacturers’ Negligence as to Design, Instructions or Warnings, 19 Sw. L.J. 43 (1965). The presentation that Noel made was at what was designated a “Symposium,” at which at least three other academics spoke. Yet, based both on the content of the papers presented and the organization sponsoring the “Symposium,” this event was a continuing education program for lawyers rather than an academic event. The Southwestern Legal Foundation, a predecessor to the Center for American and International Law, had a mission of educating domestic and international lawyers.
53 Id. at 56-60.
54 Priest, supra note 6, at 2311.
55 See generally James, supra note 28.
because that Part was about negligence liability. Yet in Part II, which addresses manufacturers’ liability in implied warranty, James did consider strict liability. While he wrote that the standards for liability in implied warranty and negligence were “[b]y and large” the same, 56 he was, consistent with his survey mission, attempting to describe the state of the law rather than his views. And although he did not explicitly address liability for design defects under implied warranty, James did cite cases in which the basis for the alleged defect was not a manufacturing defect. 57 For example, when discussing a case in which the risk posed by a chemical—its air dispersal qualities, which were unknown—was not a manufacturing defect, James did not shrink from imposing liability:

This would mean that when unexpected dangers develop from the use of a valuable new product, the industry producing it (and so, ultimately, all the beneficiaries of the product) would have to compensate the innocent victims of those dangers. This is a far better solution than the alternative of making each individual victim contribute the whole of his loss to this advancement of the arts . . . . 58

Thus, James reflects his longstanding preference for redistributing personal injury losses, here through the mechanism of strict liability for a (non-manufacturing) defect.

A passage in a 1957 publication contains an even more illuminating example of James’s normative views about the proper scope of strict liability. In a presentation at an Association of American Law Schools program, James advocated strict liability for all products that were unreasonably dangerous at the time of sale. 59 Although others were not as sweeping in endorsing strict liability as James, they also contemplated its application in cases beyond pure manufacturing defects.

I do not understand how Priest could characterize Roger Traynor as believing that strict liability was limited to manufacturing defects based on Traynor’s 1965 article, The Ways and Meanings of Defective Products and Strict Liability. 60 As Priest states, Traynor does suggest that a “deviation from the norm standard” may be overbroad in the case of unavoidably unsafe products, such as blood contaminated with the hepatitis virus. 61 Yet, in the same discussion, Traynor suggests that some

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57 Id. at 213-15, 221-23.
58 Id.
59 Fleming James, Jr., General Products—Should Manufacturers Be Liable Without Negligence?, 24 TENN. L. REV. 923, 923 (1957). Priest does cite this article in a footnote in a different and later section of his article, acknowledging that James would include design defects in his strict liability scheme. Priest, supra note 6, at 2321 n.77. That contrasts with his earlier statement that James’ 1955 survey “discussed design questions solely in terms of negligence.” Id. at 2311.
60 Priest, supra note 6, at 2314. Traynor’s article is Roger J. Traynor, The Ways and Meanings of Defective Products and Strict Liability, 32 TENN. L. REV. 363 (1965).
61 Priest, supra note 6, at 2314 (citing Traynor, supra note 60, at 367-68) (internal quotation marks omitted).
drugs “of uniform quality” are defective under section 402A if their risks outweigh their benefits.\(^62\) This is strict liability for design defects writ large—the entire product fails a cost-benefit test.\(^63\) Traynor does little to disguise his approval for such a result, although he was a member of the Supreme Court of California at the time. Even Traynor’s concept of deviation from the norm is subtly different from manufacturing defects, for which the basis of comparison is the same product as intended by the manufacturer. Traynor envisions that the deviation could be from similar products made by other manufacturers.\(^64\) Such a test would include defects that we understand today as design defects, although Priest fails to recognize or acknowledge this.\(^65\) Going beyond deviation from the norm, Traynor proffers the idea that products can be defective because their danger is a surprise.\(^66\) Thus, Traynor expresses sympathy for strict liability for products like cigarettes at a time before their dangers were understood.\(^67\)

John Wade’s views on defective design are illuminating for a number of reasons. First, his thoughts in a 1965 paper belie Priest’s claim that none of the founders were thinking about strict liability for design defects. On the contrary, Wade observed that while manufacturing defects could readily be determined, the “more difficult problem[s]” were with dangerous products that were “made in the way . . . intended . . . and in the condition planned,”\(^68\) namely design defects. Wade suggests that the standard should focus on the dangerousness of the product and whether it is “not reasonably safe.”\(^69\) At the same time, given the familiar negligence “reasonable-person” standard, Wade claims that his product-focused standard can be converted to a conduct-based rule by asking if the manufacturer would have acted reasonably by putting the product on the market.\(^70\) Priest rightly quotes Wade’s comment that this rule “is simply a test of negligence.”\(^71\) What Priest

\(^62\) Traynor, supra note 60, at 368-69.

\(^63\) One might, I suppose, claim that this is nothing more than a negligence standard applied to the product overall, but no one had thought that negligence might be so employed prior to and even in the aftermath of section 402A. The idea of categorical liability for a product whose dangers exceed its benefits was borne of the adoption of strict products liability.

\(^64\) See Traynor, supra note 60, at 367. That Traynor was thinking about the design of similar products by other manufacturers is revealed in his comparison of the challenged product to “the average quality of like products.” Id. Thus, Priest ignores this nuance in claiming that Traynor describes Greenman as a manufacturing defect case.

\(^65\) Priest asserts that “Traynor clearly has manufacturing defects in mind” in this explanation of defects. Priest, supra note 6, at 2314.

\(^66\) Traynor, supra note 60, at 370.

\(^67\) Id. at 370-71, 374 (discussing aspirin’s defectiveness before its risks were understood).


\(^69\) Id. at 15.

\(^70\) Id.

\(^71\) Id. Wade was one of the stalwarts opposed to the use of consumer expectations because he was concerned that in many cases there would not be any relevant expectations by which to determine defectiveness as well as by the test’s treatment of latent dangers. See John W. Wade, On the Nature of Strict Tort Liability for Products, 44 Miss. l.J. 825, 829 (1973); see also Richard
omits is that Wade had a clear idea of how his test was different from negligence, as immediately after the acknowledgment quoted above, Wade states: “In strict liability, except for the element of defendant’s scienter, the test is the same as that for negligence.” 72 In other words, rather than proving the foreseeability of risk, Wade developed his famous imputation-of-knowledge standard for strict products liability. 73 The issue was whether a manufacturer who knew of the dangerous condition in the product would put it on the market, thereby eliminating the matter of foreseeability, a central concept in negligence claims. Wade’s foreseeability-free standard for design defectiveness is, thus, not the same as negligence, as we dramatically discovered when products whose risks were unknowable at the time of manufacture appeared front-and-center on the products liability stage.

Wade reiterated his views eight years later in an article published in the Mississippi Law Review in 1973, 74 which is probably the “single most influential” article on how courts understand strict products liability and give content to the defectiveness concept. 75 In that article, he articulated a seven factor test for strict products liability. 76 This test, which was not limited to any specific kind of defect, largely reflected risk-utility concerns that courts have relied on since. Responding to the anticipated criticism that his seven factors were simply a negligence test, Wade argued that this was much like the strict liability of negligence per se in that the fault of the defendant was irrelevant and concluded that

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72 Wade, supra note 68, at 15.


74 Wade, supra note 71.

75 The article in which Wade advocated a risk-benefit standard by which to judge design defects has been described by others as “‘[t]he single most influential piece of guiding scholarship’ in the period . . . when [product defect] was being defined and expanded.” LOUIS R. FRUMER & MELVIN I. FRIEDMAN, PRODUCTS LIABILITY § 1.02 n.26 (2008) (quoting, in part, David G. Owen, Rethinking the Policies of Strict Products Liability, 35 WAND. L. REV. 681, 682 (1980)).


76 Wade, supra note 71, at 837-38.
courts should be honest about what they were doing: “If by doing this it is really establishing strict liability, we might as well call it that and be accurate.”

I had previously been critical of that test as a test for a design defect, not because it was or was not about strict liability, but because it fails to recognize the appropriate factors for a risk-benefit test for design defects. That criticism, however, stemmed from my failure to appreciate the founders’ conception of a defect—because I was so imbued with the modern model of three distinct bases for defect. Now, with a better understanding of the founders’ conception, Wade’s factors make far more sense. Let me explain.

My criticism of Wade’s factors was that they failed to recognize the trade-offs inherent in designing a product and the necessity to address, at the margin, the benefits and risks of any change. This is the contemporary understanding of a design defect that involves a design that can be changed in some way to provide greater safety. Rather, Wade’s factors focus on the characteristics of the product itself, its social utility and dangers, instead of honing in on the risks that can be eliminated by changing the product’s design and the costs of doing so. Thus, I had claimed that social utility—Wade’s first factor—of, say, an AIDS vaccine—is irrelevant to the matter of its defective design:

[I]Imagine that we have identified a one hundred percent effective vaccine for AIDS. Suppose the vaccine causes a mild auto-immune reaction—a rash that lasts for a week—in one out of a million persons who take the vaccine. The side effect can be eliminated by changing one of the inert ingredients with

77  *Id.* at 835. To be fair, within a page, Wade concedes that the evidence sufficient to prove a design defect would also be sufficient to prove negligence in the design of the products and that the only basis on which strict products liability differs from negligence is with regard to manufacturing defects. *See id.* at 836.

78 Those factors are:

1. The usefulness and desirability of the product—its utility to the user and to the public as a whole.
2. The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.
3. The availability of a substitute product which would meet the same need and not be as unsafe.
4. The manufacturer’s ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
5. The user’s ability to avoid danger by the exercise of care in the use of the product.
6. The user’s anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.
7. The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

Wade, *supra* note 71, at 837-38; see also Wade, *supra* note 68, at 17 (providing a similar list of factors to be employed in a risk-benefit balancing but that omit the loss-spreading criterion).
which the vaccine is coated to another inert ingredient, no more expensive and
equally adept at serving its purpose. The vaccine is defectively designed despite
its enormous social utility. Risk-benefit analysis operates at the margin—the
utility of the existing design compared to the alternative—not at the level of the
entire product. 79

I still think that is correct, but I now appreciate Wade and the
other founders’ perspectives. 80 They were not thinking about marginal
design changes in a product. Rather, their conception of strict liability
was based on products whose risks in the course of the ordinary use of
the product were so serious that liability was legitimately imposed on the
manufacturer. This is much more like the standard imposed by implied
warranty, which although under-theorized in the context of products
caus[ing] physical harm, relies on the idea that a product should not cause
unexpected serious harm in normal use or utterly fail in its essential
purpose, causing physical injury.

State Farm Mutual Automobile Insurance Co. v. Anderson-
Weber, Inc. 81 illustrates this conception of defect. It is not only
instructive, but exemplifies the kinds of cases in which implied warranty
was employed to impose strict liability. A car that was ten days old and
had been driven 300 miles caught fire while being driven, allegedly as
the result of a short circuit in the electrical system. 82 The plaintiff relied
on implied warranty and, after surveying cases from New Jersey and
Tennessee in which brakes and steering failed in new cars, the court
proclaimed: “Brakes should not be defective from the beginning.
Steering mechanism should not fail, nor cars burn up within 10 days.
When such things happen and there is evidence as to the cause, courts
should be reluctant to deny the purchaser the right to submit his claim to
a jury.” 83 Beyond State Farm, there are a multitude of cases prior to the
Restatement (Second) and dating back at least to the early part of the
twentieth century in which courts recognized the use of an implied
warranty theory for a product that failed to perform safely in its intended
use. Those courts exhibited indifference to the source of the defect; in
many of them it is difficult to determine from the court’s description of
the facts whether the source of the defect was one of design or
manufacture. The issue was whether the product performed with
adequate safety—in most of the reported cases, the products failed
abysmally. 84

79 Green, supra note 75, at 619.
80 Professor Priest similarly misunderstood Wade and his test for strict liability,
criticizing it for failing to appreciate the need for an alternative design by which to frame the risk-
utility analysis. See Priest, supra note 6, at 2325-26.
81 110 N.W.2d 449 (Iowa 1961).
82 Id. at 452.
83 Id. at 456. The court was concerned with proof of the fire’s cause because the
defendant presented a theory that the fire was caused by events unrelated to a defect in the car. Id.
burst into flames and burned 75% of plaintiff’s body); McBurnette v. Playground Equip. Corp., 137
In summary, the academics interested in products liability in the run-up to section 402A were most concerned with the contractual impediments to liability that they sought to sweep away. Priest is right about that. There was less attention to the standard of liability that any strict liability theory might impose. Generally, the focus was on the extent of danger posed by the product and when it exceeded some threshold—"unreasonable," for instance, or "extrahazardous"—a defect (whether in negligence or warranty) existed that would subject the seller to liability. Although courts were confronted with design defect cases and at least some academics were writing about them, the source of the defect—whether manufacturing, informational, or design—was not a significant concern, regardless of the theory of liability being asserted. Thus, Priest's thesis, which relies on a clear dichotomy between manufacturing defect and design defect cases, does not fit well with the evidence that exists. And because the focus was on the dangerousness of the product, the founders, by and large, did not address the question of how to apply this new strict products liability to a claim that a product should have employed an alternative and marginally safer design.

This appreciation for the early conception of defect explains why the California Supreme Court, in *Cronin v. J.B.E. Olson Corp.*, felt no need to elaborate about what constituted a defect, even if the defect may have stemmed from the product's design. In *Cronin*, bread trays secured in racks in the back of a truck came loose in an accident and due to sudden deceleration of the truck were driven forward, struck the plaintiff-driver, and propelled him through the windshield. The trays were released because the safety hasp designed to hold the trays in place was defective. In the course of holding that a jury should not be

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So. 2d 563, 564 (Fla. 1962) (sharp piece on playground equipment amputated three-year-old's finger); McCabe v. L. K. Liggett Drug Co., 112 N.E.2d 254, 257 (Mass. 1953) (coffee maker exploded in plaintiff's face); Bruns v. Jordan Marsh Co., 26 N.E.2d 368, 373 (Mass. 1940) (heel separated from plaintiff's shoe as she descended staircase); Souden v. Fore River Shipbuilding Co., 112 N.E. 82, 84 (Mass. 1916) ("The fact that the explosion occurred while the boiler was subject to the use for which it was designed is of itself evidence of a defective condition."); DiVello v. Gardner Mach. Co., 102 N.E.2d 289, 293 (Ohio C.P. 1951) (grinder disintegrated in hands of Plaintiff during normal use).

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86 My reading of the negligent design cases of the day is that they did not employ a rigorous risk-utility test to claims that a safer alternative design should have been employed. Courts took a host of avenues that short-circuited such claims rather than permitting a jury determination. See Noel, supra note 29, at 866-77.


88 Id. at 1155.

89 The metal in the safety hasp was porous and pitted, suggesting a manufacturing defect. Id. at 1156. Yet the court never described the case as one involving a manufacturing defect, and, in the course of declining to distinguish between the two sources of defects, recognized that the safety hasp defect could have been either a design or manufacturing defect, depending on what the
instructed in terms of section 402A’s “unreasonably dangerous” language, the Court stated that all the jury need decide and be instructed about is whether a defect existed. No further elaboration of the concept of a defect was required. That was true either for manufacturing or design defects. But the reason the court could conclude that is because its conception of defect was the same one on which the founders were operating as well: Did the product fail to perform as would be expected? Whether the source of this failure was design or manufacture was not important.

The idea that defectiveness was based on the product containing an unacceptable level of (latent) risk when used in its intended fashion, regardless of the source of the risk, provides a better explanation of Greenman v. Yuba Power Products, Inc. than Priest’s treatment. Greenman, of course, is the case in which Justice Traynor persuaded the remainder of the California Supreme Court to adopt the strict products liability for which he had advocated in Escola v. Coca-Cola Bottling Co. There were two defects alleged by the plaintiff in Greenman. One was that inadequate set screws were employed to hold parts of a lathe together, enabling stock on which the plaintiff was working to be thrown from the machine, injuring him. The other was that there were better ways of fastening the parts together than using set screws. Inadequate set screws, of course, could stem either from a manufacturing defect or a design defect and is thus ambiguous. But a better way to hold the machine parts together could only be a design defect. Perhaps that is why Justice Traynor, in his opinion, described the strict liability being adopted as encompassing “a defect in design and manufacture.”

Priest claims, as a result of Justice Traynor’s 1965 article, that Greenman was a manufacturing defect case. Priest also asserts that Traynor’s view was that section 402A was limited to manufacturing
defect cases. Priest concludes that the disjunction between Traynor’s view and his description in Greenman of the lathe containing defects “in design and manufacture” results from the failure of those like Traynor to focus on design deficiencies as a source of defect. I do not disagree that the founders had not thought deeply about the appropriate standard for a design defect—as I explained above, Cronin is evidence that that was true of at least one leading court. Yet, Priest infers that the intent was to limit strict liability to manufacturing defects. I think a better inference from the evidence is that at this stage in the strict products liability reform, sorting out the source of the defect did not matter. Commercial products implicitly are safe for the jobs for which they are intended, and when they are not and cause harm to a consumer, strict liability should ensue.

Henningsen v. Bloomfield Motors, Inc. is the other classic pre-section 402A strict liability case. Based on a theory of implied warranty rather than strict tort, the New Jersey Supreme Court focused on stripping away the impediments that most commentators had been writing about, including privity and disclaimers. In Henningsen, an almost brand-new car, with less than five-hundred miles on its odometer, suddenly made a ninety degree turn and crashed into a wall. Henningsen appears clearly to involve a manufacturing defect. Yet there is nothing explicit nor indeed any indication in the case that the court thought its decision was so limited. At no point does the court use the term “manufacturing defect.” In responding to the defendant’s claim that there was insufficient proof of breach of the implied warranty, the court revealed its conception of a defect by explaining that the circumstances of the accident justified a finding of the “unsuitability for ordinary use” of the product. In a case that was explicitly one about implied warranty, upon which section 402A’s standard for strict liability was based, the concern that emerges is the extent of danger of a product in ordinary use, rather than a deviation from the norm established by other products of the manufacturer in the same line.

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98 Id. at 2315.
99 Id. at 2315 n.60 (quoting Greenman, 377 P.2d at 901) (internal quotation marks omitted).
100 Greenman, 377 P.2d at 901.
102 Professor Priest identifies Greenman and Henningsen as the two critical cases leading to the advent of strict products liability. See Priest, supra note 20, at 507.
103 Henningsen, 161 A.2d at 75.
104 Id. at 98. The court wrote:

The facts, detailed above, show that on the day of the accident, ten days after delivery, Mrs. Henningsen was driving in a normal fashion, on a smooth highway, when unexpectedly the steering wheel and the front wheels of the car went into the bizarre action described. Can it reasonably be said that the circumstances do not warrant an inference of unsuitability for ordinary use against the manufacturer and the dealer?

Id.
B. The Structure of Section 402A

Professor Priest’s structural argument proceeds quickly past the black letter language of section 402A, acknowledges that the two most salient comments are ambiguous about which kinds of defects are included, finds supportive evidence in two other comments, and ultimately relies on the numerous examples contained in the comments. Of the fifty-four examples in which the fact or possibility of a product defect is adverted to, Priest finds that thirty-seven involved manufacturing defects, eleven were about unavoidably unsafe products and therefore did not implicate a type of defect, and six were of uncertain source as to the defect.

However, before examining Professor Priest’s evidence, let us tarry on the black letter of section 402A, which requires that a product be in a “defective condition unreasonably dangerous” for strict liability to be imposed. Early drafts of section 402A imposed strict liability when food was in a “condition dangerous to the consumer.” Dean Prosser explained the evolution of this language to the final “defective condition unreasonably dangerous” language at the ALI annual meeting in 1961, when a motion was made to delete the “defective condition” language. In the ensuing debate, Prosser added that the original language, employing “dangerous,” had been modified to add “defective condition” to ward off concerns that what are now known as unavoidably unsafe products would be subject to strict liability merely because they posed some significant, yet irremediable, risk.

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105 Priest, supra note 6, at 2318.
106 Id. at 2319 (“The strongest evidence that the founders focused exclusively on strict liability for manufacturing defects is that they did not present a single example in the Comments of an alternative strict liability application.”).
107 Id. I do not find this enumeration of types of defects contained in the discussion in the comments persuasive. First, the point of the discussion is not, contrary to Priest, to explain the “types of cases to which the strict liability standard was meant to apply,” in the sense of the types of defects to which section 402A applied. Id. Nothing in the commentary addresses the types of defects to which section 402A “applied.” Second, many of the examples are of non-defective products, as in comment h, which refers to a “bottled beverage knocked against a radiator to remove the cap,” food to which too much salt has been added by the user, or over-consumption of candy by a child, or in comment f, which uses the example of a neighbor who sells a jar of jam to explain who is in the “business of selling,” as required by the black letter. RESTATEMENT (SECOND) OF TORTS § 402A cmts. f, h (1965). Counting those examples as suggesting that section 402A is limited to manufacturing defects is silly. Third, there are, as Professor Priest acknowledges, several examples in which the defect is of uncertain origin. Id. Fourth, Professor Priest’s count is at least modestly padded in his favor. He counts a reference, in comment f, to the owner of an automobile who resells it as reflecting a manufacturing defect, when the text is insufficient to draw any conclusion about the source of the defect. Priest, supra note 6, at 2320. Finally, whatever slim evidence this provides is overwhelmed by the other language and structure of section 402A discussed in the text.
110 The following colloquy took place:

DEAN PROSSER: Mr. Dickerson has stated an original point of view which I first brought into the Council of The American Law Institute in connection with this section.
Thus, the key operative language in section 402A is the word “dangerous,” rather than the “defective condition” language, which showed up only to address a narrow class of cases, such as knives, butter, and whiskey, that have dangers built in that cannot be removed. That the focus was on danger reveals that Prosser was focused not on the condition or source of the risk in the product. Thus, section 402A’s premise was that products that, in the ordinary course of their use, caused harm to users because of the extent of danger they posed were subject to strict liability. “Defective” might have been a reference to a deviation from the norm meant by the manufacturer—a manufacturing defect—but its inclusion later in the ALI process reveals that it had both a narrower and more stylized purpose than adverting to manufacturing defects.

Moreover, the adoption of consumer expectations as the standard for determining when a product was subject to strict liability reflects the contract heritage of section 402A and the contribution of implied warranty as the basis for strict liability. The parties’ intent and expectations are a contract concept and displace fault as the basis for determining the content of a contract and whether it was breached. And, as suggested above, the implied warranty cases involving personal injury are concerned with unexpected and unacceptable danger in a product,

“[F]ood in a condition unreasonably* dangerous to the consumer” was my language. The Council then proceeded to raise the question of a number of products which, even though not defective, are in fact dangerous to the consumer—whiskey, for example [laughter]; cigarettes, which cause lung cancer; various types of drugs which can be administered with safety up to a point but may be dangerous if carried beyond that—and they raised the question whether “unreasonably dangerous” was sufficient to protect the defendant against possible liability in such cases.

Therefore, they suggested that there must be something wrong with the product itself, and hence the word “defective” was put in; but the fact that the product is dangerous, or even unreasonably dangerous to people who consume it is not enough. There has to be something wrong with the product.

Now, I was rather indifferent to that. I thought “unreasonably dangerous,” on the other hand, carried every meaning that was necessary, as Mr. Dickerson does; but I could see the point, so I accepted the change. “Defective” was put in to head off liability on the part of the seller of whiskey . . . .

... PRESIDENT TWEED: The motion is to eliminate “defective” in the black letter . . . .

... PRESIDENT TWEED: The noes seem to me to have it.

38 ALI Proceedings 86-89 (1961), reprinted in W. PAGE KEETON ET AL., PRODUCTS LIABILITY AND SAFETY: CASES AND MATERIALS 223-25 (2d ed. 1989). Prosser’s statement that the “unreasonably” language was in his original draft is incorrect. The first draft, in 1958, subjected food “in a condition dangerous to the consumer” to strict liability. RESTATEMENT (SECOND) OF TORTS § 402A (Prelim. Draft No. 6, 1958). “Dangerous” was first modified with “unreasonably” at the same time as “defective condition” was added and contained in the Tentative Draft that was the subject of the discussion set out above. RESTATEMENT (SECOND) OF TORTS § 402A (Tentative Draft No. 6, 1961). Richard Wright thus gets it backward in his claim that the “unreasonably dangerous” language was included to address unavoidably unsafe products. Wright, supra note 8, at 1069.
regardless of whether it stems from a manufacturing, design, or informational deficiency.

If strict liability were limited to manufacturing defects, there would have been no need for consumer expectations to be employed in section 402A. Manufacturing defects can readily be determined by reference to other identical products and whether the questioned product deviated from all of those others. If so, it is subject to strict liability. That is precisely the way in which the *Restatement (Third)* imposes strict liability for manufacturing defects, eschewing any reference to consumer expectations in the definition or description of a manufacturing defect. 111 Consumer expectations are a warranty and product-performance standard, not a standard designed to assess a specific kind of defect.

Aspects of the commentary to section 402A beyond the black letter and consumer-expectations standard for determining defect also contradict the idea that manufacturing defects were the exclusive subject for strict liability. Comment k, addressing unavoidably unsafe products, belies that section 402A was limited to manufacturing defects. If it were, there would have been no need for comment k to address unavoidably unsafe products—those products are by definition ones in which the danger exists in all such products as an inherent quality of the product. 112 The same is true of comment j, which covers the requirement of warning for products such as those in comment k that pose generic dangers to users. 113 Comment k also reveals that the American Law Institute had no difficulty communicating that a class of products posing danger were not subject to section 402A’s strict liability. 114 Yet, there is no comparable comment excluding design or informational inadequacies from the strict liability of section 402A. 115


112 Professor Priest does not address comment k in his structural analysis of section 402A. Priest, supra note 6, at 2317-24. He does, however, state at the outset that there are several passages “susceptible to more expansive interpretations of strict liability,” but none of the ones he subsequently discusses includes the language in comment k. Id. at 2318; *see also* Schwartz, supra note 8, at 947 n.185 (“If the Restatement had no intention of applying to design issues, there would have been no need for comment k, on ‘unavoidably unsafe products.’”); Ellen Wertheimer, *Calabresi’s Razor: A Short Cut to Responsibility*, 28 STETSON L. REV. 105, 116 n.35 (1998) (“Finally, sections such as comments j and k, which deal with defects other than those in manufacture, would have been unnecessary . . . .”).

113 Comment i, as well, speaks to everyday products and the universal risks that are posed by their use in the course of explaining that they are not unreasonably dangerous. *See* Henderson & Twerski, *Achieving Consensus*, supra note 35, at 879-80.

114 *See* *RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).*

115 Priest makes the complementary point that the comments do not contain a “single example . . . of an alternative [to manufacturing defects] strict liability application.” Priest, supra note 6, at 2319. The reason is that, as already observed, Prosser and the other founders were not thinking in terms of subcategorizing defects. The fact that, by Priest’s count, there are six examples of product defects that were of uncertain source is additional evidence of the lack of attention to and concern about the defects’ sources. Id.
Professor Priest finds language in comment h supportive. Comment h states that the defective condition of a product “may arise not only from harmful ingredients, not characteristic of the product itself, either as to presence or quantity, but also from foreign objects contained in the product, from decay or deterioration before sale, or from the way the product is prepared or packed.” 116 This language, Priest explains, is exemplary of different ways that a manufacturing defect may exist, with only the possible exception of the “quantity” idea. 117 That is true, but it is also insignificant when one considers the source of this language. It first appeared in the earliest Preliminary Draft of section 402A, which applied only to food products. 118 The source of defects in food surely was classical manufacturing defects. But food is not “designed” in the way that durable goods are, and so we would not have expected a strict liability provision applicable only to food to advert to the way that a product—say, a lawn chair that rocks—might be defective because a metal piece, sharp as a guillotine blade, is underneath the arm rest and slices off a user’s finger. 119

Another indication that there was no conscious decision to limit section 402A to manufacturing defects is that it contains references to the necessity of providing warnings. Failure to provide these warnings, when required, renders the seller subject to liability under section 402A. Thus, section 402A suggests that informational inadequacies can, in themselves, constitute a defective condition unreasonably dangerous. 120 Comment j, titled “Directions or warning,” states flat out that “[i]n order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning . . . .” To be sure, liability for these informational inadequacies does not look very strict—there is no mention of dispensing with the negligence requirement of foreseeability, the context is often one in which the manufacturer would have knowledge, and, in one instance, the warning obligation is explicitly conditioned on seller anticipation of the danger. Professor Priest only refers to comment j, calling it “peculiar” and dismissing it because all of the examples it discusses involve unavoidably unsafe products. 121 Yes, but comment j is not about only unavoidably unsafe products, and its first sentence, quoted above, is not qualified in that respect. Comment k is about unavoidably unsafe products and has its own reference to the requirement that that class of products be accompanied with proper warnings.

117 Priest, supra note 6, at 2318.
119 See Matthews v. Lawnlite Co., 88 So. 2d 299, 300 (Fla. 1956).
120 See RESTATEMENT (SECOND) OF TORTS § 402A cmts. h, j, & k (1965).
121 Priest, supra note 6, 2323.
Professor Priest’s final argument based on structure stems from the treatment of contributory negligence in comment n, which denies any defense based on certain negligent conduct of the plaintiff. Professor Priest finds this denial “peculiar” because from the perspective of the modern law and economics movement, contributory negligence is an important adjunct to obtaining the efficiency provided by strict liability so that consumers have adequate incentives to avoid injuries for which they are the cheaper cost avoiders. Yet, Priest reasons, if strict liability under section 402A is limited to manufacturing defects, then there is little need for consumer incentives since there is little that a consumer can do to avoid harm from a latent manufacturing defect that is unknown. Denying contributory negligence in section 402A, thus, can be squared with economic efficiency.

That the law and economics movement developed well after section 402A had been drafted, debated, and published goes unappreciated and unmentioned by Professor Priest. That tort law might not be cast purely in terms of economic efficiency, even after those ideas moved from the academy to the courts, similarly escapes Professor Priest’s argument. That, in fact, contributory negligence was not a defense to other strict liability claims when section 402A was adopted also goes unrecognized in Priest’s treatment. Finally, Professor Priest’s claims about comment n ignore a critical flaw in the economics’ claim for the need for contributory negligence to insure victim care.

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122 We need not tarry on the scope of conduct encompassed by comment n, which is not as broad as the holdings in cases cited by Professor Priest, because the breadth of comment n is unimportant to the issue raised by Priest’s treatment.

123 Priest, supra note 6, at 2322-23.

124 See id.


126 See RESTATEMENT (SECOND) OF TORTS §§ 515, 524 (1977) (paralleling comment n denying a claim for unreasonable conduct but providing a defense based on knowingly and unreasonably assuming the risk).

127 The flaw is that there are other, more powerful incentives for protection of self against personal injury than liability incentives, predominantly the risk of pain, suffering, and even death. See Gary T. Schwartz, Contributory and Comparative Negligence: A Reappraisal, 87 YALE L.J. 697, 704-27 (1978) (explaining the non-financial incentives for taking care to avoid physical injury to oneself). In 1986, in the third edition of his book, Judge Posner nodded in the direction of this criticism, acknowledging that damages may not provide full compensation for personal injuries and that potential victims may therefore have an unspecified “incentive” to take care even if tort law does not sanction their unreasonable behavior. RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 154 (3d ed. 1986). Similarly, Steve Shavell recognizes that if victims “would not or could not be fully compensated for . . . serious personal injury or death,” they would “have an incentive to take care” independent of tort law. STEVEN SHAVELL, ECONOMIC ANALYSIS OF ACCIDENT LAW 11 n.9 (1987).
IV. THE RESTATEMENT (THIRD)'S TREATMENT OF DESIGN DEFECTS RECONSIDERED

I had not intended to spend so much of this paper attending to Professor Priest's manufacturing defect hypothesis. The more I read, however, the more intriguing his claim and evidence became. The more I explored, the more convinced I became that the founders and section 402A were concerned not about specific kinds of defects and their amenability to strict liability, but about products that were excessively dangerous. As I have attempted to show, the evidence in support of that proposition is quite overwhelming, and there is almost nothing, upon careful examination, supporting the idea that section 402A was meant to be limited to manufacturing defects.

However, the fact that section 402A was not limited to design defects does not mean, as stated earlier, that it adopted a consumer expectations test for design defects, as others have suggested. Returning to where we began and where I found common ground with Professor Priest, the founders, with their focus on products that performed in an excessively dangerous manner, just were not thinking about marginal safety improvements or that failure to employ an alternative design might be the basis for strict liability. Nor did they consider the propriety of consumer expectations in deciding such cases. Almost a decade after section 402A was approved and after early real design defect cases were emerging, John Wade remained concerned with defects of the implied warranty variety—products that contained excessive or unreasonable danger, regardless of the source of the danger.

Yet the difficulties of a consumer expectations test for designs at the margin have been well documented. Once the strict products liability movement got going after section 402A was published, cases that presented the issue of “how safe is enough?” began emerging. And courts began expressing concerns about the use of consumer expectations when consumer expectations about the matter were indeterminate or non-existent, leaving resolution of the matter of defect entirely to the unencumbered judgment of the jury.

Once again, the California experience is revealing. Six years after Cronin, the California Supreme Court was confronted with a case,

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128 See supra text accompanying notes 12-15. Bill Powers explains the difficulties and waning influence of the consumer expectations test as more difficult design defect cases became a staple of products liability litigation. See William Powers, Jr., A Modest Proposal to Abandon Strict Products Liability, 1991 U. ILL. L. REV. 639, 646, 653-54. Although he focuses more on complex designs than on difficult determinations about whether the safety performance of the product was deficient, his analysis and explanation of why courts have moved away from it is illuminating.

129 See supra text accompanying notes 78-80.

130 See, e.g., Heaton v. Ford Motor Co., 435 P.2d 806, 807-09 (Or. 1967) (pickup truck that had wheel come apart after hitting a rock five or six inches in diameter).
Barker v. Lull Engineering Inc.,\textsuperscript{131} in which the plaintiff explicitly asserted that a high-lift loader, used at a construction site, should have had several improvements to its design to make it safer.\textsuperscript{132} The context was not a routine construction-site environment, but one where the loader would be used on sloping ground and was therefore more susceptible to tipping.\textsuperscript{133} The plaintiff was injured when, in the course of lifting a load of lumber, the loader tipped over.\textsuperscript{134} Reaffirming its decision in Cronin that section 402A’s “unreasonably dangerous” language should not be used in charging a jury on strict products liability, the court nevertheless recognized the need for some guidance to be provided to the jury on the matter of how safe a product need be designed. The court provided a dual-disjunctive standard for determining defectiveness in a design case.\textsuperscript{135} The first adopted the Greenman performance-based consumer expectations standard.\textsuperscript{136} As the court recognized, this standard for defectiveness will often be proved by circumstantial evidence bearing on the accident that occurred, rather than proof of the specific defect.\textsuperscript{137} The second test for defectiveness entailed proof, based on a balancing of the risks of the existing design compared to the greater safety of an alternative design with the utility or benefits of the existing design compared to the alternative design.\textsuperscript{138}

By 1994, however, the court appreciated the indeterminacy of consumer expectations for marginal design defect claims. In Soule v. General Motors Corp.,\textsuperscript{139} the plaintiff was hurt in an automobile accident when the toepan beneath her feet was crushed rapidly backwards in the collision.\textsuperscript{140} Among the defects alleged by plaintiff was the design of the frame, which permitted the toepan to be rapidly deflected toward the driver.\textsuperscript{141} But a collision with a closing speed between thirty and seventy miles per hour just does not afford any basis for determining how well an automobile should protect a driver against rapidly deflecting parts. The circumstances of this accident just did not permit an inference of a defect in the car. The court declared that consumer expectations, in this

\textsuperscript{131} 573 P.2d 443 (Cal. 1978).
\textsuperscript{132} Plaintiff’s expert identified several improvements in the loader’s design whose absence allegedly made it defective: (1) equipping it with outriggers so that it would be steadier, especially on sloping ground; (2) providing a roll bar and seat belt for the operator; (3) improving the leveling control provided for the operator; and (4) including a “park” position on the loader’s transmission. \textit{Id.} at 447-48.
\textsuperscript{133} \textit{Id.} at 447.
\textsuperscript{134} \textit{Id.}
\textsuperscript{135} \textit{Id.} at 452.
\textsuperscript{136} \textit{Id.} at 454.
\textsuperscript{137} \textit{Id.} Yet it seemed to be inapplicable in Barker. The regular operator of the loader called in sick on the day that plaintiff was injured because he thought the sloping ground and narrow base of the loader were incompatible, creating a dangerous situation. \textit{Id.} at 448 n.2.
\textsuperscript{138} \textit{Id.} at 454-55.
\textsuperscript{139} 882 P.2d 298 (Cal.1994).
\textsuperscript{140} \textit{Id.} at 301.
\textsuperscript{141} \textit{Id.} at 302.
situation, could not be used to determine if the car was defective. Use of consumer expectations had to be limited. Although the court’s explanation referred to complex designs as being beyond the ken of a jury, it was not the complexity of the automobile’s design that presented the problem. Rather, it was that the performance of the automobile, under the circumstances, was not such that an inference of defect was possible. On the other hand, if the same automobile with the same complexity of design exploded while idling at a traffic light, the court acknowledged that consumer expectations would permit a finding of defect. Thus, the court left difficult marginal design defect claims to be resolved by the risk-benefit prong of Barker, while preserving consumer expectations for the performance-based failure to provide a floor of safety that all products should provide and that were, in my assessment, the focus of section 402A.

The Restatement (Third) reflects these lessons learned with the emergence of marginal design defect claims and yet, in my judgment, remains true to section 402A’s conception of defect, contrary to some critics. In section 2(b), the Restatement provides a risk-utility standard for design defects. This is a negligence standard, pure and simple, given its requirement that the risks be foreseeable. At the same time, section 3 contains an alternative formulation for finding a defect—an alternative that is roughly congruent with the “excessively dangerous” conception of defect contained in section 402A. Although couched as the strict liability analog to res ipsa loquitur and often referred to as the “malfunction theory” of defect, this section encompasses the kinds of cases that were the model for section 402A: a brand-new car that takes an uncommanded right turn and crashes into an obstacle; a rocking lounge chair that cuts off a user’s finger; or a power tool that fails adequately to hold stock in place. Interestingly, two of these examples appear as Illustrations to section 3 in the Restatement (Third), yet are drawn from the facts of the two classic cases supporting section 402A.

142 Id. at 301.
143 Id. at 308.
144 See Powers, supra note 128, at 646 (noting that “it is difficult to ascertain consumer expectations in all but the simplest cases”).
145 Soule, 882 P.2d at 308 n.3.
146 Id. at 308-09.
147 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) (1998). The balancing of risks and benefits is obscured because it is not explicitly stated in the black letter of section 2(b). Comment f clarifies the essential inquiry, a balancing of the safety benefits of the alternative design with its costs and other disadvantages compared to the actual design.
148 Id. § 3 (1998). I do not want to overstate the equivalence of section 3 of the Restatement (Third) and section 402’s concept of defect that I have explained in this Article. I have not, at this point, thought through all of the issues that are implicated. We will also need more opportunity to see how courts interpret and apply section 3 before a final judgment is appropriate.
149 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 3 illus. 5, 7 (1998). That Illustration 7 does not result in liability does not diminish the point, as the reason for non-liability is that the source of the defect was equally probably the result of someone other than the seller.
To the Reporters’ credit, in the midst of their drafting and facing heavy criticism over their adoption of a risk-utility test for design defects, they modified section 3 in an important respect. In Council Draft No. 1, the predecessor to section 3 provided that an inference could be drawn when the circumstances were such that the malfunction “was caused by a manufacturing defect.”\textsuperscript{150} This section remained limited to manufacturing defects through Tentative Draft No. 1, but in subsequent drafts and the final version was extended to design defects as well.\textsuperscript{151} Notably, one version of this section revealed its kinship with the performance-based standard for dangerous product defects in section 402A by explaining that it was available when a product failed “to function as a reasonable person would expect” and caused harm in a manner justifying an inference that a defect was responsible.\textsuperscript{152} Although discarding the warranty “consumer” from the consumer expectations test and substituting the tort “reasonable person,” the relationship between section 402A in the \textit{Restatement (Second)} and section 3 in the \textit{Restatement (Third)} is plain.\textsuperscript{153}

Just as section 402A was indifferent to the source of the defect, section 3 is indifferent to whether the misperformance is due to design or manufacturing. Indeed, I take it that, even if we know the source of the defect, a plaintiff may rely on section 3 if the circumstances of the accident justify the inference of defect contemplated by that section. Thus, to return to \textit{Matthews v. Lawnlite Co.},\textsuperscript{154} the case in which a lounge chair amputated the user’s finger, even if we knew that the source of the defect was one of design, a plaintiff would be able to pursue a section 3 claim and would not be required to prove a reasonable alternative design under section 2(b).\textsuperscript{155}

\textsuperscript{150} \textit{Restatement (Third) of Torts: Products Liability} § 102 (Council Draft No. 1, 1993).
\textsuperscript{151} See \textit{Restatement (Third) of Torts: Products Liability} § 3 (Tentative Draft No. 2, 1995); \textit{Restatement (Third) of Torts: Products Liability} § 3 (1998).
\textsuperscript{152} \textit{Restatement (Third) of Torts: Products Liability} § 3 (Tentative Draft No. 1, 1994).
\textsuperscript{153} The final version of section 3 became the product liability analog of res ipsa loquitur, eliminating any perspective and relying on the circumstances of the harm-causing incident for an inference that a product defect, rather than some other cause, was responsible. See \textit{Restatement (Third) of Torts: Products Liability} § 3 (1998).
\textsuperscript{154} 88 So. 2d 299 (Fla. 1956).
\textsuperscript{155} See \textit{Restatement (Third) of Torts: Products Liability} § 3 cmt. b (1998). Comment b is muddled in its treatment of this issue. It states that a plaintiff injured by a plane whose wings suddenly fall off may know that it was due to design, but when the circumstances justify an inference of defect under section 3, “it should not be necessary for the plaintiff to incur the cost of proving whether the failure resulted from a manufacturing defect or from a defect in the design of the product.” \textit{Id.} But the issue in the plane crash case is not whether the plaintiff should incur the cost of identifying the source of the defect; the issue is whether the plaintiff, when the source of the defect is known to be one of design, is limited to section 2(b), the design defect standard. However, comment b to section 2 of the \textit{Restatement (Third)} makes clear that section 3 is an alternative method of proving a design defect. See also Henderson & Twerski, \textit{Achieving Consensus}, supra note 35, at 906 (“Inferences of defect based on product malfunction obviate the need to apply the general design standard, thereby rendering that subset of design cases relatively easy to decide.”).
This brings me to my conclusion: the Products Liability Restatement does not contract the scope of liability for design defects from that provided in section 402A. When section 402A was developed, there already existed a negligent design cause of action. Section 402A, without a great deal of consideration of the precise boundaries, added a basis for liability for defects that made a product unreasonably dangerous.

V. CONCLUSION

Section 402A and the scholars and courts that crafted it were concerned about easy cases in which products failed in performing at a minimal level of safety. Impediments to establishing liability on an implied warranty theory were the primary concern. Relevant also were difficulties of proof of the elements of negligence, as negligence matured into a broad-based theory that could be applied by injured purchasers, users, and bystanders against those involved in the manufacture and sale of a product. In this era, the type of defect was not important, and the founders, although aware of the different ways in which a product might be defective, paid little attention to the matter as section 402A was being developed. Thus, I do not think that George Priest’s now twenty-year-old claim that section 402A was intended to be limited to manufacturing defects squares with the available evidence.

At the same time, the performance-oriented standard adopted from the warranty of merchantability proved inadequate to address the new kinds of cases that plaintiffs’ lawyers began bringing in the heady early days of strict products liability. Cars that crashed were alleged to be inadequately designed to provide adequate protection to the occupants. Industrial machinery should have been provided with additional safeguards to prevent momentary carelessness by an operator from resulting in an amputation, even if the employer did not choose to purchase such guards. Brakes and steering mechanisms on earth movers should have been more effective, permitting the operator to manipulate the machinery more nimbly. Consumer expectations, which could be so readily employed in the classic cases of misperformance that led to the adoption of strict products liability, proved inadequate to its task. Confronted with the inevitably of tradeoffs in determining how safe a product should be designed, a movement toward a risk-utility standard began to take hold and was accelerated and confirmed by the Restatement (Third) of Torts.

156 See RESTATEMENT (SECOND) OF TORTS § 398 (1965). To be sure, that negligent design cause of action did not require proof of an alternative design, which the Restatement (Third) does. Yet, if the design defect is egregious enough (and I do not suspect that there are many products in which this is the case), section 3 provides for liability without the need for proof of an alternative design.

Yet in fashioning a risk-utility test for design defects while adopting a separate provision for products whose misperformance is sufficiently egregious for liability to be imposed, the Restatement (Third) brings us very close to where we were when section 402A was adopted. Section 3 of the Restatement (Third) imposes strict liability when a product just does not meet minimum standards of safety, and the risk-utility test of section 2(b) provides a negligent design standard to be employed when the issue is how safe products must be designed. Critics on both sides of the debate on strict liability and the Restatement (Third)’s role have missed its essential role in this return to basics.
This Is Your Products Liability Restatement on Drugs

Lars Noah†

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[Ill health offers adventure; no one has a better chance to live dangerously than the ill who must take their medicine.]

—Roger Traynor†

† Professor of Law, Univ. of Florida. My title alludes to a public service ad campaign (showing an egg in a frying pan) aired by the Partnership for a Drug-Free America in 1982.
I. INTRODUCTION

Lawsuits against the manufacturers of drugs and medical devices have become increasingly important in the last few decades, both in their volume and in the conceptual challenges that they have presented, and courts have created a variety of special rules to accommodate products liability litigation against the sellers of medical technologies. The work of the American Law Institute (ALI) has played an important role in this process, though so far the special provisions of the Products Liability Restatement applicable to prescription drugs and devices have had little discernable impact. These provisions have, however, provoked a great deal of scholarly commentary, and the few courts to consider the issue have uncritically relied upon the published critiques. As explained at length herein, I find little merit in most of these negative assessments, though I point out a number of flaws, ambiguities, and arguable inconsistencies in the new Restatement’s special provisions that seemingly no one else has identified.

This Article attempts to offer a comprehensive evaluation of the various facets of the Products Liability Restatement that relate to medical technologies, and it does so from a perspective rooted in the regulatory as opposed to the doctrinal challenges posed by these products. Part II addresses production defects, focusing on the heated debate over what standards to use in deciding whether a prescription drug suffers from a defective design. Part III considers defects related to the information that accompanies prescription drugs, especially those advertised directly to consumers. Finally, Part IV touches on some of the peculiar issues raised by investigational products, generic drugs, prescription medical devices, and the duties of non-manufacturing sellers.

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2 See Alex Berenson, Drug Industry Braces for New Suits over Even More of Its Products, N.Y. TIMES, Apr. 22, 2006, at C1 (“As Merck reels from 11,500 suits over Vioxx, its arthritis drug, the rest of the industry is girding for challenges over another half a dozen widely used [and still marketed] medications [including Seroquel, Ortho-Evra, Prempro, and Fosamax] that plaintiffs’ lawyers say have hidden and severe side effects or were improperly marketed.”); id. (“Eli Lilly agreed to spend $700 million to settle 8,000 lawsuits over Zyprexa . . . . Wyeth has spent $15 billion since 1998 to resolve lawsuits over its fen-phen diet-drug combination . . . .”); Lisa Girion, State Vioxx Trial Is Set as Drug Suits Boom; An Explosion in Litigation Spurs Calls for Legal Reform and Regulatory Changes, L.A. TIMES, June 27, 2006, at C1 (calling “the pharmaceutical industry the nation’s No. 1 target of product liability lawsuits,” adding that “[m]ore than 71,000 drug lawsuits have been filed in federal courts since 2001 and . . . now account for more than a third of all product liability filings”); Julie Schnrut, More Drugs Get Slapped with Lawsuits, USA TODAY, Aug. 23, 2006, at 3B.
II. FLAWS IN PRODUCTION

A product must have some sort of defect before an injured consumer may recover damages from the manufacturer or other member of the chain of distribution. This Part discusses, in turn, manufacturing and design defect claims against pharmaceutical manufacturers. It reviews several case studies that other commentators have offered, concluding that the most important potential design feature relates to the manner in which sellers restrict access to pharmaceutical products.

A. Manufacturing Defects

The Products Liability Restatement uses the same standard to define manufacturing defects in prescription drug and medical device cases as it does for other consumer goods. Thus, if a product falls out of specifications for any reason, then it has a defect (a true strict liability standard). Manufacturing defect claims involving pharmaceuticals, such as instances of product contamination, generally pose few difficulties for courts. As with other types of consumer goods, however, plaintiffs may have to rely on circumstantial evidence of such flaws, seeking an inference of defectiveness from the occurrence of an obvious malfunction. Although patients injured by medical devices may rely on a product malfunction approach, injuries associated with drug products

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4 See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(b)(1) (1998) (cross-referencing § 2(a), which provides that a product "contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product").

5 See, e.g., Transue v. Aesthetech Corp., 341 F.3d 911, 917-20 (9th Cir. 2003) (holding that the trial judge erred in failing to use a strict liability instruction on a manufacturing defect claim involving silicone-gel breast implants); id. at 919 (quoting Products Liability Restatement § 6 comment c as further support).

6 See, e.g., In re Copley Pharm., Inc., “Albuterol” Prods. Liab. Litig., 158 F.R.D. 485, 487-88 (D. Wyo. 1994) (certifying a class action on behalf of patients who were injured by bacterial contamination of four batches of a bronchodilator drug later recalled by the manufacturer); see also Martin v. Am. Med. Sys., Inc., 116 F.3d 102, 103, 105 (4th Cir. 1997) (allowing a patient to pursue a breach of express warranty claim for an implant that was not sterile); Ferren v. Richards Mfg. Co., 733 F.2d 526, 527-28, 530-31 (8th Cir. 1984) (affirming judgment for plaintiff where metal defect in hip implant caused injury). But cf. infra notes 332-34 and accompanying text (discussing questions about the line between manufacturing and design defects in connection with tainted blood products and contaminated heparin).


rarely lend themselves to this sort of an analysis: given the variability in patient response and the inevitably of unexpected adverse events, a seemingly inexplicable failure of a metabolized chemical hardly bespeaks some deviation from the manufacturer’s specifications.

B. Design Defects

As for claims of defective designs in pharmaceuticals, section 6(c) of the Products Liability Restatement provides as follows:

A prescription drug . . . is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug . . . are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug . . . for any class of patients.9

As elaborated in the accompanying comment, this language sought to create a “very demanding objective standard, [and] liability is likely to be imposed only under unusual circumstances.”10 As the Reporters’ notes explained, “[s]ection 6(c) is a significant departure from the general defective design rules . . . , in recognition of the unique characteristics of prescription drugs.”11

In adopting section 402A of the Restatement (Second) of Torts more than thirty years earlier, the ALI had attempted to address these issues in comment k (“unavoidably unsafe products”),12 which generated much confusion among courts and commentators.13 In resolving design

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9 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) (1998) (omitting parallel references to “medical device”).
10 Id. cmt. f (“[A]s long as a given drug . . . provides net benefits for a class of patients, it should be available to them, accompanied by appropriate warnings and instructions. Learned intermediaries must generally be relied upon to see that the right drugs . . . reach the right patients.”).
11 Id.
12 See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). As the Reporter later explained:

The argument that industries producing potentially dangerous products should make good the harm, distribute it by liability insurance, and add the cost to the price of the product, encounters reason for pause, when we consider that two of the greatest medical boons to the human race, penicillin and cortisone, both have their dangerous side effects, and that drug companies might well have been deterred from producing and selling them.


defect claims against prescription (Rx) drug manufacturers, a few courts preferred to apply the warranty-inspired consumer expectations approach,14 which the Products Liability Restatement rejects as a freestanding test for any products other than foods.15 Other courts employed a risk-utility standard in such cases,16 which section 2(b) of the new Restatement endorses for all other types of consumer goods, including nonprescription drugs.17

One year before getting underway with work on the Products Liability Restatement, the future Reporters summarized the problems with trying to make sense of comment k: “Case law that is unintelligible cannot be intelligently restated. There is a need in this area to clarify the issues and to provide direction to the courts as to how this very special genre of cases can be sensibly approached.”18 Instead of asking whether a

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14 See, e.g., Allison v. Merck & Co., 878 P.2d 948, 951-56, 961 (Nev. 1994) (plurality) (rejecting comment k in a case where a vaccine allegedly caused encephalitis, opting instead for the consumer expectations test or a product malfunction theory); cf. Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 780-82 (R.I. 1988) (treating comment k as an affirmative defense that allows the manufacturer to respond to a consumer expectations based design defect claim with risk-utility balancing). But see Brown v. Superior Court, 751 P.2d 470, 477-78 (Cal. 1988) (explaining that the consumer expectations test has no place in cases involving Rx drugs).

15 See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) & cmts. f-h (1998); id. § 7. Because the Reporters put so much emphasis on differential marketing to justify section 6(c), one should note that physicians may “prescribe” nutritional (non-drug) products to treat patients with special dietary needs. See 21 U.S.C. § 360ee(b)(3) (2006) (defining “medical food” as “a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation”); 21 C.F.R. § 101.9(j)(8) (2008) (elaborating on the definition); Symposium, Medical Foods: Their Past, Present, and Future Regulation, 44 FOOD DRUG COSM. L.J. 461 (1989); cf. Lambert v. Yellowley, 272 U.S. 581, 589-97 (1926) (upholding a Prohibition-era federal law that allowed for the medicinal use of certain liquors only when prescribed by a physician who had a special permit and only in strictly limited quantities).


17 See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) & cmt. k (1998). Some courts have used the consumer expectations test in such cases. See Green v. Smith & Nephew AHP, Inc., 629 N.W.2d 727, 741-55 (Wis. 2001) (rejecting the risk-utility standard on a design defect claim against the seller of latex gloves used by health care workers, and holding that the defendant would face liability even if it could not have known of the risk of allergic reactions at the time of sale); see also West v. Johnson & Johnson Prods., Inc., 220 Cal. Rptr. 437, 458 (Ct. App. 1985) (allowing a plaintiff to use the consumer expectations test in a design defect claim against the manufacturer of a tampon that caused toxic shock syndrome). In jurisdictions that continue to use both tests for design defect, some courts allow plaintiffs to use a risk-utility standard because otherwise an adequate warning might defeat a design claim based on consumer expectations. See Reese v. Good Samaritan Hosp., 953 P.2d 117, 122-23 (Wash. Ct. App. 1998); cf. Haddix v. Playtex Fam. Prods. Corp., 138 F.3d 681, 684-86 (7th Cir. 1998) (affirming summary judgment for a tampon manufacturer because the plaintiff could not opt to use the risk-utility test for such a simple product and her design defect claim failed under the consumer expectations test where the labeling included a clear warning of the risk of toxic shock syndrome).

18 James A. Henderson, Jr. & Aaron D. Twerski, A Proposed Revision of Section 402A of the Restatement (Second) of Torts, 77 CORNELL L. REV. 1512, 1545 (1992); see also id. at 1537 (“[Comment k] is poorly drafted and inter[n]ally inconsistent. . . . To draw on comment k as authority to resolve problems that no one even contemplated at the time of its adoption is sheer foolishness.”).
reasonable alternative design (RAD) exists, the new test asks whether a fully-informed health care provider would ever select the product for any class of patients. Although a good deal clearer than its predecessor, section 6(c) of the Products Liability Restatement has proven to be no less controversial or subject to misunderstanding.\(^\text{19}\) Insofar as the availability of safer substitutes undoubtedly would impact a reasonable physician’s decision, section 6(c) does not differ so terribly from the risk-utility test of section 2(b).\(^\text{20}\) In a subsequent article, the Reporters clarified that RADs would remain relevant in this limited fashion.\(^\text{21}\) They clearly meant, however, to avoid a test that focused on

\(^\text{19}\) See George W. Conk, Essay, Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?, 109 YALE L.J. 1087, 1089 (2000) (arguing that section 6(c) “demands less than reasonable care from manufacturers of drugs” and that “the rule will create a dangerous chasm in the tort law and ultimately will undermine the credibility of the ALI”); id. at 1106 (complaining that “the ALI adopted section 6(c) without benefit either of floor debate or of a solid bedrock of judicial decisions”); Richard L. Cupp, Jr., Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach, 63 GEO. WASH. L. REV. 76, 91-110 (1994); William A. Dreier, Manufacturers’ Liability for Drug and Medical Devices Under the Restatement (Third) of Torts: Products Liability, 30 SETON HALL L. REV. 258 (1999); Teresa Moran Schwartz, Prescription Products and the Proposed Restatement (Third), 61 TENN. L. REV. 1357, 1365-68, 1378-85 (1994); Dustin R. Marlowe, Note, A Dose of Reality for Section 6(c) of the Restatement (Third) of Torts: Products Liability, 39 GA. L. REV. 1445 (2005); Jeffrey D. Winchester, Note, Section 6(c) of the Proposed Restatement (Third) of Torts: Is It Really What the Doctor Ordered?, 82 CORNELL L. REV. 644 (1997); see also Frank J. Vandall, The American Law Institute Is Dead in the Water, 26 HOFSTRA L. REV. 801, 809-10 (1998) (complaining that section 6(c) “reads as if it were written by a lobbyist for the pharmaceutical companies”). This generally unflattering reception generated a pair of responses penned by the Reporters. See James A. Henderson, Jr., Prescription Drug Design Liability Under the Proposed Restatement (Third) of Torts: A Reporter’s Perspective, 48 RUTGERS L. REV. 471 (1996); James A. Henderson, Jr. & Aaron D. Twerski, Essay, Drug Designs Are Different, 111 YALE L.J. 151, 180 (2001) (noting that section 6 “has become a lightning rod for criticism”); id. (“[W]e plead guilty to the charge that we did not restate existing case law. One could hardly be expected to restate gibberish. Instead, we opted for a fresh look at the question of design liability for prescription products . . . .”); see also Michael D. Green, Prescription Drugs, Alternative Designs, and the Restatement (Third): Preliminary Reflections, 30 SETON HALL L. REV. 207 (1999) (staking out a middle ground in the debate).

\(^\text{20}\) In this sense, it also might align closely with the older case-by-case approach to deciding whether to apply section 402A comment k (or, for that matter, the retention of negligence claims for design defect in jurisdictions applying comment k across the board). See, e.g., Toner v. Lederle Labs., 732 P.2d 297, 306-11 (Idaho 1987). It might even align with the older consumer expectations test, at least insofar as the question gets asked from the perspective of a fully-informed health care professional. See Shanks, 835 P.2d at 1195; see also Henderson & Twerski, supra note 19, at 177-78 (“[A] patient never actually expects to suffer a devastating side-effect from taking a drug that is supposed to be beneficial. . . . and, assuming adequate warnings have been given, a reasonable, intelligent prescribing physician always expects that, over the run of patients, warned-against side-effects will occur.”).

\(^\text{21}\) See Henderson & Twerski, supra note 19, at 155 (conceding that “some of the relevant language in both the blackletter of, and comments for, section 6(c) is ambiguous”); id. at 155-56 (“Obviously, such a reasonable provider should consider available alternative drugs in deciding which drug, if any, to prescribe. Indeed, that may be said to be the essence of the healer’s craft—assessing and comparing all available courses of medical treatment.”); id. at 152 (“Plaintiffs may establish definitiveness by showing that safer alternative drugs were available on the market that reasonable health care providers would have prescribed in place of a defendant’s drug for all classes of patients.”). In his rejoinder to their response to his essay, Mr. Conk cried foul. See George W. Conk, The True Test: Alternative Safer Designs for Drugs and Medical Devices in a Patent-Constrained Market, 49 UCLA L. REV. 737, 739 (2002) (expressing “surprise[ ]” at the “new, expansive construction of the rule”); id. at 740 (observing that no one else previously had interpreted section 6(c) in this way); id. at 744-45 (“If both prescription drugs and medical devices were
the availability of hypothetical RADs in part because full substitutability seemed far harder to predict in this context: the Reporters insisted that a purported RAD serve all potential classes of patients, and they rejected any reference to Rx drugs that had not yet received approval from the Food and Drug Administration (FDA).

Taking a cue from the medical profession promised a firmer basis for making such tricky judgments, especially when coupled with an assumption of full information. The Reporters had in mind an aspirational rather than simply a custom-based standard, even though, in practice, a fully-informed health care provider represents a largely intended to be vetted for defective design by comparison to other products on the market—why doesn’t the Restatement say so plainly? A blackletter rule that leads careful observers to conclude that the Restatement rejects such analysis is defective . . . .”). Even before I read their dueling essays, this point struck me as fairly obvious: after all, two of the three decisions cited in the accompanying Reporters’ notes had engaged in precisely such a comparison (before finding that the purportedly safer available alternatives failed to serve the needs of all classes of patients), though the third decision (and the only one finding a defective design) had not done so. See infra Part II.C.1. Moreover, an article published in 1994 had seen this type of RAD analysis as one possible interpretation. See, e.g., Schwartz, supra note 19, at 1383 (doubling, however, that the Reporters had intended such a broad reading of the proposed standard that eventually became section 6(c)).

See Henderson & Twerski, supra note 19, at 158. This led one persistent critic to assail their “endorsement of custom” as satisfying the industry’s standard of care. See Conk, supra note 21, at 746; see also id. at 746-49; id. at 751 (objecting to section 6(c)’s “cramped approach” to design defects); id. at 753-54 (arguing that a malpractice-inspired “lower standard is inconsistent with the thrust of modern products liability law”); id. at 755 (“The new Restatement’s lax standard for prescription drug and medical device design liability requires less than reasonable care.”). Mr. Conk preferred a test allowing a plaintiff to base a design defect claim on expert testimony that a “postulated alternative has a reasonably good chance of withstanding FDA review.” Id. at 761.

Commentators who worry about this approach leave me perplexed. See, e.g., Schwartz, supra note 19, at 1382 (“Clearly, medical practice should not be the basis for determining the safety of pharmaceutical products.”). Clearly, she would prefer that juries make these judgments without taking any cue from medical professionals (or regulatory officials)! See id. at 1383 (“[I]t would seem more straightforward and less confusing to ask [the fact finder] whether a reasonable manufacturer . . . would have put the product on the market. This approach, at least, would reduce the risk of the medical custom becoming the liability standard for design claims.” (footnote omitted)).

If the labeling fails to fully inform physicians, then the plaintiff will have an inadequate warning claim. See Henderson, supra note 19, at 493 (“[M]assive misprescription of drugs and medical devices almost certainly must be caused by defendants’ providing inadequate warnings to medical care providers.”); see also id. at 483 (arguing that, under such circumstances, there should be “joint responsibility of the prescribing physicians, for misprescribing obsolete drugs, and of the drug industry for continuing to promote the prescription and consumption of such drugs”). Allowing a design defect claim under this standard would serve no independent purpose. See id. at 493 (challenging critics “to try to compose a list of reported decisions in which defective design is the only basis for liability, not undercut by failure to warn”); see also Henderson & Twerski, supra note 19, at 171; cf. Neade v. Portes, 739 N.E.2d 496, 500-03 (Ill. 2000) (dismissing claims for breach of fiduciary duty as duplicative of malpractice claims).

See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) cmt. f (1998) (“That some individual providers do, in fact, prescribe defendant’s product does not in itself suffice to defeat the plaintiff’s claim. Evidence regarding the actual conduct of health-care providers, while relevant and admissible, is not necessarily controlling.”). Thus, the mere fact of widespread (and perhaps misinformed usage) would not defeat testimony from an expert for the plaintiff that these patterns reflected irrational prescribing. Cf. Philip G. Peters, Jr., The Role of the Jury in Modern Malpractice Law, 87 IOWA L. REV. 909, 912-21 (2002) (describing the shift away from a custom-based standard of care); id. at 958-61, 966-69 (applauding the movement to a reasonable physician standard). See generally Symposium, Empirical Approaches to Proving the Standard of Care in Medical Malpractice Cases, 37 WAKE FOREST L. REV. 663 (2002).
unattainable ideal. In cases involving genuinely—and, if properly labeled, unabashedly—worthless and dangerous drugs, plaintiffs should have no particular difficulty finding qualified experts willing to testify that no reasonable physician would have used such a drug in any class of patients, which, apart from a malpractice claim against the prescribing physician, would provide the basis for a design defect claim unless the manufacturer nonetheless managed to identify such a class.

26 See Lars Noah, Medicine’s Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community, 44 ARIZ. L. REV. 373, 376, 381-84, 391-95, 402-06, 421-22, 432-33, 438-40, 465 (2002); see also Karen E. Lasser et al., Adherence to Black Box Warnings for Prescription Medications in Outpatients, 166 ARCHIVES INTERNAL MED. 338, 342 (2006); Andrea Petersen, How Drug Alerts Trickle Down to Your Doctor: Amid Flurry of Red Flags About Serious Side Effects, Prescribing Turns Trickier, WALL ST. J., Sept. 15, 2004, at D4 ("[R]esearch underscores how difficult it is for doctors to stay on top of the mass of drug information, and decide how or whether to act. The number of drugs has exploded in recent years, so there are simply more side effects and potential drug-to-drug interactions to keep track of."); Jonathan D. Rockoff, Doctors Buried by Drug Data; Volume of Advisors from the FDA Has Some Seeking Clarity from Private Sources, BALT. SUN, Apr. 7, 2006, at D1.

27 See Harvey L. Kaplan et al., Third Restatement: New Prescription for Makers of Drugs and Medical Devices, 61 DEF. COUNS. J. 64, 73 (1994); Aaron D. Twerski, From a Reporter’s Perspective: A Proposed Agenda, 10 TOURLO L. REV. 5, 17-18 (1995) (explaining that in the case of drugs with “no social utility” for even a discrete group of patients[,] . . . the manufacturer clearly would have a duty to warn that the drug simply does not function or does not have a particularly good use"). Of course, it seems entirely implausible that the labeling for an FDA-approved drug would ever contraindicate use in all potential classes of patients.

28 In recent years, and putting aside the regular condemnations from Ralph Nader’s associates, see, e.g., Marilyn Chase, Consumer Crusader Sidney Wolfe, M.D., Causes Pain to FDA, AMA and the Health Industry, WALL ST. J., Apr. 7, 1992, at A18, a number of prominent physicians have assailed drug approval decisions by the FDA, see, e.g., Diedra Henderson, Watchdog Draws Grows in Return: Cardiologist-FDA Adviser Says His Goal Is Drug Safety; Critics Say He’s Bucking to Run Agency, BOSTON GLOBE, June 5, 2007, at C1 (discussing Dr. Steven Nissen from the Cleveland Clinic). Indeed, it has become increasingly fashionable to berate the FDA and the drug industry in the pages of leading medical journals. See, e.g., Eric J. Topol, Failing the Public Health—Rofecoxib, Merck, and the FDA, 351 NEW ENG. J. MED. 1707 (2004); see also Linda A. Johnson, Doctors Fed up with Drugmakers’ Tactics, STAR-LEDGER (NEWARK), Sept. 11, 2008, at Bus.26 (“Just about every segment of the medical community is piling on the pharmaceutical industry these days . . . . Recent articles and editorials in major medical journals blast the industry.”); Karl Stark, JAMA Articles Say Merck Used Vioxx Ghostwriters, PHILA. INQUIRER, Apr. 16, 2008, at C1 (describing a pair of articles published in the Journal of the American Medical Association that lambasted Merck’s research, adding, however, that “[n]everal of the JAMA authors had consulted for plaintiffs’ attorneys”).

29 See Madsen v. Am. Home Prods. Corp., 477 F. Supp. 2d 1025, 1034, 1037 (E.D. Mo. 2007) (assuming that, because the Iowa Supreme Court previously had adopted Products Liability Restatement §§ 1-2, it would use section 6 to resolve informational and design defect claims against the manufacturer of fenfluramine and dexfenfluramine, and granting the defendant summary judgment on the design defect claim in light of uncontested testimony that some physicians would have continued prescribing these withdrawn diet drugs to some of their obese patients even after learning of the risk of valvular heart disease); Savina v. Sterling Drug, Inc., 795 P.2d 915, 926 (Kan. 1990) ("Although Pantopaque was preferred by some radiologists for limited situations, the testimony of the experts established that Amipaque, containing metrizamide, was the preferred contrast agent at the time of plaintiff’s myelogram. Later, preference for metrizamide was replaced by other water-soluble contrast agents."); id. at 927 ("[T]he testimony of all the radiologists indicates that, although Pantopaque may be utilized for some limited situations, the preferred contrast agent at the time of plaintiff’s myelogram was Amipaque. Thus, Pantopaque was not an alternative product that would have as effectively accomplished the full and intended purpose of metrizamide."); cf. Sita v. Danek Med., Inc., 43 F. Supp. 2d 245, 256 & n.9 (E.D.N.Y. 1999) (noting that a manufacturer of pedicle screws used in spinal fixation had compiled supportive testimony from 270 surgeons).
By asking what a reasonable physician would select, the test presumably did not mean fully-informed only about the risks and benefits of the particular drug; instead, it imagined an expert with knowledge about the peculiar needs of the patient as well as perspective about the entire range of (drug and non-drug) options available for treatment.\(^{30}\) Thus, section 6(c) has less to do with reasonable alternative designs than with the broader (though related) question of substitutability.\(^{31}\) Indeed, manufacturers might fare better under section 2(b) in cases where fully-informed physicians would prefer a surgical procedure over a prescription product with a challenged but unalterable design.\(^{32}\) So far, however, courts generally have not embraced this new approach.

After noting that no precedent existed to support what it called the “reasonable physician test” for judging design defect claims, the Nebraska Supreme Court offered a number of reasons for rejecting section 6(c) based on criticisms that had appeared in the academic literature: it is difficult to apply (and premised on a misapprehension of what influences prescribing decisions), unjustifiably protects less essential drugs (including merely “cosmetic” drugs such as Accutane\(^{33}\)), and would deny plaintiffs recovery even in cases where a RAD existed.\(^{33}\) In 2003, an intermediate appellate court in Georgia likewise rejected the approach endorsed by the *Products Liability Restatement*:

> [Section] 6(c) has been criticized for its failure to reflect existing case law, its lack of flexibility with regard to drugs involving differing benefits and risks, its unprecedented application of a reasonable physician standard, and the fact that a consumer’s claim could easily be defeated by expert opinion that the drug had


\(^{32}\) See Violette v. Smith & Nephew Dyonics, Inc., 62 F.3d 8, 13-14 (1st Cir. 1995) (upholding a jury verdict that found an endoscopic device intended for the treatment of carpal tunnel syndrome defectively designed because a clearly safer surgical procedure existed); Hill v. Searle Labs., 884 F.2d 1064, 1069-70 (8th Cir. 1989) (rejecting comment k defense for intrauterine device (IUD) because safer non-IUD options existed to achieve contraception); see also Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 648 (2003) (suggesting that a “plaintiff might argue that—in light of the current state of the art—the older fertility drugs are defectively designed insofar as the risk of multifetal pregnancy now outweighs their limited benefits when compared with alternative, safer ARTs” including procedures such as in vitro fertilization).

\(^{33}\) See Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827, 839-40 (Neb. 2000); see also id. at 840 (instead applying the consumer expectations test, but allowing the manufacturer to respond by reference to risk-utility factors). Separately, and after an even more conclusory analysis, the court also rejected section 9 (relating to non-fraudulent misrepresentation), see id. at 844-45, but it adopted section 6(d) (the learned intermediary rule for defining the scope of the duty to warn for prescription products), see id. at 842, which is discussed more fully below in Part III. For more on the drug Accutane, see infra Part II.C.5.
some use for someone, despite potentially harmful effects on a large class of individuals.34

The track record in medical device cases looks about the same so far.35

To be sure, the older case law provided little direct support for the standard announced in section 6(c). Even so, as elaborated in the sections that follow, the substantive objections do not withstand close scrutiny: courts can manage any asserted difficulties (which seem no greater than problems one might encounter, for example, in resolving medical malpractice claims); adequately labeled prescription products leave contested questions of utility in the proper hands (namely, physicians and patients rather than judges and jurors); and, given unpredictable variability in patient response, it makes no sense to say that a RAD exists for a drug if a fully-informed health care professional would select it for some patients. In fact, if section 6(c) suffers from any flaws, I argue below that it may offer incomplete protection against inappropriate claims of defective design.

1. MUDs and Child’s Play

Section 6(c) shares important similarities with another contentious pocket of design defect scrutiny. Although elsewhere the Products Liability Restatement rejected the proposition that some types of products (e.g., cigarettes and handguns) may create such a high risk of injury and have so little social utility that they should be regarded as defective even without proof of a RAD,36 the Reporters conceded that some products, such as toy guns that shoot hard rubber pellets, may suffer from a “manifestly unreasonable” design (MUD) if courts defined the relevant product category (and substitutes) too narrowly.37 In short, if

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34 Bryant v. Hoffman-La Roche, Inc., 585 S.E.2d 723, 727 (Ga. Ct. App. 2003); see also id. at 728 (instead adopting comment k as an affirmative defense); id. at 730 (concluding that the manufacturer had failed to establish that the drug’s utility outweighed its risks); cf. id. at 731-34 (Andrews, J., concurring) (advocating adoption of section 6(c)). If the court had decided otherwise, one wonders how the standard might have operated in that case because the drug was withdrawn less than one year after approval: Posicor® (mibefradil), a calcium channel blocker (used to treat angina and hypertension), caused serious interactions with several other commonly prescribed drugs (including beta blockers, another class of antihypertensives) though seemed to be relatively safe and effective when reserved for patients not taking other drugs. See Robert Langreth, Recall of a Popular Roche Drug Raises Questions on Testing, Approval Process, WALL ST. J., June 10, 1998, at B16. It sounds to me like a failure-to-warn claim at most.

35 See infra notes 326-28 and accompanying text.


37 See Restatement (Third) of Torts: Products. Liability § 2 cmt. e (1998) (“The court would declare the product design to be defective and not reasonably safe because the extremely high degree of danger posed by its use or consumption so substantially outweighs its negligible social utility that no rational, reasonable person, fully aware of the relevant facts, would choose to use, or to allow children to use, the product.”); see also Michael J. Tóke, Note, Categorical Liability for
no parent in their right mind would purchase such a product, then a jury could conclude that the manufacturer should not have made it available in the first place (in effect, to protect children against the foolishness of their parents and their own lack of judgment).  

Because prescription drugs often represent a class onto themselves without clear substitutes, and because their purchase requires assent from a person more sophisticated than the end user, section 6(c) created a similar standard for judging design defects.  

Manif etly Unreasonable Designs: Why the Comment d Caveat Should Be Removed from the Restatement (Third), 81 COR NELL L. REV. 1181, 1201-02 (1996) (describing this concession as a response to objections lodged by members of the plaintiffs’ bar); id. at 1222-24 (warning that this exception to the design defect standard might swallow the rule).  


39 See Frank R. Lichtenberg & Tomas J. Philipson, The Dual Effects of Intellectual Property Regulations: Within—and Between—Patent Competition in the U.S. Pharmaceuticals Industry, 45 J.L. & ECON. 643, 651-52 (2002) (identifying “five levels of the drug classification hierarchy” in descending order of specificity: class, subclass, drug, subdrug, and drug product); id. at 652 (“For economic purposes, subdrugs may be close but not perfect substitutes, but drug products within the same subdrug are certainly close to perfect substitutes.”); see also id. at 655 (“Drugs are a very useful product market to study in this respect because the disease categories in which so-called therapeutic competition occurs are relatively well defined compared to other markets.”); id. at 668-71 tbl.A1 (listing more than 150 recognized classes). Only generic versions of brand-name drugs serve as true substitutes, but they raise entirely separate liability issues discussed below in Part IV.B.  

In the context of insurance coverage for drugs, debates have arisen about therapeutic interchange or substitutability. See Council on Ethical & Judicial Aff., AMA, Managed Care Cost Containment Involving Prescription Drugs, 53 FOOD & DRUG L.J. 25, 25 (1998) (“The needs of specific patients may be ignored in this framework because approved drugs are selected on the basis of average patient outcome, not individual effectiveness.”); Donald P. Hay & Linda K. Hay, Diagnosing and Treating Depression in a Managed Care World, 42 ST. LOUIS U. L.J. 55, 57-58 (1998) (criticizing formularies for excluding new generations of costly antidepressant drugs that pose fewer risks for some patients); Milt Freudenheim, Not Quite What Doctor Ordered: Drug Substitutions Add to Discord over Managed Care, N.Y. TIMES, Oct. 8, 1996, at D1. Antitrust issues also may turn on drug substitutability. See Eric L. Cramer & Daniel Berger, The Superiority of Direct Proof of Monopoly Power and Anticompetitive Effects in Antitrust Cases Involving Delayed Entry of Generic Drugs, 39 U.S.F. L. REV. 81, 117-18, 126-34 (2004); id. at 129 (“[D]ifferent drug molecules within the same therapeutic class, despite possible therapeutic similarities, tend not to be close economic substitutes for purposes of defining relevant markets in delayed generic entry cases.”); id. at 113 (conceding that a broader product market definition may be appropriate in merger cases); M. Howard Morse, Product Market Definition in the Pharmaceutical Industry, 71 ANTITRUST L.J. 633, 639-40, 643-52, 659-70, 676 (2003).  

40 See Conk, supra note 19, at 1102, 1118-19; Victor E. Schwartz & Phil Goldberg, A Prescription for Drug Liability and Regulation, 58 OKLA. L. REV. 135, 153-54 (2005) (suggesting by way of illustration that the COX-2 inhibitors Vioxx® and Celebrex® “are each unique products, not alternative designs of each other”); id. at 154 n.137 (drawing a parallel to the MUD test); see also Green, supra note 19, at 227-28, 231; id. at 227 (noting “a certain irony” that section 6(c) “permits categorical liability (condemnation of a drug as not worthy of being on the market) given the ‘pitched battle over categorical liability’ with regard to other products). For a critique (purportedly grounded in “feminist theory”) that completely missed this parallel, see Dolly M. Trompeter, Comment, Sex, Drugs, and the Restatement (Third) of Torts, Section 6(c): Why Comment e Is the Answer to the Woman Question, 48 AM. U. L. REV. 1139, 1151-52, 1171-76 (1999) (advocating extension of the MUD standard to prescription products).
Although paternalism in medicine has acquired a bad reputation, patients seek out professional assistance precisely because they lack the expertise to make such choices unaided.\footnote{See Mark A. Hall, The Legal and Historical Foundations of Patients as Medical Consumers, 96 GEO. L.J. 583, 584-85, 596-97 (2008); Carl E. Schneider, After Autonomy, 41 WAKE FOREST L. REV. 411, 436-38 (2006) (explaining that many patients do not want to make decisions about their medical care); \textit{id.} at 417-25, 432-36 (discussing the impossibility of truly informed consent); \textit{id.} at 440 (concluding that “the central bioethical enterprise of confiding decisions to patients in some strong sense is doomed”); Jan Hoffman, Awash in Information: Patients Face a Lonely, Uncertain Road, N.Y. TIMES, Aug. 14, 2005, § 1, at 1; see also Ezekiel J. Emanuel & Linda L. Emanuel, Four Models of the Physician-Patient Relationship, 267 JAMA 2221, 2226 (1992) (“Many have attacked physicians as paternalistic, urging the empowerment of patients to control their own care. . . . This model embodies a defective conception of patient autonomy, and it reduces the physician’s role to that of a technologist.”); \textit{id.} (advocating instead a “deliberative” model).} The parallel to products that children may use also helps to explain other aspects of the special provisions governing design and informational defect claims involving prescription products.\footnote{See \textit{infra} notes 194, 280-82 and accompanying text. Just as physicians choose treatments for use by their patients, parents must select products for their young children and then supervise the safe use of these products. Although the Reporters thought that the opportunity to engage in “differential marketing” (to ensure distribution only to appropriate users) was unique to prescription drugs and devices, see Henderson & Twerski, supra note 19, at 170-71, toys share similarities in this regard. If some toys (e.g., those with small pieces that can create a choking hazard) pose excessive dangers to one class of youngsters but not to another, then they must carry clear instructions and warnings (e.g., “not appropriate for children less than three years old”). See Lars Noah, The Imperative to Warn: Disentangling the “Right to Know” from the “Need to Know” About Consumer Product Hazards, 11 YALE J. ON REG. 293, 333 (1994). In short, instructions and warnings directed to parents help to ensure that the right toys get to the right children.} Similarly, section 2(b) imagines that the utility of some products may outweigh their risk only when used by a subset of potential consumers (e.g., adults or experts), which then requires that labeling define the appropriate subset.\footnote{See \textit{infra} note 19, at 215-16 (elaborating on this parallel).} In short, rather than the “unprecedented” (even “radical”) new test assailed by critics, section 6(c) announces a blended standard drawn from entirely familiar tests for judging design defects in other contexts.

\textit{RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB.} § 2, cmts. f-g, i & j (1984) (products, but only if their utility to society greatly outweighed their risks).
Some commentators have criticized section 6(c) for insulating both lifesaving and lifestyle (read “trivial”) prescription products, but they make the same mistake as those who would call lawfully marketed products that appeal to some (wrong-headed?) consumers defectively designed even in the absence of a RAD (and in the face of an adequate warning). One central objection to the recognition of a broader form of “product category” liability is that it would allow courts to decide that lawfully marketed products should not be available to consumers. Of course, a jury verdict does not amount to an injunction against further sales of a product, and defenders of a more expansive standard of liability for design defects would say that it simply amounts to an obligation to pay for harm caused (and to spread those costs among all users who may derive utility from the product). If nothing else has

44 See, e.g., Richard L. Cupp, Jr., The Continuing Search for Proper Perspective: Whose Reasonableness Should Be at Issue in a Prescription Product Design Defect Analysis?, 30 SETON HALL L. REV. 233, 252-54 (1999) (focusing on “cosmetic” uses such as treating baldness); id. at 257 (“[W]hen seeking to structure some well-deserved protection for extremely useful drugs, courts should note that prescription products are not all created equal, and that uses of prescription products are not all created equal.”); see also Green, supra note 19, at 214 (“[T]he vast majority of new drugs provide little therapeutic advantage. . . . Rogaine may be near and dear to the hearts of some, but it is not the social-welfare equivalent of antibiotics.”); infra note 343 (citing commentators who object to special protections for cosmetic devices such as silicone-gel breast implants). In contrast, as one commentator argued, “it is an unexplained why such useful products as microchips, personal computers, telephones, trains, planes, and automobiles should always come in second to medical products in the calculus of social good.” Conk, supra note 19, at 1127 (“[W]hy should things that we hope will bring us pleasure be subject to a more stringent standard of products liability than products that we hope will restore or maintain our health?”). For more on the lifestyle drug point, see infra notes 105-19 and accompanying text.

45 See James A. Henderson, Jr. & Aaron D. Twerski, Closing the American Products Liability Frontier: The Rejection of Liability Without Defect, 66 N.Y.U. L. REV. 1263 (1991); Tõke, supra note 37, at 1205-24. Of course, for those who criticize the MUD standard as anemic and would prefer a broader form of product category liability, see supra note 36, restricting design defect scrutiny for prescription products would have to find justification elsewhere. For the record, I have expressed similar qualms about agencies reaching beyond the limits of their delegated authority in pursuit of well-intentioned public health crusades. See Lars Noah, Regulating Cigarettes: (Non)sense and Sensibility, 22 S. ILL. U. L.J. 677, 689-90 (1998); see also Lars Noah, Interpreting Agency Enabling Acts: Misplaced Metaphors in Administrative Law, 41 WM. & MARY L. REV. 1463, 1476-80, 1488, 1529-30 (2000).

46 Cf. In re Paxil Litig., No. CV 01-07937 MRP, 2002 WL 31375497, at *1 (C.D. Cal. 2002) (declining to issue a preliminary injunction in a class action lawsuit brought on behalf of users of an antidepressant who requested an order barring the manufacturer from claiming in television ads that the drug was not habit-forming); Bernhardt v. Pfizer, Inc., 2000 WL 1738645, at *1 (S.D.N.Y. 2000) (refusing to issue an injunction ordering a drug manufacturer to notify physicians and patients about the results of a study finding that its antihypertensive agent worked less well than diuretics because this presented an issue for the FDA to resolve).

47 See, e.g., Conk, supra note 21, at 783. A few commentators have gone still further, disputing the proposition that prescription pharmaceuticals differ fundamentally from other products and favoring the imposition of tort liability even on such high utility products (and even for entirely unknowable risks), which would mean a rule of absolute liability on sellers of all consumer products, dispensing with any need to establish a defect (though retaining a comparative negligence defense for instances of consumer misuse). See Barry R. Furrow, Enterprise Liability for Bad Outcomes from Drug Therapy: The Doctor, the Hospital, the Pharmacy, and the Drug Firm, 44 DRAKE L. REV. 377, 415-33 (1996) (emphasizing both compensatory and deterrence rationales); Elizabeth C. Price, Toward a Unified Theory of Products Liability: Reviving the Causative Concept of Legal Fault, 61 TENN. L. REV. 1277, 1329-37, 1353-55 (1994); Ellen Wertheimer, Unavoidably Unsafe Products: A Modest Proposal, 72 CHI.-KENT L. REV. 189, 217 (1996) (emphasizing fairness and cost-spreading
emerged from the otherwise confused preemption jurisprudence of the last fifteen years, however, the Supreme Court has left little doubt about the potential regulatory effect of tort judgments.48

A conclusion that a prescription drug has a design defect may well amount to a command that would deprive other patients of access to the product.49 If a manufacturer has provided an adequate warning to the health care providers responsible for selecting an intervention for a particular patient, a jury generally would have no basis for deciding that a drug had no legitimate use in any class of patients, even if a physician may have erred in selecting it for the plaintiff.50 As it did in recognizing MUDs in only the narrowest of circumstances, the Products Liability Restatement crafted a design defect standard for prescription products to guard against the risk of such judicial tunnel-vision.51

When risks come to light after approval, some courts have allowed design defect claims framed by asking whether a reasonable

rationales); id. at 200-06 (discussing vaccines); id. at 207 n.58 (prescription drugs); id. at 197 n.29 (unknowable risks).
49 See Henderson & Twerski, supra note 19, at 169 n.78.
50 Cf. Swayze v. McNeil Labs., Inc., 807 F.2d 464, 468, 471-72 (5th Cir. 1987) (rejecting the plaintiff’s claim that, if the manufacturer could not reduce the risk that health care professionals would act negligently and administer excessive doses of fentanyl, it should have withdrawn the drug from the market). In fact, when enhanced warnings fail to alter dangerous prescribing behavior (as happens far too often), pharmaceutical manufacturers may withdraw from the market products that continue to have legitimate uses. See Noah, supra note 26, at 438-40; see also Karen E. Lasser et al., Timing of New Black Box Warnings and Withdrawals for Prescription Medications, 287 JAMA 2215 (2002) (explaining that the use of such warnings may not save a drug from eventual withdrawal).
51 See Henderson, supra note 19, at 493-94 (explaining that, “if a drug truly is the only one that can help a class of patients who otherwise are going to suffer serious medical injury, it would be unacceptable to deny them the drug just because doctors are misprescribing it to patients who should not be taking it,” and calling this a matter “of interpersonal fairness”); Henderson & Twerski, supra note 19, at 152-53 (defending their “refusal to sacrifice the welfare of one class of patients to enhance the welfare of another”); Noah, supra note 48, at 2163; Winchester, supra note 19, at 657 (“One could easily imagine that a jury, faced with the tragic facts of the case before it, could be convinced that the act of marketing an injury-causing drug was inherently unreasonable, simply because the drug did indeed cause the injury its maker knew would occur in a certain percentage of the people who took it.”); see also Lars Noah, Civil Jury Nullification, 86 IOWA L. REV. 1601, 1669, 1656-57 (2001). In this sense, we have the book-end to the longstanding idea that strict liability focuses on the nature of the product rather than the conduct of the seller (see Barker v. Lull Eng’g Co., 573 P.2d 443, 447 (Cal. 1978); RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1 cmt. a (1998)): it makes no more sense to say that a product was defectively designed for this particular user. Cf. Simeon v. Doe, 618 So. 2d 848, 851 (La. 1993) (suggesting that, in allergic reaction cases, the “defect” is really found in the person rather than the product”).
drug manufacturer would have continued selling the product.52 A few critics of section 6(c) have expressed a preference for this standard,53 in part out of a concern that physicians often continue prescribing obsolete drugs because the FDA can withdraw a product only under the rarest of circumstances.54 This represents a serious misapprehension of the relevant legislation and agency practice. The statutory provision that they cite relates only to the power to withdraw a license summarily,55 while the immediately preceding clause of that subsection broadly authorizes withdrawal on any of a number of grounds but entitles the license holder to a hearing.56 Moreover, the FDA has the leverage to order nominally “voluntary” withdrawals, thereby avoiding the need to abide by any procedural niceties,57 and it has done so recently to remove prescription drugs once safer substitutes became available.58

52 See, e.g., Feldman v. Lederle Labs., 479 A.2d 374, 385 (N.J. 1984); see also Tobin v. Astra Pharm. Prods., Inc., 993 F.2d 528, 536-37, 540 (6th Cir. 1993) (same, but not involving postapproval discovery of risks).

53 See, e.g., Conk, supra note 19, at 1119-27; id. at 1126 (“Harm preventable by reasonable care or by reliance on practical, feasible, and available alternative designs is not ‘unavoidable,’ and manufacturers should be held responsible for failing to prevent such harms.”); Conk, supra note 21, at 752 (“[T]he designer-manufacturer is in a position to make choices from a superior vantage point.”); id. at 761, 787-88; Cupp, supra note 44, at 241 (“The reasonable manufacturer test utilizes a broader perspective and is flexible enough to recognize that, even if there is a class of persons for whom the drug is acceptable when taken as designed, the manufacturer still might be unreasonable in marketing the drug if its social costs outweigh its benefits.”); id. at 257 (“The broad perspective of the reasonable manufacturer test is needed to provide at least some tort accountability for defective prescription-product designs.”); Teresa Moran Schwartz, The Impact of the New Products Liability Restatement on Prescription Products, 50 FOOD & DRUG L.J. 399, 409 (1995); id. at 407 (calling an earlier version of section 6(c) “a kind of ‘super’ negligence standard that imposes liability only where . . . the drug or device should not have been on the market at all”); Winchester, supra note 19, at 663, 670-88, 693; see also Green, supra note 19, at 224-32 (agreeing with section 6(c)’s prohibition on “interdrug risk-utility comparisons, but concluding that, “[t]o the extent that drugs can be manipulated to make them safer [e.g., changing combinations of ingredients or dosage], the case for an exemption from tort liability is hard to justify, even with FDA regulatory oversight”). Predicting the consequences of tweaking an existing drug product (to create a hypothesized superior version) may, however, pose greater difficulties than making comparisons among arguable therapeutic substitutes already approved for marketing. See infra Part II.B.3.

54 See Cupp, supra note 44, at 236 n.17 (“The inferior drug may continue to be prescribed because statutorily a drug may only be removed from the market when there is an ‘imminent hazard to the public health.’” (citing Schwartz, supra note 19, at 1382)).


56 See Warner-Lambert Co. v. Heckler, 787 F.2d 147, 150-51 (3d Cir. 1986). The agency may utilize a summary judgment procedure to deny hearing requests when it withdraws approval, see Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 620-22 (1973), and reviewing courts show tremendous deference to the FDA, see Schering Corp. v. FDA, 51 F.3d 390, 399-400 (3d Cir. 1995).


58 See, e.g., Denise Grady, Doctors Call for Caution on Two More Diabetes Drugs, N.Y. TIMES, May 20, 2000, at A10 (Rezulin®); Gardner Harris, Studies Lead to Withdrawal of Drug for Bowel Ailment, N.Y. TIMES, Mar. 31, 2007, at A12 (Zelnorm®); Parkinson’s Drug Pulled off the Market, WASH. POST, Mar. 30, 2007, at A8 (reporting that the FDA requested the withdrawal of pergolide, a dopamine agonist, because it had been associated with heart valve damage since 2002.
Although a reasonable manufacturer test sounds like the other side of the same coin as the reasonable physician test, it may not provide a suitable safeguard for patient welfare. On the one hand, some manufacturers may persist in marketing drugs past the point of genuine obsolescence; on the other hand, overly conscientious pharmaceutical manufacturers may remove drugs from the marketplace even though reasonable physicians would have continued prescribing them for a subset of patients. Once serious risks with an approved drug become

and “[t]here are other drugs in the same class that can be substituted”; see also Conk, supra note 21, at 754 (“The FDA may . . . withdraw permission to market because a new drug comes on the market that is of superior safety.”). See Restatement (Third) of Torts: Products. § 6 Reporters’ Note, cmt. f (1998) (“When a drug or device provides no net benefits to any ascertainable patient class—when reasonably informed medical providers would not prescribe the drug and no reasonable, informed manufacturer would place it on the market—then the product design is defective and the manufacturer should be liable for the harm caused by selling it.” (emphasis added)). But cf. Ray v. BIC Corp., 925 S.W.2d 527, 530-31 (Tenn. 1996) (rejecting suggestions that the consumer expectation test and prudent manufacturer test of design defect represented two sides of the same coin). The Reporters subsequently explained that their choice of perspective “was made to objectify the test and to cleanse it from any sense of partisanship. Reasonable health-care providers have no stake whatsoever in whether a drug should remain on the market.” Henderson & Twerski, supra note 19, at 155-56 n.18 (adding that use of a reasonable manufacturer standard typically would give plaintiffs less protection).

See, e.g., FDA, Notice, Sandoz Pharmaceuticals Corp.; Bromocriptine Mesylate (Parlodel) for the Prevention of Physiological Lactation; Opportunity for a Hearing on a Proposal to Withdraw Approval of the Indication, 59 Fed. Reg. 43,347, 43,348 (Aug. 23, 1994) (recounting the manufacturer’s decade-long pattern of resisting agency requests to modify labeling for the drug); see also id. at 43,351 (“In light of the limited benefit of using bromocriptine for the prevention of lactation, and the effectiveness and lack of serious adverse effects of conservative treatments such as . . . mild analgesics, the risk that bromocriptine may cause a serious adverse effect in a postpartum woman is unacceptable.”); cf. Glastetter v. Novartis Pharm. Corp., 252 F.3d 986, 991 (8th Cir. 2001) (“The FDA’s 1994 decision that Parlodel can cause strokes is unreliable proof of medical causation in the present case because the FDA employs a reduced standard (vis-a-vis tort liability) for gauging causation when it decides to rescind drug approval.”). In the end, Sandoz did not request a hearing to challenge the agency’s proposal to withdraw this indication. See FDA, Notice, Sandoz Pharmaceuticals Corp.; Bromocriptine Mesylate (Parlodel); Withdrawal of Approval of the Indication for the Prevention of Physiological Lactation, 60 Fed. Reg. 3404 (Jan. 17, 1995); see also Kuhn v. Sandoz Pharm. Corp., 14 P.3d 1170, 1174-75 (Kan. 2000) (summarizing the FDA’s negotiations with the manufacturer); Rick Weiss, Drug Will No Longer Be Sold to Stop Breast Milk, WASH. POST, Aug. 23, 1994, at F7 (explaining that emerging tort litigation and a petition filed by Public Citizen had prompted the FDA’s action and the manufacturer’s decision, noting one specialist’s complaint that the withdrawal represented “another victory of legal intimidation over sound medical judgment”). Parlodel continues to have appropriate uses in other classes of patients, including those with Parkinson’s disease, so it would not face design defect claims under section 6(c), though plaintiffs might well pursue informational defect claims.

See supra note 50. Some commentators point to the withdrawn analgesic Vioxx® (rofecoxib) as an example of a defectively designed drug. Although informational defect claims may well have merit in this case, it makes no sense to call the product defective in any other sense. See Richard A. Epstein, Regulatory Paternalism in the Market for Drugs: Lessons from Vioxx and Celebrex, 5 YALE J. HEALTH POL’Y L. & ETHICS 741, 751-54 (2005); id. at 768 (“Vioxx is better in some circumstances and worse in others. The only case in which the FDA should urge the ban is when some other drug dominates Vioxx on all relevant dimensions.”); Marc Kaufman, FDA Panel Opens Door for Return of Vioxx: Many Advisers Urge New Restrictions on Painkillers, WASH. POST, Feb. 19, 2005, at A1; see also Stephanie Saul, Pfizer in $894 Million Drug Settlement, N.Y. TIMES, Oct. 18, 2008, at B2 (Bextra and Celebrex). For the latest on this unfolding litigation, see Heather Won Tesoriero, Vioxx Rulings Raise Bar for Suits Against Drug Firms—Decisions by Courts in Texas, New Jersey Boost Merck’s Strategy in Liability Cases, WALL ST. J., May 30, 2008, at B1.
known, risk-averse firms may not see much countervailing revenue in continuing to serve a narrow patient population, and patients deprived of a drug from which they derived therapeutic benefits would have no claim for continued access. Thus, framing the question from the perspective (or through the lens) of a reasonable health care provider better guards against the twin dangers of tunnel-vision (risk-utility judged solely from a plaintiff’s perspective) and preference aggregation (risk-utility evaluated from a societal perspective), both of which might unduly sacrifice the needs of a minority of patients for whom the risk-utility balance differs from either the particular victim or the norm.

2. Snowflakes (and Cost-Consciousness) in Medical Practice

Section 6(c) appropriately recognizes the variability in patient response and the inadvisability of considering a particular product design as the best choice for treating a condition in every case. When it comes to pharmaceutical interventions, one size does not fit all. The

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63 Courts have rejected such claims when brought by subjects enrolled in halted clinical trials of investigational drugs. See, e.g., Abney v. Amgen, Inc., 443 F.3d 540, 550-53 (6th Cir. 2006); cf. Dahl v. HEM Pharm. Corp., 7 F.3d 1399, 1404-05 (9th Cir. 1993) (holding that the plaintiffs had a contract claim entitling them to an additional one-year supply); Michael M. Grynbaum, Judge Orders Drug Maker to Provide Experimental Treatment to Terminally Ill Teenager, N.Y. TIMES, Aug. 21, 2008, at C3.

64 Selecting the correct frame of reference can make a tremendous difference in avoiding simple mistakes. See, e.g., Lars Noah, An Inventory of Mathematical Blunders in Applying the Loss-of-a-Chance Doctrine, 24 REV. LITIG. 369, 393-404 (2005) (arguing that courts resolving these medical malpractice claims should convert estimated reductions in the odds of survival into relative risk figures); cf. Marcantonio v. Moen, 937 A.2d 861, 875-76 (Md. Ct. Spec. App. 2007) (citing this article but still entirely missing the point), rev’d, 959 A.2d 764, 776 (Md. 2008) (getting the result right but for the wrong reason by focusing only on the antecedent chance of survival); id. at 881-85 (Meredith, J., dissenting) (getting it right).

65 See Green, supra note 19, at 230-31; Henderson & Twerski, supra note 19, at 168-72; id. at 180 (“To deny one group of patients a beneficial drug merely because adequately—warned physicians may misprescribe the same drug for another group of patients would be unfair and inefficient . . . .”); see also Williams v. Ciba-Geigy Corp., 686 F. Supp. 573, 577 (W.D. La.) (“Rather than simply permitting juries to apply, haphazardly and case-by-case, the risk-utility test whenever harm results, the court must require, as a part of the plaintiff’s burden of producing evidence, an articulable basis for disregarding the FDA’s determination that the drug should be available.”), aff’d mem., 864 F.2d 789 (5th Cir. 1988); id. at 578 (“The consequences of the nonavailability of Tegretol for those patients who suffer serious seizures, which can be fatal if not controlled, but who cannot take other anticonvulsants [because they “do not respond to, or are endangered by, more conventional anticonvulsants”], would be grave indeed.”).

66 See John C. Ballin, Editorial, Who Makes the Therapeutic Decisions?, 242 JAMA 2875, 2875 (1979) (“As every physician recognizes, a drug may be the agent of choice for the majority of patients, but it is not necessarily the best therapy for all patients. Individual pharmacologic responses and idiosyncracies require that a variety of similar agents be available.”); Benjamin Freedman et al., Placebo Orthodoxy in Clinical Research I: Empirical and
requirements of patients vary widely, depending on factors such as the nature of their symptoms, progression of the underlying disease, presence of any concurrent conditions or use of other medications, and sensitivity to (or tolerance of) specific side effects. For example, differences in metabolic patterns depending on age, gender, and ethnic background may indicate selection of a drug for some patients even if its risk-utility balance is less favorable for most other persons in the population.\(^67\)

Physicians frequently must try different medications at different dosages until they find the one that seems to work best in a particular patient, and they may have to try various combinations.\(^68\) In some cases, a patient proves to be refractory to the “drug of choice” but responds well to a second- or third-line (often more dangerous) therapeutic agent.\(^69\) This may happen, for instance, when a patient encounters a resistant strain of a common infectious agent.\(^70\) These characteristics make pharmaceutical products fundamentally unlike most consumer goods, which anyone equipped with basic information could select and use successfully to achieve the product’s intended purpose.

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\(^{67}\) See Grant R. Wilkinson, Drug Metabolism and Variability Among Patients in Drug Response, 352 NEW ENG. J. MED. 2211, 2211 (2005); infra Part IV.D.2 (discussing pharmacogenomics); see also Mark A. Hall, The Defensive Effect of Medical Practice Policies in Malpractice Litigation, LAW & CONTEMP. PROBS., Spring 1991, at 119, 144 (referring to the “snowflake” theory, which posits that no two patients are exactly alike).


\(^{69}\) See Robert M. Temple, Commentary on “The Architecture of Government Regulation of Medical Products,” 82 VA. L. REV. 1877, 1888 (1996) (“In some cases, a relatively toxic drug will be identified as a ‘second-line,’ a drug to be used only in people who cannot tolerate, or do not respond to, safer agents.”); Chris Adams, Trial Judge: At FDA, Approving Cancer Treatments Can Be an Ordeal, WALL ST. J., Dec. 11, 2002, at A1 (reporting that, after initially rejecting Eloxatin as a “first line” therapy for colorectal cancer patients because the manufacturer had not shown extended survival, the FDA approved the drug as a “second line” treatment based on a trial demonstrating tumor shrinkage in 9% of patients who had not responded to chemotherapy); Andrew Pollack, After a Long Struggle, Cancer Drug Wins Approval, N.Y. TIMES, May 14, 2003, at C1 (reporting that the FDA approved Velcade for multiple myeloma patients who have relapsed after trying at least two other treatments).

\(^{70}\) See, e.g., Gardiner Harris, F.D.A. Warns of Liver Failure After Antibiotic, N.Y. TIMES, June 30, 2006, at A14; see also Alexandra Calmy et al., Letter, First-line and Second-line Antiretroviral Therapy, 364 LANCET 329, 329 (2004).
In theory, of course, there always might be at least one hypothetical patient who does not tolerate or mysteriously fails to respond to every other alternative treatment in whom a reasonable physician—at a loss for any other ideas—would try a particular drug.\(^71\) The Reporters had made it clear, however, that this possibility would not suffice to demonstrate the existence of a class of patients for whom physicians appropriately might select a drug.\(^72\) Labeling helps in this connection: indications (and contraindications) may specify those subpopulations of patients with a condition in whom use of the drug would (or would not) be appropriate.\(^73\) Occasionally after drug withdrawal, the FDA permits continued use by an even more narrowly defined class of patients.\(^74\) Finally, courts could take a cue from the FDA’s orphan drug regulations, which require that manufacturers identify a “medically plausible” subset of patients with a relatively

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\(^72\) See Henderson, supra note 19, at 477 (explaining that the test “refers to more than a single patient, although the number necessary to constitute a class is not specified” (footnote omitted)); see also RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. f (1998) (“That some individual providers do, in fact, prescribe defendant’s product does not in itself suffice to defeat the plaintiff’s claim. Evidence regarding the actual conduct of health-care providers, while relevant and admissible, is not necessarily controlling.”). The “respectable minority” rule in medical malpractice poses similar difficulties. See Noah, supra note 26, at 458 & nn.382-83.

\(^73\) See Richardson v. Miller, 44 S.W.3d 1, 8 n.2, 16-17 (Tenn. Ct. App. 2000). When clinical trials produce equivocal results, sponsors may engage in statistical analyses designed to stratify the subject population in the hopes of identifying some subset in which the investigational product worked without causing unacceptable side effects. See Jennifer Kulynch, *Will FDA Relinquish the “Gold Standard” for New Drug Approval? Redefining “Substantial Evidence” in the FDA Modernization Act of 1997* 54 FOOD & DRUG L.J. 127, 141-43 (1999) (discussing “post hoc subgroup analysis”) and the FDA’s reluctance to consider it as proof of effectiveness; Aldo P. Maggioni et al., *FDA and CPMP Rulings on Subgroup Analyses*, 107 CARDIOLOGY 97, 98-101 (2007) (explaining that labeling may describe the results of such analyses); Salim Yusuf et al., *Analysis and Interpretation of Treatment Effects in Subgroups of Patients in Randomized Clinical Trials*, 266 JAMA 93, 94 (1991) (“[T]rials adequate for detecting an overall treatment effect cannot be expected to detect effects within even relatively large subgroups . . . .”).

common condition if they seek the incentives available for products designed to treat “rare” diseases.75

In contrast to the multi-factor test of section 2(b) of the Products Liability Restatement, section 6(c), with its inquiry limited to “therapeutic benefits” and using a physician-based frame of reference, may fail to protect legitimate design choices and prescribing decisions. In particular, it may undervalue matters of patient convenience, even though in practice this may have genuine public health consequences.76 For instance, simplified dosing or delivery may improve patient compliance with prescribed treatment.77 Changes in dosage forms may, however, present trade-offs between safety, efficacy, and convenience. In the early 1970s, scientists found that oral contraceptives containing high doses of estrogen posed a greater risk of cerebral thrombosis, and, even though it now appears that lower-dose versions did not work quite as well,78 at the time it seemed that high-dose products offered no advantage in preventing pregnancy. Nonetheless, doctors sometimes prescribed the higher-dose versions to patients who suffered “break-through bleeding” when using the lower-dose products, a bothersome side effect that may

75 See 21 C.F.R. § 316.20(b)(6) (2008); see also Marlene E. Haffner, Orphan Products—Ten Years Later and Then Some, 49 FOOD & DRUG L.J. 593, 596-98 (1994) (discussing the “salami slicing” problem, and explaining that “characteristics of the therapy (e.g., toxicity that limits the use of a drug)” may provide the basis for a medically plausible subset of patients, for instance if there is a drug with a property that “limits its use in some way to certain individuals”). Instead, one commentator has looked to the orphan drug regulations for entirely different purposes. See Conk, supra note 19, at 1107 n.86 (suggesting that these rules contemplate that different manufactures could design competing versions of the “same” drug). Regulations that define notions of sameness in functional terms (and for purposes of awarding market exclusivity for orphan indications to sponsors of drugs no longer protected by patent), in this or any number of other FDA-related contexts (e.g., paper NDAs and generic bioequivalence), tell us nothing about whether it makes sense to imagine redesigning an approved drug.

76 See Amy Dockster Marcus, The Real Drug Problem: Forgetting to Take Them, WALL ST. J., Oct. 21, 2003, at D1; Andrew Pollack, Take Your Pills, All Your Pills; Drug Makers Nag Patients to Stay the Course, N.Y. TIMES, Mar. 11, 2006, at C1; cf. Hill v. Searle Labs., 884 F.2d 1064, 1070-71 (8th Cir. 1989) (distinguishing, in a contraceptive failure-to-warn case, between “convenience or cost” and “medical necessity”).

77 See Justin Gillis, FDA Approves Inhalable Insulin, WASH. POST, Jan. 28, 2006, at A1 (explaining that the agency’s “decision confronts millions of Americans—diabetics make up 7 percent of the population—with a complicated new strategic problem, requiring them to figure out how much long-range risk they’re willing to incur for the convenience, and possibly greater disease control, of using inhaled insulin”); Ranit Mishori, Special Delivery: Coming Soon: New Ways to Take Drugs, Without Needles or Pills, WASH. POST, Feb. 8, 2005, at F1; Shankar Vedantam, Implants May Reshape Schizophrenia Treatment; New Techniques Raise Fears of Coercion, WASH. POST, Nov. 16, 2002, at A1 (reporting that long-acting antipsychotics delivered by injection could reduce problems with patient non-compliance); see also Mary Duffy, Patch Raises New Hope for Beating Depression, N.Y. TIMES, Dec. 3, 2002, at F7 (explaining that alternatives to oral formulations avoid the digestive track, which may allow for lower dosages and fewer side effects).

reduce patient compliance with daily dosing directions and, thereby, reduce effectiveness in practice.  

Moreover, in judging the design of older prescription drugs, the reasonable physician standard (and section 6(c)'s emphasis on “therapeutic benefits”) might make manufacturers more vulnerable to defect claims than the risk-utility test that governs other consumer products and takes cost into account. Consider this the flipside of the more typical cost-related criticism of section 6(c), with a few commentators worrying that the sole supplier of a prescription drug would have no incentive (at least not mediated by the tort system) to adopt an even slightly more costly but much improved design insofar as reasonable physicians would have no choice but to continue demanding the cheaper and more dangerous product in the absence of substitutes. Such a scenario would, of course, provide a golden opportunity for a competitor to enter this market. One commentator responded by


80 See, e.g., Banks v. ICI Am., Inc., 450 S.E.2d 671, 675 n.6 (Ga. 1994). If the reasonable physician standard governed design defect claims against automobile manufacturers, would vehicles that sacrificed some amount of passenger safety for greater affordability (or merely aesthetics) get driven from the marketplace? Cf. Linegar v. Armour of Am., Inc., 909 F.2d 1150, 1154 (8th Cir. 1990) (“A manufacturer is not obliged to market only one version of a product, that being the very safest design possible. If that were so, automobile manufacturers could not offer consumers sports cars, convertibles, jeeps, or compact cars.”); id. at 1154-55 (explaining the lower cost and other utilities of less-protective bullet proof vests).

81 See Cupp, supra note 19, at 103 (“Failing to make a design alteration that would save the lives of ninety percent of a prescription product’s users but not affect the other ten percent would apparently be justified if the alternative design would raise the product’s price by one pe[n]ny.”). Putting aside the obvious implausibility of the one cent differential (and the assumption that competitors would not respond to such an obvious opportunity to capture a large share of this market), this hypothetical incorrectly assumes that one can predict that the redesign would not sacrifice any therapeutic utility to the ten percent of patients who benefit from the existing design. Cf. infra note 102 and accompanying text (discussing adverse consequences of attempts to reduce OxyContin’s abuse potential). Furthermore, as argued in the text, added expense may excise a failure to adopt a safer alternative design under section 2(b) but play essentially no role under section 6(c).

82 See, e.g., Dreier, supra note 19, at 261-62 (suggesting that the duty to test might take care of this problem); Winchester, supra note 19, at 686 (“[W]hat about the case in which there is only one drug available on the market for an identifiable group of patients, yet . . . the manufacturer had in fact determined how to make the product safer, but decided not to?”); id. at 685-88 (suggesting that adoption of a reasonable manufacturer standard might obviate this problem).

emphasizing that the patent system creates barriers to entry,84 but those relate primarily to delayed price competition from generic (“knock off”) versions rather than genuinely safer alternative designs.85

Imagine a new biotechnology drug that is safer and more effective in every type of patient with a certain condition, but it costs $50,000 annually as compared to $500 for the old standby;86 from a purely medical standpoint, no reasonable physician would prescribe the older product,87 at least not unless affordability got factored into the equation.88 With time, older medical technologies will fade from the

84 See Conk, supra note 21, at 757-61; id. at 787 (“The patent system’s limits on competitive development of safer and more effective designs makes the tort system’s functions of deterrence and compensation of particular importance in regard to the designs of drugs . . . .”). For a more detailed response to this point, see infra notes 176-81 and accompanying text.

85 See Lichtenberg & Philipson, supra note 39, at 644 (“A patent protects an innovator only from others who produce the same product, but it does not protect him from others who produce better products under new patents.”); id. at 651 (“[W]ithin-patent competition after patent expiration is from so-called generic manufacturers and between-patent competition is from so-called brand-name manufacturers engaging in therapeutic competition within a given disease class.”); id. at 646-47 (“[C]reative destruction through between-patent competition accounts for at least as much erosion of innovator returns as within-patent competition caused by patent expiration, and often considerably more.”); Kevin O. Ouster, The Vanishing Public Domain: Pharmaceutical Innovation and Intellectual Property Law, 67 U. PITT. L. REV. 67, 95 n.159 (2005) (“Within a particular class, many drugs may reach the market, very frequently with different patent holders.”); id. at 95 n.162 (“The average time before a second member of a therapeutic class is marketed is about 1.2 years.”).

86 See Denise Gellene, New Cancer Drugs Are Driving up Cost of Care, L.A. TIMES, May 14, 2005, at C1 (reporting that the switch from standard chemotherapy agents to “targeted” drugs has, for instance, doubled the average life expectancy of patients with inoperable colon cancer (to 22 months), while treatment costs increased 500-fold (to $250,000)); Rachel Zimmerman, Drug Slows a Deadly Cancer, Study Finds, but Price Is Steep, WALL ST. J., June 16, 2005, at D2 (reporting that Velcade®, a newly approved proteasome inhibitor that costs more than $45,000 for a nine month course of treatment, allowed multiple myeloma patients to live an average of three months longer than those given the standard treatment of dexamethasone, a generic corticosteroid that costs $170 and causes fewer serious side effects); see also Thomas H. Lee & Ezekiel J. Emanuel, Tier 4 Drugs and the Fraying of the Social Compact, 359 NEW ENG. J. MED. 333 (2008); Deborah Schrag, The Price Tag on Progress: Chemotherapy for Colorectal Cancer, 351 NEW ENG. J. MED. 317 (2004); Marilyn Chase, Cancer Tab: Pricey Drugs Put Squeeze on Doctors, WALL ST. J., July 8, 2008, at A1.

87 Unlike some other industries (e.g., consumer electronics), technological advance in medicine brings with it increasing rather than declining costs. See David M. Kent et al., New and Dis-improved: On the Evaluation and Use of Less Effective, Less Expensive Medical Interventions, 24 MED. DECISION MAKING 281, 282 (2004) (“Although lower quality, lower cost products are ubiquitous in most consumer markets, barriers remain for . . . cost-saving medical technologies.”); id. at 285 (“Clinical medicine is perhaps unique as a consumer market for the absence of innovations promoted for being less costly, albeit less effective, than the best standard.”).

88 Cf. Savina v. Sterling Drug, Inc., 795 P.2d 915, 924 (Kan. 1990) (explaining that other courts included cost as a risk-utility factor in resolving pharmaceutical design defect claims); Peter D. Jacobson & C. John Rosenquist, The Use of Low-Osmolar Contrast Agents: Technological Change and Defensive Medicine, 21 J. HEALTH POL’Y, POL’Y & L. 243, 250-54 (1996); Laura Landro, The Informed Patient: Weighing Which Babies Get a Costly Drug—Small Numbers Who Benefit May Not Justify $6,000 Price of Preventive RSV Therapy, WALL ST. J., Apr. 16, 2008, at D1 (Synagis®). Perhaps physicians would worry that some patients would not comply with a treatment regimen because of the expense. Cf. Cupp, supra note 44, at 237 (suggesting “that physicians are acting reasonably in prescribing the cheaper Proscar to the subclass planning to cut the pills to use safely for baldness”). For the most part, however, they know little about the prices of drugs or how these may impact their patients. See Michael E. Ernst et al., Prescription Medication Costs: A Study of Physician Familiarity, 9 ARCHIVES FAM. MED. 1002, 1004-06 (2000); Alex D. Federman,
scene, but manufacturers may persist in marketing them, especially if cost-conscious purchasers continue to demand "safe enough" prescription drugs.\textsuperscript{89} Section 6(c) appropriately discourages the continued marketing of genuinely obsolete prescription products that pose undue risks to patients when the FDA has not acted to withdraw these products,\textsuperscript{90} but it also should incorporate section 2(b)'s willingness to factor affordability and convenience into the equation.

3. Myths About Designer (and "Lifestyle") Drugs

Section 6(c) recognizes that pharmaceuticals are not designed in the same sense as other consumer goods; instead, new drugs are discovered.\textsuperscript{91} The advent of new techniques of "rational drug design,"\textsuperscript{92} which some commentators point to when disputing the supposed distinctiveness of pharmaceutical products,\textsuperscript{93} will not fundamentally change things anytime soon.\textsuperscript{94} A pharmaceutical manufacturer cannot

\textsuperscript{89} See supra note 39 (discussing restricted formularies); see also Scott Gottlieb, Op-Ed, Congress Wants to Restrict Drug Access, WALL ST. J., Jan. 20, 2009, at A15. Thus, an insurer might defend a policy that covered only generic drugs in the sense that it ensured payment for the state-of-the-art as it had existed approximately one decade earlier (and as it still exists in many industrialized countries where price controls have slowed the introduction of expensive innovations). Cf. Outterson, supra note 85, at 73 ("Rich consumers pay for and receive the latest innovations (2005 medicine), while the poor might well be satisfied with the less effective, but much less expensive, 1991 all-generic pharmacopoeia."); Daniel Yi, Savings Ahead in Generic Medicines: Patents Are Expiring on Four Big Brand Names, L.A. TIMES, July 15, 2006, at A1.

\textsuperscript{90} See Conk, supra note 21, at 749-50 (conceding that section 6(c) would impose liability on a prescription product if it "became obsolete as a result of other subsequently developed and approved drugs of superior safety and equivalent efficacy that have entered the market, without the challenged drug being removed from the marketplace" (footnote omitted)). For instance, the approval of recombinant growth hormone (rhGH) entirely displaced the form derived from cadavers, which suppliers had withdrawn after reports that it transmitted Creutzfeldt-Jakob disease. See Lars Noah, Managing Biotechnology's [R]evolution: Has Guarded Enthusiasm Become Benign Neglect?, 11 VA. J.L. & TECH. 4, 21 (2006).


\textsuperscript{93} See, e.g., Green, supra note 19, at 220; id. at 213 (conceding that this remains "generally more theoretical than contemporaneously real," but predicting that it will become more significant in the future); see also Conk, supra note 19, at 1107 (arguing that a RAD-based standard "could prove increasingly useful as genetic engineering and microbiology advance and the range of design choices for pharmaceutical product designers becomes broader and less opaque"); Conk, supra note 21, at 756 (same). Advances in genetics may, instead, make pharmaceutical cases even more challenging to resolve under existing products liability doctrine. See infra Part IV.D.2.

\textsuperscript{94} See Peter Landers, Human Element: Drug Industry's Big Push into Technology Falls Short, Wall St. J., Feb. 24, 2004, at A1 (reporting that combinatorial chemistry and high-throughput screening have not panned out); see also John Markoff, Herculean Device for Molecular Mysteries, N.Y. TIMES, July 8, 2008, at F2 ("Experimentation in the use of supercomputers to model molecular
market a theoretical redesign until it discovers this allegedly superior drug, subjects it to the full battery of preclinical and clinical testing over a period of several years, and then patiently waits for the FDA’s blessing.95 Hypothesized redesigns have unpredictable safety and efficacy profiles, which makes it impossible for an expert to predict whether it would pass muster with the FDA.96

In some cases, a design defect may relate to the proportions of (or interactions between) ingredients used in a combination drug product rather than the design of the separately approved chemicals themselves.97

interactions has been going on for more than a decade, but the field is still largely in its infancy.”). Even if improved genetic information and enhanced computing power allow for greater initial precision in the identification of promising agents, testing in animals and humans will have to continue for the foreseeable future. See Helen M. Berman & Rochelle C. Dreyfuss, Reflections on the Science and Law of Structural Biology, Genomics, and Drug Development, 53 UCLA L. REV. 871, 883-86 (2006).

95 See Ackley v. Wyeth Labs., Inc., 919 F.2d 397, 398-404 (6th Cir. 1990); id. at 401 (“Without an FDA license to produce another design, Wyeth was legally prohibited from distributing either a fractionated cell or an acellular [pertussis] vaccine . . . .”); Pease v. Am. Cyanamid Co., 795 F. Supp. 755, 757, 760 (D. Md. 1992) (explaining that the FDA did not approve an acellular version until 1991, and then only as a booster because of doubts about its effectiveness in infants); Jones v. Lederle Labs., 785 F. Supp. 1123, 1127-28 (E.D.N.Y.) (granting a JNOV to the manufacturer), aff’d, 982 F.2d 63, 64 (2d Cir. 1992); White v. Wyeth Labs., Inc., 533 N.E.2d 748, 753 (Ohio 1988) (describing evidence concerning the relative safety and effectiveness of alternative vaccine designs as “speculative at best”); see also Henderson & Twerski, supra note 19, at 175 (“[A]s long as marketing of such safer drugs requires FDA approval, in-court replication of the formal approval process will continue to exceed the limits of adjudication.”). But see Graham v. Wyeth Labs., 666 F. Supp. 1483, 1496-98 (D. Kan. 1987); Toner v. Lederle Labs., 732 F.2d 297, 308 (Idaho 1987).


97 See, e.g., Ezagui v. Dow Chem. Corp., 598 F.2d 727, 731-32 (2d Cir. 1979) (alleged defect related to the use of a different inactive ingredient that caused endotoxins to leak from the pertussis component of a combination vaccine); id. at 733-36 (finding sufficient evidence in the record to present a jury question); see also Green, supra note 19, at 211-12, 219 (using other illustrations to make these points). Along similar lines, consider the following hypothetical:

Suppose the vaccine causes a mild auto-immune reaction—a rash that lasts for a week—in one out of a million persons who take the vaccine. The side effect can be eliminated by changing one of the inert ingredients with which the vaccine is coated to another inert ingredient, no more expensive and equally adept at serving its purpose. The vaccine is defectively designed despite its enormous social utility.

Michael D. Green, The Schizophrenia of Risk-Benefit Analysis in Design Defect Litigation, 48 VAND. L. REV. 609, 619 (1995) (“Risk-benefit operates at the margin—the utility of the existing design compared to the alternative—not at the level of the entire product.”); see also Green, supra note 19, at 225 (“At the margin, we should always be willing to examine whether we can improve the overall benefit-to-risk ratio of a product.”). In support of the argument that design defects may relate to the relative portions of different active ingredients in combination drugs, critics often cite Brochu v. Ortho Pharm. Corp., 642 F.2d 652 (1st Cir. 1981), but the claims against the manufacturer of the oral contraceptive at issue in that case had more to do with the risks and benefits of just one of
Design issues also may relate to fixed dosage levels.\textsuperscript{98} Even minor changes in formulation (e.g., different inactive ingredients) would, however, require the submission of a new drug approval (NDA) supplement to the FDA with supporting data to demonstrate bioavailability of the active ingredient.\textsuperscript{99} For instance, OxyContin\textsuperscript{100} caused deaths among abusers who had managed to defeat the delayed-release mechanism by crushing or dissolving the pills.\textsuperscript{100} After the filing of several lawsuits, the manufacturer announced plans to add an ingredient that could deactivate the oxycodone when crushed, but the changed formulation would have to await FDA approval.\textsuperscript{101} In fact, these reformulation efforts have encountered roadblocks.\textsuperscript{102}

Apart from laboring under misimpressions about the ease of redesigning prescription drugs, critics of efforts to constrain design defect scrutiny point out that pharmaceutical products do not all have equally high utility. In making product approval decisions, the FDA routinely struggles with such questions.\textsuperscript{103} Obviously, the agency will see id. at 654-55 & nn.1&4.

\textsuperscript{98} See Green, supra note 19, at 212-13; see also Suz Redfearn, Low-Dose Hormone Approved, WASH. POST, Mar. 25, 2003, at F1 (reporting that the manufacturer of Prempro\textsuperscript{11} had responded to new risk information by securing approval for a lower-dose (and presumably safer) version, and noting a similar response many years earlier by sellers of oral contraceptives); Andrew Schneider, Banned Pesticide Allowed as Medicine: U.S. Bars Lindane, Except to Treat Lice, BALTIMORE SUN, Aug. 14, 2006, at 1A (reporting that the FDA sought to limit the number of doses dispensed at a time). Changes in dosing instructions, however, relate more to questions of labeling than design. Cf. Abigail Zuger, Caution: That Dose May Be Too High, N.Y. TIMES, Sept. 17, 2002, at F1 (reporting that manufacturers often reduce recommended dosages in response to postapproval safety concerns).

\textsuperscript{99} See 21 C.F.R. § 314.70 (2008) (distinguishing—for purpose of requiring NDA supplements—between “major,” “moderate,” and “minor” changes); see also Mead Johnson Pharm. Group v. Bowen, 838 F.2d 1332, 1334-35 & n.2 (D.C. Cir. 1988) (explaining that lower-level agency reviewers have the authority to approve NDA supplements but not NDAs). Perhaps hypothetical redesigns that would require only an NDA supplement (especially for changes that did not qualify as “major”) might provide fair game for design defect claims while those that would require the filing of a new (full blown) NDA should remain off limits.

\textsuperscript{100} See Barry Meier, U.S. Asks Painkiller Maker to Help Curb Wide Abuse, N.Y. TIMES, May 1, 2001, at A16. OxyContin is an extended-release formulation of oxycodone, a synthetic form of morphine effective in relieving severe or chronic pain such as that experienced by cancer patients.

\textsuperscript{101} See Lars Noah, Challenges in the Federal Regulation of Pain Management Technologies, 31 J.L. MED. & ETHICS 55, 62 (2003) (discussing the use of naltrexone); see also Sandra Blakeslee, Drug Makers Hope to Kill the Kick in Pain Relief, N.Y. TIMES, Apr. 20, 2004, at F1 (reporting that another approach involves adding a chemical irritant such as capsacin).

\textsuperscript{102} See Andrew Pollack, Company Said to Develop Substitute for Painkiller, N.Y. TIMES, Nov. 5, 2003, at C4; see also Marc Kaufman, Drug Firms Trying to Make Painkillers Less Abusable, WASH. POST, June 14, 2004, at A7 (reporting that “some combination drugs that might reduce the abuse potential of painkillers are also likely to reduce their effectiveness”).

\textsuperscript{103} See, e.g., E.R. Squibb & Sons, Inc. v. Bowen, 870 F.2d 678, 681-86 (D.C. Cir. 1989) (upholding the FDA’s decision to withdraw approval of drugs where the agency found no “medical significance” to the use of antifungal ingredients intended to reduce candidal overgrowth after a course of antibiotics); Warner-Lambert Co. v. Heckler, 787 F.2d 147, 154-56 (3d Cir. 1986) (rejecting the plaintiff’s claim that “effectiveness” as used in the Act means only that the drug will have the effect the manufacturer claims for it,” and concluding that the demonstration of effectiveness must include evidence of a therapeutic level of action compared with placebo); see also Rob Stein, Medication Under a Microscope: Studies Raise Questions About Drugs’ Efficacy Against
tolerate substantial risks for drugs that may save lives,104 while products that treat minor conditions or offer only symptomatic relief will not get approved unless fairly benign.105 Between these two extremes lie difficult judgments about the nature of the condition intended for treatment,106 as illustrated by recent debates over the use of psychotropic drugs,107 stimulants in children with behavioral disorders,108 and natural set of changes to be managed,” noting “the FDA’s discomfort with the way that hormone replacement treatments for little-known ailments [e.g., restless leg syndrome]. Studies published in a respected medical journal. . . accused the big pharmaceutical companies of ‘medicalising’ problems such as high cholesterol and sexual dysfunction.”); see also Marc Kaufman, Hormone Replacement Gets New Scrutiny: Finding of Increased Risks Prompts Federal Effort, WASH. POST, Aug. 14, 2002, at A1 (reporting that “federal officials want to explore whether hormone therapies and their producers have encouraged women to believe menopause is a condition to be treated, rather than an inevitable and natural set of changes to be managed,” noting “the FDA’s discomfort with the way that hormone treatments have been widely presented as an antidote to menopause”).

107 See Colleen Cebuliak, Life as a Blonde: The Use of Prozac in the ‘90s, 33 ALTA. L. REV. 611 (1995) (discussing emotional enhancement and cosmetic pharmacology); Jeff Donn, Are We Taking Too Many Drugs?, NEWSDAY, Apr. 19, 2005, at B13 (“[T]he Centers for Disease Control voiced concern about huge off-label growth of antidepressants to treat such loosely defined syndromes as compulsion, panic or anxiety and PMS. Drug makers, doctors and patients have all been quick to medicate some conditions once accepted simply as part of the human condition.”); Shankar Vedantam, Drug Ads Hyping Anxiety Make Some Uneasy, WASH. POST, July 16, 2001, at A1 (describing the successful marketing of Paxil® (paroxetine), and noting that “pharmaceutical companies, traditionally in the business of finding new drugs for existing disorders, are increasingly in the business of seeking new disorders for existing drugs”); see also Lars Noah, Comfortably
the abortifacient drug Mifepristone® (mifepristone), and the vaccine Gardasil® (designed to prevent a sexually transmitted disease, human papillomavirus (HPV), linked to cervical cancer). Some commentators would hold manufacturers of “lifestyle” drugs to a higher standard. One laundry list of such products included treatments for erectile dysfunction (ED), arthritis, obesity, and urinary incontinence, but it failed to explain the reasons for lumping these disparate drugs together: was it that they offered primarily symptomatic relief (or targeted a mere risk factor) and required chronic use? Aside from problems of recreational abuse, are powerful analgesics properly dismissed as merely “lifestyle” drugs? Contraceptives sometimes get trivialized in this fashion.113

108 See Gardiner Harris, F.D.A. Strengthens Warnings on Stimulants’ Risks, N.Y. TIMES, Aug. 22, 2006, at A14; Shankar Vedantam, Debate over Drugs for ADHD Reignites: Long-Term Benefit for Children at Issue, WASH. POST, Mar. 27, 2009, at A1 (reporting that prescriptions for ADHD drugs have reached almost 40 million annually); see also Gardiner Harris, Use of Antipsychotics in Children Is Criticized, N.Y. TIMES, Nov. 19, 2008, at A20.

109 See Lars Noah, A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics, 36 WAKE FOREST L. REV. 571, 593 (2001) (“Some opponents have suggested that the agency might . . . recast mifepristone’s intended use in terminating pregnancy as a risk to the fetus rather than (or perhaps in addition to) a benefit to the mother, which might then justify summary withdrawal of the drug as an imminent hazard to public health.”); see also id. at 580 (“[T]he clinical utility of a drug that can terminate pregnancy must lie in the fact that it provides a safer (or more convenient) alternative to a surgical abortion.”); id. at 581-82 (questioning the product’s eligibility for accelerated FDA approval as a treatment for “serious illness”).

110 See Charlotte J. Haug, Editorial, Human Papillomavirus Vaccination: Reasons for Caution, 359 NEW ENG. J. MED. 861, 861-62 (2008); Sylvia Law, Human Papillomavirus Vaccination, Private Choice, and Public Health, 41 U.C. DAVIS L. REV. 1731, 1733-42, 1755-64 (2008); see also Note, Toward a Twenty-first Century Jacobson v. Massachusetts, 121 HARV. L. REV. 1820, 1838-41 (2008) (suggesting a distinction, for purposes of evaluating the constitutionality of compulsory immunization programs, between “medically necessary” vaccines, which offer the only real means of protection against infectious diseases, and “practically necessary” vaccines that protect, for instance, against STDs (e.g., HPV and hepatitis B), which could be avoided through other means).

111 See Joseph Weber & Amy Barrett, The New Era of Lifestyle Drugs: Viagra and Other Blockbusters Are Transforming the $300 Billion Industry, BUS. WK., May 11, 1998, at 92; see also David Gilbert et al., Lifestyle Medicines, 321 BRIT. MED. J. 1341, 1342 (2000) (offering a similar list, and focusing on payment issues); Cindy Parks Thomas, Incentive-Based Formularies, 349 NEW ENG. J. MED. 2186, 2188 (2003) (“Some insurers have created a fourth, ‘lifestyle,’ tier for more discretionary or ‘cosmetic’ drugs . . . .”)

112 What once qualified as mere risk factors may, over time, get recharacterized as diseases in their own right, as in the case of hypertension. See, e.g., Denise Grady, As Silent Killer Returns, Doctors Rethink Tactics to Lower Blood Pressure, N.Y. TIMES, July 14, 1998, at F1 (reporting that “it is not known whether all drugs that lower blood pressure also protect against heart attack and stroke”). Thereupon, physicians began diagnosing patients with pre-hypertension. See Elizabeth Agnvall, Making Us (Nearly) Sick: A Majority of Americans Are Now Considered to Have at Least One “Pre-Disease” or “Borderline” Condition. Is This Any Way to Treat Us?, WASH. POST, Feb. 10, 2004, at F1; see also January W. Payne, Forever Pregnant—Guidelines: Treat Nearly All Women as Pre-Pregnant, WASH. POST, May 16, 2006, at F1.

Even if not elevated to the vaunted status of a genuine “disease,” bothersome conditions (e.g., irritable bowel syndrome) and disfiguring ailments (e.g., cystic acne) undoubtedly have adverse effects on the sufferers’ quality of life, which can take an emotional and financial toll on them.\textsuperscript{114} If not unduly dangerous, the FDA does permit marketing of prescription products that presumably everyone would label as “lifestyle” drugs (e.g., wrinkle reducers),\textsuperscript{115} though even unmistakably cosmetic products such as Botox\textsuperscript{®} may have secondary therapeutic uses.\textsuperscript{116} In the final analysis, all drugs are, to one degree or another, lifestyle drugs.\textsuperscript{117}

In theory, section 6(c)’s reference to “therapeutic benefits” and use of a physician-based standard might expose “lifestyle” drugs to unforgiving design defect scrutiny.\textsuperscript{118} Although it appears that the

\textsuperscript{114} See, e.g., Denise Grady, F.D.A. Pulls a Drug, and Patients Despair, \textit{N.Y. Times}, Jan. 30, 2001, at F1 (reporting that those who favored withdrawing Lotronex\textsuperscript{®} (alosetron), a drug indicated for use in patients with irritable bowel syndrome, had argued that its risks of severe constipation or ischemic colitis were unacceptable because it only treated a non-life-threatening condition, while the majority of patients on the drug who had suffered no serious side effects protested the withdrawal because the drug had helped them to cope with a condition that significantly interfered with their daily life activities).


\textsuperscript{118} See Henderson, \textit{supra} note 19, at 492 (“[W]hen defendant’s drug is the only one of its kind on the market and serves what members of the medical profession ostensibly believe to be a useful purpose, plaintiff should not reach the trier of fact.”). A subsequent article co-authored by one of the Reporters (but unrelated to section 6) repeatedly drew a distinction between “lifestyle” and “therapeutic” drugs. \textit{See} Margaret A. Berger & Aaron D. Twerski, \textit{Uncertainty and Informed
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Reporters meant to include even “cosmetic” products that required the intervention of a health care provider, courts may refuse to credit these separately published glosses on the blackletter formulation. If taken at face value, section 6(c) could have the effect of delegating judgments about the utilities of prescription products to reasonable physicians whose professional training presumably would give us a far narrower range of legitimate clinical endpoints, which would make some pharmaceutical manufacturers more vulnerable to design defect claims than they would have been under the more flexible and consumer-oriented standard of section 2(b).

Aside from questions about the special utility of prescription drugs, some commentators have argued that, unlike other consumer goods, these products rarely cause third-party effects, but this claim of distinctiveness strikes me as clearly incorrect. It disregards, for instance, recurring litigation over birth defects (including cases where the drug has no intended use related to pregnancy), sedation (as it relates to

Choice: Unmasking Daubert, 104 MICH. L. REV. 257, 259, 272, 288 & n.148 (2005) [hereinafter Informed Choice]; id. at 279 (imagine a drug that “has little therapeutic value and provides only aesthetic or palliative relief”); see also id. at 269-70 (using Parlodel, which allegedly “created gratuitous risk with very little benefit” in lactation suppression, especially compared to the use of OTC analgesics for this same purpose, to justify the recognition of a new type of failure-to-warn claim that would not require proof of causation); cf. David E. Bernstein, Correspondence, Learning the Wrong Lessons from “An American Tragedy”: A Critique of the Berger-Twerski Informed Choice Proposal, 104 MICH. L. REV. 1961, 1967-68 (2006) (disputing their suggestion that the morning sickness remedy Bendectin qualified as a lifestyle drug, explaining that, in severe cases, it could reduce dehydration and the accompanying need for hospitalization and risks of fetal harm). Their rejoinder never attempted to respond to the point that Bendectin served genuine therapeutic purposes, opting instead for rhetorical flourishes to underscore their thesis. See Margaret A. Berger & Aaron D. Twerski, Correspondence, From the Wrong End of the Telescope: A Response to Professor David Bernstein, 104 MICH. L. REV. 1983, 1989 (2006) (“When one seeks to huckster drugs as if they were M&M’s, brutal honesty is called for.”); id. at 1992 (referring to decisions “to imbibe non-therapeutic drugs,” as if these amounted to alcoholic beverages); see also id. at 1991-92 (suggesting that Vioxx “offered little or no therapeutic benefits”).

119 See Henderson, supra note 19, at 484-86 (discussing a hypothetical choice between different breast implant designs, and arguing that fully-informed patients should be allowed to opt for a riskier version on aesthetic grounds); Henderson & Twerski, supra note 19, at 176-77 (noting that “there exists a class of patients who benefit emotionally and psychologically,” even if not physically, from such products, and recognizing that “prescription drugs and devices [with] aesthetic properties can have profoundly beneficial effects on an individual’s psychic well-being”); cf. Savina v. Sterling Drug, Inc., 795 P.2d 915, 927 (Kan. 1990) (“The policy considerations underlying strict liability and Comment k would apply to a diagnostic drug as well as to a drug used for treatment.”). It remains unclear how they would evaluate secondary utilities such as convenience and cost that seemingly have no therapeutic benefit broadly conceived. See supra notes 76-90 and accompanying text.

120 See Green, supra note 19, at 216 (“Only in the rarest situation is there any potential for third-party effects from drugs.”); Henderson, supra note 19, at 494 (referring to “the substantial absence of third-party effects”); see also id. at 480-81 (“[W]hen negative third party effects are minimal, courts should hesitate before imposing the added costs of greater safety on users or consumers who do not volunteer to pay for additional safeguards when choosing which product designs to buy in the marketplace.” (footnote omitted)); Henderson & Twerski, supra note 19, at 177 (noting that cosmetic drugs and devices “rarely have adverse third-party effects”).

121 See infra Part II.C.2 (thalidomide and methotrexate); infra Part II.C.5 (isotretinoin); infra notes 313-14 and accompanying text (diethylstilbestrol); see also David B. Brushwood, Drug Induced Birth Defects: Difficult Decisions and Shared Responsibilities, 91 W. VA. L. REV. 51 (1988).
automobile accidents and the like), and psychosis. It also seemingly disregards claims related to abuse and diversion. Finally, though not so far as I know litigated, efficacy failures may permit contagious diseases to spread to others, pharmaceuticals may cause harm to health care workers, and medical technologies may have deleterious environmental consequences. Prescription products have many distinctive characteristics, but an absence of third-party effects is not one of them.

C. Case Studies

The operation of section 6(c) becomes more concrete when applied to particular fact patterns, real or imagined (as I note repeatedly

122 See, e.g., McKenzie v. Hawai‘i Permanente Med. Group, Inc., 47 P.3d 1209, 1210-11, 1218-22 (Haw. 2002); Coombes v. Florio, 877 N.E.2d 567, 572-75 (Mass. 2007) (plurality) (addressing the duty of physicians to warn in such cases); Osborne v. United States, 567 S.E.2d 677, 679 (W. Va. 2002); see also Stephanie Saul, Some Sleeping Pill Users Range Far Beyond Bed, N.Y. TIMES, Mar. 8, 2006, at C1 (reporting that Ambien® has been linked to sleepwalking and impaired driving).


124 See, e.g., Erony v. Alza Corp., 913 F. Supp. 195, 197 (S.D.N.Y. 1995) (allowing an inadequate warning claim to proceed on behalf of a teenager who died after sucking on his father’s discarded Duragesic® patches); see also Joseph B. Prater, Comment, West Virginia’s Painful Settlement: How the OxyContin Phenomenon and Unconventional Theories of Tort Liability May Make Pharmaceutical Companies Liable for Black Markets, 100 W. U. L. Rev. 1409 (2006); cf. Gipson v. Kasey, 150 P.3d 228, 229, 233-34 (Ariz. 2007) (holding that a patient who gave away oxycodone owed a duty to others injured by misuse). On this score, the Reporters only imagined a minor possibility that friends or family of patients would borrow their unused prescription drugs. See Henderson & Twerski, supra note 19, at 171 n.81.

125 Cf. Dave Murphy, 92 Patients Told of Possible Exposure to TB: Medical Devices in Hospital Surgeries Weren’t Sterilized, S.F. CHRON., Feb. 11, 2005, at B4 (reporting that a sterilizing device had failed to function). The flipside of this argument appears frequently (as justifying limits on liability in order to reduce disincentives to R&D); vaccines and antibiotics, for example, resemble public goods because, when they work, both the patient and third parties benefit; conversely, when antibiotics are used inappropriately, the patient derives no benefit and third parties eventually may suffer harm due to the emergence of bacterial resistance. See David Brown, Drug-Resistant Cases of TB in U.S. Increase, WASH. POST, Mar. 24, 2006, at A10; Justin Gillis & Ceci Connolly, Emphasis on Cipro Worries Officials, WASH. POST, Oct. 19, 2001, at A17 (reporting that drug-resistant bacteria contribute to 70,000 deaths each year in the United States); Anita Manning, “Superbugs” Spread Fear Far and Wide: Drug-Resistant Staph Infections No Longer Threaten Just Hospital Patients, USA TODAY, May 11, 2006, at 1A (reporting outbreaks of community-acquired methicillin-resistant staph aureus (MRSA)); see also Outterson, supra note 85, at 67-68, 73-86, 94-114, 119-123 (elaborating on problems of resistance to antibiotics and antivirals, and discussing various proposed solutions).


below, these turn out to be far more imagined than real, but that alone does not defeat the effort to draw relevant insights from these case studies. The sections that follow discuss various illustrations offered by both proponents and critics: ritodrine, thalidomide, finasteride, polio vaccines, and isotretinoin. In the subpart that follows immediately after these case studies, I draw some broader lessons and suggest a centrally important design feature of pharmaceutical products that has escaped the attention of commentators.

1. Ritodrine

The Reporters offered an illustration of a successful design defect claim under section 6(c), which they had based on the decision *Tobin v. Astra Pharmaceutical Products, Inc.* Commentators have debated whether or not *Tobin*’s holding aligns with section 6(c), but nearly everyone has taken the opinion at face value. In fact, the court’s analysis in that case seemed emblematic of precisely the sort of mischief

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128 Pure hypotheticals offered by critics of section 6(c) suffer from acontextuality. See, e.g., Cupp, *supra* note 19, at 100 n.147 (imagining a drug that provides “a slight benefit to” 10% of users, while causing a lethal allergic reaction in the other 90%, and that it was not possible to specify the subgroup of users for whom the drug worked without harm); *id.* at 97 (arguing, even more implausibly, that, “if the prescription product could reasonably be prescribed to a single person—even if it were fatal as to all other persons to whom it is prescribed—the product would be immune from design liability”). In terminally-ill patients who have exhausted alternative treatments, I would expect reasonable physicians (and their desperate patients) to opt for a 10% chance of slight benefit even in the face of a 90% chance of death; while, in non-serious conditions (or life-threatening conditions amenable to other treatments), I trust that no reasonable health care provider supplied with an adequate warning would use such a product (in the highly unlikely event that the FDA would have allowed its marketing in the first place). *See id.* at 100 n.147 (conceding as much). In a subsequent article, this same commentator offered a different hypothetical based only loosely on reality. *See Cupp, supra* note 44, at 234-38 (discussing finasteride); *id.* at 237 n.26 (conceding the hypothetical nature of the facts presented); *see also infra* Part II.C.3 (critiquing this case study).

129 *See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. f & illus. 1 (1998).*

130 993 F.2d 528 (6th Cir. 1993).

131 Strangely, a feminist critique of section 6(c) dismissed *Tobin* as atypical because it seemed to involve a drug marketed without having secured FDA approval. *See Trompeter, supra* note 40, at 1154-55; *see also id.* at 1156 (suggesting that the case really involved a product malfunction, which would allow an inference of a manufacturing defect, even though from all appearances the drug had worked to halt the plaintiff’s premature labor). Contrary to this commentator’s interpretation, see *id.* (“Thus, section 6(c) is a ‘super’ res ipsa loquitur standard, forcing the plaintiff to shoulder the difficult burden of establishing comprehensive product failure not just for her, but for every class of users.”); *id.* at 1172 (reiterating that “inefficacy is the basis of liability”); effective drugs could fail the test if equally effective interventions posed lower risks in all classes of patients. She also badly misunderstood the one judicial opinion that offered the clearest support for the protective standard announced in section 6(c). *See id.* at 1159-60 (focusing on language in *Williams v. Ciba-Geigy Corp.*, 686 F. Supp. 573 (W.D. La.), aff’d, 864 F.2d 789 (5th Cir. 1988), that discussed matters of safety, entirely ignoring other language in the opinion that explained, even if the risk were higher than established, the anticonvulsant would have been appropriate for epileptics unresponsive to other less dangerous drugs and was the only treatment available for patients with trigeminal neuralgia); *see also Cupp, supra* note 44, at 242 (making the same mistake).
that the Reporters had sought to guard against, and it also poses important questions about the operation of their blackletter formulation.

In Tobin, a woman pregnant with twins received a prescription for Yutopar® (ritodrine) to prevent premature labor. She developed serious cardiac problems while taking the drug and, after a successful delivery, required a heart transplant. The plaintiff prevailed at trial on her design defect and failure-to-warn claims, after her experts identified numerous methodological flaws in the clinical trials submitted to the FDA, which members of the agency’s advisory committee also had criticized. The federal appellate court in Tobin affirmed, concluding that, notwithstanding the fact of FDA approval (or any evidence of fraud in securing that approval or contrary postapproval data), the jury could have concluded that the manufacturer should never have marketed the drug because it had no good evidence of effectiveness in improving neonatal outcomes, though the court did concede that the drug appeared to reduce the need for maternal hospitalization. In short, if the jury found that the drug lacked all utility (because it simply did not work), then any risk would render it defectively designed. The drug’s labeling had contraindicated its use in patients with pre-existing cardiac disease (which, it turns out, this patient had, though her doctors did not know that at the time), but the court concluded that the drug also should not have been available for use in any other types of patients.

Tobin suffers from numerous shortcomings. First, the court allowed the jury to conclude (with the assistance, of course, of the

132 See Henderson, supra note 19, at 492 (conceding that section 6(c) “allows courts to second-guess the FDA on the . . . question of whether a drug approved by the FDA and marketed by a defendant should not have been approved and marketed,” though trusting that that would occur “only in relatively rare cases”); Henderson & Twerski, supra note 19, at 174 (“By countenancing a finding that a defendant’s drug is, essentially, worthless, section 6(c) tacitly assumes that the FDA will occasionally approve (or fail to order withdrawal of) a drug that should not be allowed on the market.”). I fail to see how this involves any less an exercise in “rank speculation” than trying to decide whether the FDA might approve a hypothesized alternative design, id. at 167; see also id. at 162-64; indeed, absent some confession of error by the agency, cf. supra note 60 (discussing the FDA’s decision to withdraw bromocriptine for the suppression of lactation based on postapproval risk information and reconsideration of its relative efficacy), it seems even less appropriate to invite a jury to engage in this sort of reassessment, see Green, supra note 19, at 231 (“The FDA performs a risk-benefit analysis when it approves a new drug and, as long as the FDA is provided accurate and complete study data from the drug’s sponsor, only a regulatory skeptic or a jury exalter would suggest that such a determination be reconsidered de novo in a civil case.”); see also id. at 222-23, 232 (explaining the importance of insisting on full regulatory compliance and not simply the fact of agency approval); cf. Kaplan et al., supra note 27, at 70-75 (favoring the complete elimination of design defect claims).

133 Even skeptics of a regulatory compliance defense seem to concede that it ought to cover those rare cases where plaintiffs allege defectiveness at the time of FDA approval without suggesting that the manufacturer misled the agency. See Michael D. Green, Statutory Compliance and Tort Liability: Examining the Strongest Case, 30 U. MICH. J.L. REFORM 461, 477-78, 495 (1997); see also id. at 490-92 (explaining the difficulties that courts would encounter if asked to revisit approval decisions that plaintiffs allege the applicant tainted by some violation of agency requirements); id. at 472-73, 495-96 (explaining that most cases involve risks discovered after approval and, for that reason, should proceed as failure-to-warn rather than design defect claims).

134 See Tobin, 993 F.2d at 537-40 & n.8.
parties’ experts) that the FDA should have accepted neither a surrogate marker (i.e., gestational age) for a clinical end-point (i.e., neonatal health), nor a sub-group analysis of clinical trials that the agency’s advisory committee had viewed as methodologically flawed.135 Second, the court failed to consider the fact that the FDA had not approved any other tocolytic agents as of 1993 or that neonatal intensive care was more primitive when it approved ritodrine in 1980.136 Third, the court marginalized ritodrine’s evident effectiveness in reducing the need for repeated hospitalizations during pregnancy.137 In effect, it turned a complex risk-utility judgment, using data from less than ideal clinical trials, into a no-brainer by allowing the jury to conclude that the drug was totally ineffective.138 In short, Tobin offers a poor illustration of section 6(c)’s intended scope and operation.

135 The court gave exaggerated significance to the comments of the advisory committee, disregarding the fact that the FDA had undertaken a lengthy internal review (and had no obligation to abide by the committee’s recommendations) and that the committee had in the end recommended approval. In 1992, based on newly published research, another FDA advisory committee concluded that oral ritodrine lacked effectiveness at current dosages. See F-D-C REP. (“The Pink Sheet”), Nov. 2, 1992, at 4; see also Kenneth J. Leveno & F. Gary Cunningham, Editorial, β-Adrenergic Agonists for Premature Labor, 327 NEW ENG. J. MED. 349, 349-51 (1992). The drug remains available in the United States, though only in an injectable form (oral dosage forms are still marketed in Canada).


137 The court’s evident indifference to the drug’s ability to reduce the need for maternal hospitalization reinforces previously discussed questions about section 6(c)’s emphasis on “therapeutic benefits.” See supra notes 76-90 and accompanying text.

138 Thus, I disagree with one commentator’s recent claim that judges resolving drug products liability cases focus unduly on questions of safety and “do not consider effectiveness.” Anita Bernstein, Enhancing Drug Effectiveness and Efficacy Through Personal Injury Litigation, 15 J.L. & POL’Y 1051, 1072 (2007); see also id. at 1058 (calling effectiveness “the neglected and undertheorized younger sibling of prescription drug safety”); id. at 1060 (pointing out that “the danger of harmful effects can be named in a warning much more clearly than the danger of futility”); id. at 1061 (“explo[ring] the contrary thesis that effectiveness is, and ought to be, central to personal injury litigation related to prescription drugs”); id. at 1100. Elsewhere, however, she correctly recognized that effectiveness inevitably gets taken into account when judging prescription drug defectiveness. See id. at 1084. (In contrast, Bernstein’s repeated assertion that the federal regulatory “effectiveness” standard means nothing other than truth-in-labeling, see id. at 1066-68, 1082, 1098, and her passing suggestion that the FDA does not mandate labeling about comparative effectiveness, see id. at 1084-85, have no foundation, see supra notes 69 & 103.) If a therapeutic failure occurs because of subpotency in a particular dose, an injured patient clearly could allege a manufacturing defect, and, if it occurs because a properly manufactured product does not work at all (as found in Tobin), then the patient could allege a design defect (but, if the drug only happens to fail in a particular patient, then, at most, the patient might have an informational defect claim in the event that the manufacturer exaggerated effectiveness or failed to specify known limitations on use in certain patient subgroups). The tricky issues in therapeutic failure (as opposed to adverse side effect) cases relate to causation and damages, but, apart from a brief discussion of emotional distress, see Bernstein, supra, at 1080-82, she never mentions (much less grapples with) these complexities, see e.g., Willis v. Wu, 607 S.E.2d 63, 66 (S.C. 2004) (“A ‘wrongful pregnancy’ or ‘wrongful contraception’ action is brought by the parent of a healthy but unplanned child, seeking damages from [inter alia] a . . . pharmaceutical manufacturer who allegedly was negligent in . . . manufacturing a contraceptive prescription or device.”); Noah, supra note 64, at 377-78 & n.32 (explaining that only in medical malpractice cases do courts recognize claims for the loss of a less-
2. Thalidomide

Similarly, one cannot say that the infamous teratogen thalidomide suffers from a design defect. Currently approved by the FDA for the treatment of skin lesions associated with Hansen’s disease (leprosy), though contraindicated for use in pregnancy (and accompanied by various other mechanisms designed to help ensure that physicians and patients take this limitation on use seriously), this drug appropriately passes the section 6(c) test. One wonders whether thalidomide would fare as well under a less structured risk-utility balancing approach in a case where a pregnant leprosy patient had used the drug: (1) from the perspective of her terribly deformed child, the risk clearly outweighs the utility; (2) from the perspective of the mother, the risk to her offspring also undoubtedly outweighs the drug’s utility to her (after all, less effective and more dangerous, but non-teratogenic, options such as glucocorticoids might have worked for her); and (3) from a societal than-even chance for a better outcome; see also Rivera v. Wyeth-Ayerst Labs., 283 F.3d 315, 319-21 (5th Cir. 2002) (dismissing, for lack of standing, a nationwide class action lawsuit brought on behalf of healthy users and insurers seeking only to recover their economic losses after the withdrawal of Duract prompted by safety concerns); New Jersey Citizen Action v. Schering-Plough Corp., 842 A.2d 174, 177-78 (N.J. Super. Ct. App. Div. 2003) (similar conclusion on claims based on direct-to-consumer advertising for Claritin). See generally Moin A. Yahya, Can I Sue Without Being Injured?: Why the Benefit of the Bargain Theory for Product Liability Is Bad Law and Bad Economics, 3 GEO. J.L. & PUB. POL’Y 83 (2005).


[140] See Dreier, supra note 19, at 260-61; Green, supra note 19, at 228 (calling thalidomide “the horror drug of all time,” but explaining that it would pass muster under section 6(c) now that the FDA has approved it for treating a serious skin condition associated with leprosy); cf. Brown v. Superior Court, 751 P.2d 470, 471 (Cal. 1988) (“It seems unjust to grant the same protection from liability to those who gave us thalidomide as to the producers of penicillin.”). One can say much the same of diethylstilbestrol (DES), the drug at issue in Brown. Although the discovery of risks from in utero exposure rendered its continued use in the prevention of miscarriages unjustified (especially in light of doubts that it ever worked for that purpose), see Leef Smith, The DES Legacy: Children of Women Given the Hormone DES Decades Ago Now Come with Their Own—and Even Their Children’s—Health Problems, WASH. POST, Sept. 23, 2003, at F1, the drug had other legitimate uses, see FDA, Diethylstilbestrol as Postcoital Oral Contraceptive; Patient Labeling, 40 Fed. Reg. 5351, 5354-55 (Feb. 5, 1975) (codified at 21 C.F.R. § 310.501(b) (1988)), revoked, 54 Fed. Reg. 22,585, 22,586 (May 25, 1989); cf. Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 776 n.1, 781-82 (R.I. 1988) (recognizing other uses, but nonetheless allowing a jury to find a design defect).

[141] Cf. Harbeson v. Parke Davis, Inc., 746 F.2d 517, 523-25 (9th Cir. 1984) (affirming judgment for plaintiffs on an informed consent claim where physicians failed to advise a epilepsy patient of the teratogenicity of Dilantin after she specifically had inquired about such risks in order to decide whether to attempt to conceive); Gerber v. Hoffmann-La Roche Inc., 392 F. Supp. 2d 907, 920 (S.D. Tex. 2005) (“Mr. Gerber can only argue that Shirley Gerber would not have taken Accutane in the first place if Roche’s warning had been adequate.”); Hogle v. Hall, 916 P.2d 814, 816-17 (Nev. 1996) (affirming a plaintiff’s judgment on an inadequate warning claim involving Accutane). If a physician had selected the drug to treat nausea during pregnancy rather than leprosy, then the patient and victim would have a clear malpractice claim but still not a design defect claim against the manufacturer.
perspective, the specter of a wave of birth defects arising from the very real possibility of the irresponsible use of this drug by physicians and patients might well outweigh the utility to the relatively small (and still stigmatized) community of leprosy sufferers. Section 6(c) does a better job of managing such cases than either a particularized or aggregate form of risk-utility balancing.

For another potent though far less notorious teratogen, consider methotrexate. It would make no sense to characterize this chemotherapy agent as defectively designed. As amply revealed in their labeling, cytotoxic agents have powerful and potentially lethal side effects. When used in cancer patients, often in various combinations and in conjunction with non-drug treatments such as surgery and radiation, the potential benefits may justify taking such risks. When a particular chemotherapy drug fails to slow cancer progression, it does not mean that the product

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144 Writing one year prior to its FDA approval for leprosy, one commentator used thalidomide to argue otherwise (on the assumption that agency had approved its use as an antinauseant during pregnancy and that the manufacturer marketed it as completely safe notwithstanding knowledge of reported birth defects in Europe). See Winchester, supra note 19, at 677-78. First, his hypothetical clearly would provide the basis for an informational defect claim. Second, it mistakenly assumes that the reasonable health care provider standard would ask what a physician presented with this inaccurate information would do. Third, even if the physician knew everything that the hypothetical manufacturer knew but failed to reveal, this commentator concluded that a design defect could not exist in the absence of a substitute. See id. at 678 (“If thalidomide were in fact the only ‘available’ tranquilizer for pregnant women, then section [6](c) automatically confers immunity.”). I have no doubt that a fully-informed physician would advise the patient to tough it out (is that a substitute?) rather than assume a high risk of very serious birth defects in order to treat a non-life-threatening condition. See Henderson, supra note 19, at 492-93 (“It is theoretically possible under the proposed Restatement that a plaintiff might be able to show that, notwithstanding a drug’s exclusivity for treating a particular medical condition, no reasonable, knowledgeable provider would prescribe the drug for any class of patients.”). Writing one year after the FDA approved thalidomide for leprosy, another commentator conceded that it might not fail design defect scrutiny, so he imagined instead that it only had secured approval for treating baldness! See Cupp, supra note 44, at 238 (concluding, even given full risk labeling and the admitted availability of substitutes, that such a product would survive design defect scrutiny under section 6(c)). I find this suggestion equally absurd. Even if only indicated for the treatment of male pattern baldness (rather than by women or during pregnancy), such a drug would present serious teratogenic risks because semen can carry residues of thalidomide. See Rita Rubin, Thalidomide Could Guide Use of Drugs That Risk Birth Defects, USA TODAY, July 22, 1998, at 7D. Given the availability of effective but non-teratogenic treatments, no reasonable physician would prescribe it for any class of balding patients (even if the FDA approved it).
suffers from any defect. Now what if a physician uses a cytotoxic agent for something other than cancer? For instance, doctors have used methotrexate off-label as an abortifacient. Could a patient who received this chemotherapy agent to terminate a pregnancy argue that the drug suffers from a design defect (especially now that the FDA has approved mifepristone for this purpose)? Perhaps a jury engaging in aggregate risk-benefit analysis would reach the correct conclusion (treating it instead as a case of either a failure to warn or medical malpractice), but again section 6(c) better guards against the possibility of an absurd outcome.

3. Finasteride

Richard Cupp offered an entirely different illustration designed to criticize the operation of section 6(c). He explained that, four years after the FDA approved Proscar (finasteride) for the treatment of benign prostatic hyperplasia (BPH), one study found an additional risk and another study failed to confirm its effectiveness. A jury might well second-guess the agency on the basis of such sparse evidence (as happened in Tobin), but, one decade later, the totality of published

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145 Similarly, when such a drug does arrest the cancer but causes the patient’s death, it also does not mean that the product suffers from a design flaw, and the availability of other (sometimes effective and less dangerous) interventions should not make any difference.


147 See supra note 109.


149 See Cupp, supra note 44, at 235. In fact, the news article that he cited, though mentioning an earlier study that found no benefit over placebo, had focused on a newly published study that confirmed limited efficacy. See Laura Bell, Drug Shows Promise for Prostate Patients, DALLAS MORN. NEWS, Feb. 26, 1998, at 4A; see also Michelle I. Wilde & Karen L. Goa, Finasteride: An Update of Its Use in the Management of Symptomatic Benign Prostatic Hyperplasia, 57 DRUGS 557 (1999). For a discussion of the debate over the unflattering earlier study, see Lawrence K. Altman, Common Drug for Prostrate Is Ineffective, Study Finds, N.Y. TIMES, Aug. 22, 1996, at A18.
research continues to support the widespread use of this still-approved drug for treating BPH. 150

Cupp added that the FDA had approved Hytrin® (terazosin), another drug for treating this condition, 151 and he even suggested that saw palmetto represented a safe and effective alternative for treating BPH. 152 Imagine jurors finding an FDA-approved prescription drug defectively designed because they agreed that a patient could have gone to his health food store and purchased a largely unregulated dietary supplement supported by some flimsy evidence of efficacy! 153 Section 6(c), with its reasonable physician standard, helps guard against precisely such muddle-headedness.

There is, however, more to Cupp’s story about Proscar: the FDA approved a low-dose version of finasteride (Propecia®) in 1998 for the treatment of baldness. Because, however, Proscar tablets offered five times the dose for less than one-third the price, physicians evidently prescribed it off-label (with instructions to split the pill) instead of prescribing Propecia. 154 Cupp argued that, given this pattern of off-label usage, 155 section 6(c) “might bar from recovery all of the men harmed by using Proscar for its primary, health-related purpose.” 156 Assuming just

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150 See Gina Kolata, New Take on a Prostate Drug, and a New Debate, N.Y. TIMES, June 15, 2008, at A1 (reporting that finasteride also may have prophylactic value, and noting that Proscar now competes with half a dozen generic versions of the drug); see also E. Darracott Vaughan, Jr., Editorial, Medical Management of Benign Prostatic Hyperplasia—Are Two Drugs Better Than One?, 349 NEW ENG. J. MED. 2449, 2449-53 (2003); Shankar Vedantam, More Men Are Urged to Take Drug Against Prostate Cancer, WASH. POST, Feb. 25, 2009, at A14. As explained previously, see supra notes 54-58 and accompanying text, there is no absolutely basis for Cupp’s suggestion that Proscar remains on the market only because the FDA lacks the authority to withdraw drugs except in extreme circumstances.


152 See Cupp, supra note 44, at 236 & n.15 (explaining that a “study reported that Saw Palmetto extract is more effective, far safer, and cheaper than Proscar,” citing a statement made by a member of Congress). I hear that another member of that august scientific body, Senator Tom Harkin, used to swear by bee pollen.

153 See Robert S. DiPaola & Ronald A. Morton, Editorial, Proven and Unproven Therapy for Benign Prostatic Hyperplasia, 354 NEW ENG. J. MED. 632, 632-33 (2006); Rob Stein, Vitamin Didn’t Lower Prostate Cancer Risk, WASH. POST, Oct. 28, 2008, at A9 (describing the early termination of NIH study of vitamin E and selenium); Lindsey Tanner, Many Go on Taking Discredited Remedies, SEATTLE TIMES, Feb. 27, 2006, at A5 (reporting that recent studies have found no therapeutic value to glucosamine, chondroitin, saw palmetto, echinacea, St. John’s wort, or shark cartilage); see also Whitaker v. Thompson, 353 F.3d 947, 948-49 (D.C. Cir. 2004) (upholding the FDA’s decision to reject a petition requesting permission to label saw palmetto products with a claim that they could treat BPH); Lars Noah, A Drug by Any Other Name . . . ?: Paradoxes in Dietary Supplement Risk Regulation, 17 STAN. L. & POL’Y REV. 165, 190 (2006) (urging the FDA to make fuller use of its limited statutory authority to crack down on unsafe herbal products).

154 See Cupp, supra note 44, at 236-37.

155 See id. at 237 (“It could be argued that physicians are acting reasonably in prescribing the cheaper Proscar to the subclass planning to use the pills to safely for baldness, even though Proscar’s primary use, treating prostate enlargement, would be unhelpful and unreasonably dangerous.”).

156 Id. at 237-38; see also id. at 238 (“Finding just one reasonable use, even if that use is ancillary and for purely cosmetic purposes, in effect immunizes the manufacturer regardless of how much harm a drug inflicts overall.”); id. at 241 (“Under the reasonable physician test, Proscar is
for the sake of argument (and very much contrary to reality) that finasteride would fail risk-utility analysis when used in the treatment of BPH, section 6(c) would do nothing to bar recovery for physician negligence (assuming that the manufacturer had fully warned) for using it in such patients. Moreover, I seriously doubt that any reasonable physicians would prescribe Proscar for their balding patients given the ready availability of Propecia, especially when coupled with the hazards associated with pill splitting.

4. Polio Vaccines

Another commentator offered a case study that superficially seemed to pose a more serious challenge to section 6(c). George Conk contrasted the Sabin oral polio vaccine (OPV), which uses an attenuated form of the viral agent, with the Salk injected (inactivated) polio vaccine (IPV), which uses killed virus: according to his description, both forms offer equal efficacy in all classes of recipients (at least after the development of an enhanced-potency version of IPV), but OPV carries a one-in-2.4 million risk of causing vaccine-associated paralytic polio (VAPP) in either recipients or close contacts. Conk added that several immunized from liability because it can be used safely to treat the cosmetic problem of baldness and is cheaper than the lower dosage design.”).

As explained above, reasonable physicians guided solely by “therapeutic” considerations under section 6(c) would not take cost into account. See supra notes 86-89 and accompanying text. Moreover, the availability of Propecia seriously weakens this hypothetical as a critique of section 6(c); it would have worked better to pretend that the FDA had never approved Propecia and focus instead on the recognized off-label use of Proscar (for baldness), which would create a class of patients in whom reasonable health care providers might prescribe a drug that, on Cupp’s version of the record, has no legitimate use for its labeled (BPH) indication. If Propecia did not exist, then the tougher question becomes whether a reasonable physician would prescribe Proscar off-label for a class of “patients” with nothing other than a cosmetic condition. See supra notes 118-19 and accompanying text.

See Nicolas G. Barzoukas, Pill Splitting Raises Issues of Safety and Patent Coverage, NAT’L J., May 22, 2000, at B9; see also Timmis v. Permanente, No. A102962, 2004 WL 2943993, at *1, *9 (Cal. Ct. App. 2004) (rejecting an unfair business practice claim against one HMO’s pill-splitting program); Tara Parker-Pope, Health Insurers Push Pill Splitting as a Way to Save Money on Drugs, WALL ST. J., Nov. 22, 2005, at D1. If nothing else, some fool will think that taking the full five milligram tablet would mean thicker and quicker hair growth notwithstanding the serious side effects reported at that dosage. Moreover, if Proscar did not work for BPH (and physicians preferred using other drugs to treat this condition), a profit-maximizing manufacturer would have withdrawn the drug so that physicians could not cut into its Propecia revenues. Cf. Denise Gellene, Avastin Use in Eyes Irks Genentech, L.A. TIMES, Oct. 17, 2005, at C1 (reporting that ophthalmologists have used a colon cancer drug off-label on more than 1,000 patients with macular degeneration because it costs far less than the same ingredient marketed by the manufacturer for that use, adding that the manufacturer “is in discussions with the [FDA] to modify the Avastin label to state that the drug is not for ophthalmic use”).

See Conk, supra note 19, at 1114-15. Notably, the resulting litigation focused almost entirely on inadequate warnings of this risk. See Fay F. Spence, Note, Alternatives to Manufacturer Liability for Injuries Caused by the Sabin-Type Oral Polio Vaccines, 28 WM. & MARY L. REV. 711, 716-35 (1987); see also Graham v. Am. Cyanamid Co., 350 F.3d 496, 514 (6th Cir. 2003) (rejecting a claim that OPV manufacturer had a duty to inform physicians that IPV represented the preferred choice); Johnson v. Am. Cyanamid Co., 718 P.2d 1318, 1326 (Kan. 1986) (same, though based on the fact that IPV was not commercially available at the relevant time). Conk’s essay actually had...
other industrialized countries rely exclusively on IPV (and that U.S. authorities recommended the same in 1999), though he did note that professional and public health organizations had continued to favor OPV (except in infants with compromised immune systems or who may come in close contact with unvaccinated individuals) for a variety of reasons: expense (IPV costs almost twenty times as much per dose), ease of administration, an advantage in conferring intestinal immunity, and an opportunity for providing second-hand immunity by exposing unvaccinated individuals (in effect, the risk of VAPP may have a silver lining).

In dismissing the intestinal immunity advantage as disputed, Conk failed to recognize that only OPV can prevent infection (IPV keeps an infected person from becoming sick but does not prevent them from becoming carriers and transmitting the illness to others) and that questions about (and research into) the enhanced-potency form of IPV continued well into the mid-1980s. The delay in transitioning from OPV to IPV in this country had nothing to do with stalling by profit-driven manufacturers (after all, officials had licensed the enhanced-potency form of IPV in 1987); instead, it had everything to do with the continued circulation of the wild virus in the Western hemisphere (and the risk of importation into the United States) until the early 1990s. Only after confirming its eradication did the Centers for Disease Control and Prevention (CDC) focus on blood factor concentrates, but, as explained below, see infra note 322, that case study did not as directly raise questions about section 6(c). The Reporters penned a detailed response to Conk’s arguments, but they largely ignored his polio vaccine illustration. See Henderson & Twerski, supra note 19, at 176 n.100 (noting simply that the FDA had not licensed the type of IPV used at the time in European countries); see also Conk, supra note 21, at 781-83 (conceding the same). They all failed to recognize that the FDA had licensed an enhanced-potency IPV product in 1987. See Recommendations of the Immunization Practices Advisory Comm., Poliomyelitis Prevention: Enhanced-Potency Inactivated Poliomyelitis Vaccine—Supplementary Statement, 36 Morbidity & Mortality Wkly. Rep. 795 (1987).


See Conk, supra note 19, at 1116 n.132; see also Graham, 350 F.3d at 499, 514 (summarizing the advantages); Johnson, 718 P.2d at 1321-22 (same); ACIP Recommendations, supra note 160, at 12 tbl.3; Samuel L. Katz, Conquering Polio: From Culture to Vaccine—Salk and Sabin, 351 New Eng. J. Med. 1485, 1487 (2004); David Brown, Global Polio Largely Fading: Stronger Vaccine Is Playing Key Role, Wash. Post, Dec. 26, 2005, at A1 (describing a shift to monovalent OPV). Even researchers from the companies that produce enhanced-potency IPV had to concede that OPV enjoyed an advantage (though they thought only a marginal one) in spreading immunity. See Andrew D. Murdin et al., Inactivated Poliovirus Vaccine: Past and Present Experience, 14 Vaccine 735, 740-41 (1996). See ACIP Recommendations, supra note 160, at 7-8; id. at 13 (explaining that “continued use of OPV induces intestinal immunity among vaccine recipients, thereby enhancing community resistance to transmission of wild virus (should it be reintroduced)”; see also Kearl v. Lederle Labs., 218 Cal. Rptr. 453, 455 n.1 (Ct. App. 1985) (describing a series of efficacy failures with IPV reported in Finland), abrogated by Brown v. Superior Ct., 751 P.2d 470 (Cal. 1988).

(CDC) decide that the slightly safer but in fact somewhat less effective IPV gradually should displace OPV. 164

More so than other medical technologies, the use of childhood vaccines depends heavily on the recommendations of public health officials. Unlike the FDA (which lays things out in labeling and then leaves professionals to make sensible judgments), the CDC actively attempts to influence medical practice in the use of these products. 165 In effect, a vaccine licensed by the FDA but not yet blessed by the CDC might as well not exist. In hindsight, perhaps the CDC acted too slowly in deciding to transition from OPV to IPV in the late 1990s, but the information available at the time did not favor IPV as clearly as Conk has suggested. Would he really have wanted the manufacturer of OPV to withdraw its product from the market in the early 1980s (even before the FDA had licensed a competitor’s enhanced-potency IPV in 1987, and long before the CDC dictated in 1999 that no reasonable health care professional should continue to use OPV except under unusual circumstances)? Alternatively, would he have expected health care professionals to switch from OPV to IPV in 1987 notwithstanding the CDC’s contrary (even if now arguably questionable) recommendations? In fact, even in the wake of the CDC’s revised recommendations, properly labeled OPV should not face design defect claims.

Just for the sake of argument, let us take Conk’s story at face value (and entirely disregard the CDC’s role) but also assume that, during the 1990s, the labeling for OPV accurately disclosed the incredibly small risk of VAPP and that, somewhat implausibly, the labeling for the FDA-approved enhanced-potency IPV revealed absolutely no peculiar risks at all (e.g., injection site reactions). 166 Conk

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164 See ACIP Recommendations, supra note 160, at 2, 5. Thus, starting in 1997, the CDC recommended a gradual (3-5 year) transition to IPV (with OPV used as a booster in the interim). See id. at 2, 9. It also explained, however, that parents should have the choice of using IPV alone. See id. at 12-14.


166 See ACIP Recommendations, supra note 160, at 18-19 (noting sensitivity reactions to IPV). In addition, one would have to imagine away the National Childhood Vaccine Injury Act of 1986 (NCVIA), Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-1 to -34 (2006)), which aimed to discourage the filing of tort claims by, among other things, codifying the comment k defense for covered vaccines (and, with regard to inadequate warning claims, codifying the learned intermediary doctrine coupled with an FDA compliance defense), see 42 U.S.C. § 300aa-22(b)&(c); cf. Am. Home Prods. Corp. v. Ferrari, 668 S.E.2d 236, 238-42 (Ga. 2008) (interpreting this provision as incorporating a case-by-case rather than blanket version of comment k, and allowing plaintiffs to pursue design defect claims against manufacturers of childhood vaccines for using the preservative thimerosal). See generally Lainie Rutkow et al., Balancing Consumer and Industry Interests in Public Health: The National Vaccine Injury Compensation Program and Its Influence During the Last Two Decades, 111 PENN ST. L. REV. 681 (2007). If, instead, one focused on the early 1980s, before the NCVIA (and while other countries used enhanced-potency IPV but it had not yet reached the United States), it would suffice to point out that IPV remained only a hypothetical RAD (not yet licensed domestically and still subject to open questions about effectiveness). For a parallel trajectory involving the design of the whole-cell pertussis vaccine, with plaintiffs pointing to fractionated and acellular versions used overseas but not yet licensed in this country, see supra note 95.
argued that section 6(c) inappropriately would have protected OPV’s manufacturer from design defect liability, while the risk-utility balancing of section 2(b) would lead to a conclusion that IPV represented a safer alternative design. Unlike section 6(c), however, section 2(b) allows considerations of non-therapeutic utilities such as cost and convenience, so it may not have treated IPV as a RAD for OPV.

As it happens, courts applying comment k on a case-by-case basis (which meant engaging in a form of risk-utility balancing) uniformly rejected design defect claims against the manufacturer of OPV during all relevant time periods. In fact, as Conk belatedly conceded, OPV continues to have a recognized but narrow use: “emergency mass administration to control polio outbreaks.” Thus, even with an FDA-licensed and CDC-endorsed safer alternative available, reasonable health care providers clearly would continue to select OPV for some classes of patients, and section 6(c) appropriately would foreclose a design defect claim brought by a patient injured by its use, whether or not such use had been appropriate in that particular case.

Undeterred, Conk finally revealed the premise underlying his opposition to the standard announced by the Products Liability Restatement:

The fact that emergency circumstances can be defined in which the more dangerous drug might be indicated, despite risks, does not save the sole manufacturer of polio vaccine from liability to the injured for failure to adopt the safer design in the ordinary course of mandatory inoculation. Imposition of liability for failure to offer the alternative safer design in such circumstances

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167 See Conk, supra note 19, at 1114 (“Section 6(c) would not permit, for example, a challenge to a live-virus vaccine that unnecessarily caused the disease it was designed to prevent, even if there had long been an equally effective killed-virus vaccine that does not cause infection.”); id. at 1115-16.

168 See supra notes 80-83 and accompanying text. Indeed, if these get delivered in mass immunization settings, the learned intermediary rule may not apply, which would require warnings directed to recipients. See infra note 216 and accompanying text. It also makes one wonder whether the intermediary-linked design defect standard then should fall away. See infra notes 246-50 and accompanying text.


170 Courts rejected design defect claims (1) before 1968, when OPV competed against an early version of IPV (which required three separate injections followed by booster shots), (2) between 1968 and 1987, when it lacked any commercial competition (though limited quantities of IPV were imported, see Philip M. Boffey, Polio: Salk Challenges Safety of Sabin’s Live-Virus Vaccine, 196 SCIENCE 35 (1977)), and (3) between 1987 and 2000, when it co-existed in the United States with the enhanced-potency IPV (but continued to have the CDC’s endorsement), see Spence, supra note 159, at 723 & n.81; see also id. at 715 n.32 (quoting from the Orimune’s package insert and consent forms used in the mid-1980s, which included references to the availability of IPV as an alternative).

does not bar production of the challenged product—which may have residual uses. A finding that a design is defective—for the foreseeable conditions of product use—does not make the challenged design contraband. The factual finding that the product design is defective for the conditions for which it is marketed is simply a legal predicate for the judgment that there is a fair basis on which to impose the obligation to compensate the avoidably injured.172

Putting aside the mixing of entirely different time periods and counterfactual assumptions about inappropriate marketing (or the limited legitimate uses of OPV),173 the fact that only a “sole manufacturer” served the U.S. market had at least something to do with other sellers’ legitimate fears about the imposition of liability under just such circumstances.174 If OPV’s manufacturer faces design defect liability,

172 Conk, supra note 21, at 782-83. Like other commentators who find nothing distinctive about prescription products, see supra note 47, he appears ready to impose something approaching absolute liability. Section 6(c) does well to ensure that nothing of the sort will happen. His original essay concluded by summarizing and disputing the half dozen rationales typically offered in support of section 6(c). See Conk, supra note 19, at 1127-32. For instance, Conk argued that “[t]he designer should no more be freed from its duty to market safe products by the existence of an intermediary physician than a manufacturer of industrial equipment should be relieved of the duty to include safety devices merely because employers are obligated by law to provide a safe workplace.” Id. at 1128. That parallel may, however, cut the other way. See, e.g., Searangella v. Thomas Built Buses, Inc., 717 N.E.2d 679, 683-84 (N.Y. 1999); see also infra note 317 (discussing the “sophisticated purchaser” defense).

173 Conk made similar mistakes in suggesting elsewhere that the manufacturer of the sole vaccine against smallpox (Dryvax), which ceased production in the 1980s, might face design defect claims insofar as hypothetical RADs existed for this old—and, until remaining stockpiles were hurriedly pressed back into limited use in 2002, no longer used—vaccine, including a purportedly safer version. See George W. Conk, Reactions and Overreactions: Smallpox Vaccination, Complications, and Compensation, 14 FORDHAM ENVTL. L.J. 439, 459-61 & n.55 (2003). It took almost five years for a different company to secure FDA approval of a new vaccine, though one that differs little from Dryvax except for its method of production. See John Heilprin, FDA Approves New, Easily Produced Smallpox Vaccine, ORLANDO SENT., Sept. 2, 2007, at A9; New Smallpox Vaccine to Be Reviewed by FDA, STAR-LEDGER (NEWARK), May 20, 2007, at 23; Original Smallpox Vaccine Shelved as VaxGen’s Version, STAR-LEDGER (NEWARK), Mar. 1, 2008, at 6. A genuinely safer version remains on the drawing board. See Renae Merle, Deal for Smallpox Vaccine Could Jump-Start BioShield, WASH. POST, June 7, 2007, at D1; see also Justin Gillis, Safer Smallpox Vaccines in Works: U.S. Preparing for Potential Bioterror Attack, WASH. POST, Nov. 14, 2005, at A1 (reporting that, in contrast to VaxGen’s less well studied but potentially more effective version, a modified version developed in Germany (licensed by Acambis and Bavarian Nordic) “essentially trades potency for safety”). Ultimately, VaxGen’s smallpox project stalled, while its anthrax vaccine efforts collapsed entirely. See Renae Merle, Anthrax Vaccine Contract Voided, Thwarting Administration, WASH. POST, Dec. 20, 2006, at A1. The more interesting question with Dryvax arose from earlier plans to extend (dilate) the limited existing stockpiles. See Sharon E. Frey et al., Clinical Responses to Undiluted and Diluted Smallpox Vaccine, 346 NEW ENG. J. MED. 1265 (2002).

174 See Noah, supra note 62, at 743 (discussing judicial recognition of price hikes and supply shortages that had coincided with dramatic increases in products liability litigation involving childhood vaccines); id. at 759-61, 763-64 (discussing the relationship between threatened tort liability and the removal of therapeutic products from the market); see also id. at 761-62, 764 (explaining that legislative reforms also have attempted to respond to such concerns); Noah, supra note 48, at 2159 (“Critics of the regulatory compliance defense respond that a tort judgment does not dictate any alteration of primary conduct, but in the next breath they emphasize the need to retain the threat of liability to serve a deterrent function . . . . They can’t have it both ways.”). From 1977 to 2000, only Lederle marketed OPV (as Orimune®); after 2000, no company in the U.S. produced a trivalent OPV product for the domestic market.
then it can continue producing the product (so long as it pays for any injuries that result), but why would it choose to do so (and, when it leaves the market, what will happen if polio makes a comeback)? In what sense does a manufacturer that continues to market OPV after 1999 (and properly labeled to indicate its use only in case of an emergency) act unreasonably—must it also offer IPV, or does it suffice that a pair of competitors had brought that allegedly superior product to the market more than a decade earlier?

5. Isotretinoin

In an article published two years later, Conk trotted out Accutane® (isotretinoin) as another example, though this one designed to illustrate the value of engaging in risk-utility balancing even in the absence of an FDA-approved RAD.\(^{175}\) In retrospect, this illustration also backfired, nicely demonstrating the pitfalls of his approach to judging design defect claims. First, Conk argued that the manufacturer’s method-of-use patent (perhaps one of the weakest types of patents\(^{176}\)) gave it a monopoly that discouraged the introduction of safer alternatives.\(^{177}\) Although it would keep others from selling isotretinoin tablets of particular doses for the treatment of acne, it in no way prevented the

\(^{175}\) See Conk, supra note 21, at 761-71. As he explained in closing the discussion:

The Accutane example demonstrates that the institutional competence problems with the section 2(b) alternative safer design test . . . are not so formidable as they might appear at first blush. . . . [S]mall changes yielded significant safety gains but were neglected until [the] approaching loss of a broad patent monopoly threatened the manufacturer-designer with loss of market control.


\(^{177}\) See Conk, supra note 21, at 762-63 (“Such a patent-constrained market environment can create a type of market failure that impedes the availability of alternative, safer compositions or methods of manufacture, or alternative safer dosing methods.”). The method-of-use patent for isotretinoin would not have limited “safer compositions or methods of manufacture” as he claimed because those represent different types of patents, and it would not even prevent a “safer dosing method” that fell outside of the bounds of the range of doses disclosed in the patent. Cf. Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1249-54 (Fed. Cir. 2000) (holding that a generic drug manufacturer’s micronized version would not infringe patents for nifedipine crystals of a defined specific surface area). Indeed, the decision in the Prozac case that he quotes at length, see Conk, supra note 21, at 758-59 n.87, invalidated a method-of-use patent, see Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 969-72 (Fed. Cir. 2001); see also Merck & Co. v. Teva Pharm. USA, Inc., 395 F.3d 1364, 1372-77 (Fed. Cir. 2005) (invalidating a method-of-use patent covering the once-weekly formulation of Fosamax® on grounds of obviousness); Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1351-53, 1366 (Fed. Cir. 2003) (rejecting a claim by the manufacturer of Neurontin® (Gabapentin), which was labeled only for treating epilepsy but widely used in patients with neurodegenerative diseases, that approval of a generic version would infringe (or induce infringement of) its method patent covering such off-label uses).
development of other vitamin A derivatives for such uses (or of isotretinoin for entirely other uses). He cited one patent covering short-course treatments for less serious forms of acne, but this would not have involved any alteration in the dosage formulation (only revisions in the drug’s labeling), and nothing prevented researchers from publicizing such an off-label use. Conk suggested that Roche should have had an obligation to look into this method and revise its instructions accordingly, but in the next breath he correctly recognized that this would have provided a basis for liability under section 6(d). So why on earth does he keep complaining about the unduly narrow scope of design defect claims under section 6(c)?

Conk also emphasized that, shortly before expiration of its patent, Roche filed an application for FDA approval of a new and

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178 See Ortho Pharm. Corp. v. Cosprophar, Inc., 828 F. Supp. 1114, 1117 (S.D.N.Y. 1993) (summarizing, in the course of resolving a Lanham Act case, the history behind tretinoin (Retin-A®), an FDA-approved retinoid-based topical acne drug sold by a subsidiary of Johnson & Johnson, which began developing a cream version (Renova®) for use against wrinkles after published research confirmed the efficacy of this off-label use), aff’d, 32 F.3d 690 (2d Cir. 1994); Lawrence K. Altman, Medical Dilemma: Necessary Drugs with Intolerable Dangers, N.Y. TIMES, May 3, 1988, at C3 (reporting that Accutane “was the first to be licensed in what is expected to be a series of drugs derived from Vitamin A, called retinoids”); Gina Kolata, A Second Skin Drug Is Called Major Threat for Birth Defects, N.Y. TIMES, May 1, 1988, § 1, at 1 (“Drug manufacturers have created 1,500 compounds that are closely related to Accutane, . . . and researchers are testing some to see if they can cure skin diseases, treat a variety of cancers or prevent cancer of the breast, lung or colon.”).

179 See Conk, supra note 21, at 763-64 & n.108. In arguing that Roche failed to investigate this potentially safer method of use, Conk misunderstood the difference between Accutane’s indication (severe recalcitrant nodular acne) and the researcher’s method-of-use patent (for “a patient having mild cystic acne or with scarring non-cystic acne”). Even after the expiration of Roche’s method patent, the researcher could not market such a product without going through the FDA approval process for this new indication and dosing regimen.

180 For more background on the drug’s regulatory milestones, including a history of its many labeling revisions, see FDA, Isotretinoin (Marketed as Accutane) Capsule Information, http://www.fda.gov/cder/drug/infopage/accutane/default.htm (last visited June 19, 2008). In the last twenty-five years, the agency has imposed increasingly stringent controls on access to this drug. See Robert S. Stern, When a Uniquely Effective Drug Is Teratogenic: The Case of Isotretinoin, 320 NEW ENG. J. MED. 1007, 1008 (1989); Gardiner Harris, F.D.A. Imposes Tougher Rules for Acne Drug, N.Y. TIMES, Aug. 13, 2005, at A1 (“The new program is the latest and by far most drastic of more than 40 efforts by the agency in the last 22 years to reduce harm from Accutane . . . while allowing its continued use.”); see also Ami E. Doshi, Comment, The Cost of Clear Skin: Balancing the Social and Safety Costs of iPLEDGE with the Efficacy of Accutane (Isotretinoin), 37 SETON HALL L. REV. 625, 659-60 (2007) (concluding that the FDA should withdraw approval).

181 See, e.g., Boaz Amichai et al., Low-dose Isotretinoin in the Treatment of Acne Vulgaris, 54 J. AM. ACAD. DERMATOLOGY 644 (2006). Another commentator provided a better apparent illustration of Conk’s point, suggesting that Amgen had shelved a patent on a protein binding factor that would have dramatically slowed the excretion (and therefore the dosages needed) of its blockbuster anemia drug Epogen® (recombinant erythropoietin). See Kurt M. Saunders, Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression, 15 HARV. J.L. & TECH. 389, 395-96 (2002). To support this allegation, he relied entirely on an e-mail message later posted on a blog. See id. at 395 n.31. The only published information about this episode that I could find suggested that government officials failed to take this conspiracy theory the least bit seriously. See Consumer Advocates Say Company May Be Suppressing Research at University-Run Lab, CHRON. HIGHER EDUC., May 1, 1998, at A49 (describing a letter from Ralph Nader and an associate requesting an investigation by the Federal Trade Commission).

182 See Conk, supra note 21, at 764.
improved (micronized) formulation of isotretinoin, and he cited the
favorable internal agency reviews prepared in advance of an advisory
committee meeting held in 2000. He expressed outrage that section
6(c) would allow the manufacturer to get away with “an egregious case
of warehousing an alternative safer design for deployment when the
patent term expires.” Sounding like the good plaintiff’s lawyer that he
is, Conk continued:

A jury might reasonably conclude that the manufacturer’s timetable for
development of the new, low-dose, more controllable product was dictated too
much by market considerations and too little by concern for the safety and
health of those who consumed the product, those who were aborted, or those
born with grave deformities that might have been avoided if the dosing pattern
had been lowered and the new formulation had been deployed earlier.

A clarion call for punitive damages if I ever heard one! Except for one
minor problem: in spite of the endorsement of the internal reviewers, and
notwithstanding the subsequent publication of the research that indicated
limited advantages to the micronized version (though not at all with
respect to the serious risk of birth defects), the FDA never approved
the new formulation. Moreover, even if it had done so, this would not
have prevented agency approval of generic versions of the original
formulation, and sponsors willing to conduct new clinical trials could

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183 See id. at 765-66, 767-69.
184 Id. at 769; see also id. (“[T]he social cost of the tardy development of the new product
provides the basis for a finding of liability in favor of the deformed children of mothers who took
Accutane (the old formula) when Roche could have brought the new formulation to market earlier
instead of waiting for the end of the old product’s patent monopoly period.”).
185 Id. at 770; see also id. (adding that other plaintiffs probably will not have such
damning evidence to use in bringing their design defect claims).
186 See John S. Strauss et al., A Randomized Trial of the Efficacy of a New Micronized
Formulation Versus a Standard Formulation of Isotretinoin in Patients with Severe Recalcitrant
Nodular Acne, 45 J. AM. ACAD. DERMATOLOGY 187, 194-95 (2001); John S. Strauss et al., Safety of
a New Micronized Formulation of Isotretinoin in Patients with Severe Recalcitrant Nodular Acne: A
Randomized Trial Comparing Micronized Isotretinoin with Standard Isotretinoin, 45 J. AM. ACAD.
DERMATOLOGY 196 (2001); id. at 199 & tbl.2 (indicating that the researchers removed one subject
who had become pregnant while taking the micronized version and then aborted). Indeed, to the
extent that patients might find the micronized version more tolerable (because less likely to cause
bothersome side effects such as dry eyes), see id. at 207, and because nothing suggested a reduced
teratogenic risk at the lower (but equally bioavailable) dosage, one might have seen an increase in
the overall number of birth defects had the FDA approved the newer version.
187 See Michelle Meadows, The Power of Accutane: The Benefits and Risks of a
Breakthrough Acne Drug, FDA CONSUMER, Mar.-Apr. 2001, at 18 (discussing the limited product
changes that came out of the September 2000 advisory committee meeting); see also John S. Strauss
et al., Guidelines of Care for Acne Vulgaris Management, 56 J. AM. ACAD. DERMATOLOGY 651, 656
(2007) (discussing the latest views about the use of isotretinoin, but making no mention of a
micronized version apart from citing his pair of co-authored articles from 2001). For the current
version of Accutane’s package insert, see http://www.rocheusa.com/products/accutane/pi.pdf (last
visited Aug. 12, 2008).
188 In fact, generic versions of the drug became available in 2002. See Gideon Koren et
al., Generic Isotretinoin: A New Risk for Unborn Children, 170 CAN. MED. ASS’N J. 1567 (2004);
see also Margaret A. Honein et al., Can We Ensure the Safe Use of Known Human Teratogens?:
(explaining that each generic version must use a parallel risk-management program).
have secured approval of other variations of the original formulation of isotretinoin. Thus, Conk unwittingly again demonstrated the wisdom of the Reporters’ refusal to allow plaintiffs to rely on hypothetical RADs for prescription products.

D. Designing Access Restrictions

Critics have objected that section 6(c) conflicts with the well-accepted proposition that product manufacturers should not get to warn their way out of a duty to adopt reasonable alternative designs. Apart from the previously discussed difficulties with redesigning drugs, this complaint fails to appreciate the centrality of labeling in helping to define a pharmaceutical product’s niche. Moreover, these issues may go beyond labeling to include choices about how and to whom a seller markets a drug.

For instance, with teratogens such as thalidomide and isotretinoin, plaintiffs might pursue negligent marketing claims on the theory that a prescription drug manufacturer should have further applicants would not, however, have gotten approval if the FDA had withdrawn the NDA for the pioneer’s original formulation on safety grounds. See 21 C.F.R. § 216 (2008) (listing such withdrawals). I found only a single instance where, at the license holder’s request, the agency had done so. See FDA, Notice, Hoffmann-La Roche, Inc.: Withdrawal of Approval of a New Drug Application, 68 Fed. Reg. 53,384, 53,385 (Sept. 10, 2003) (withdrawing Tegison® (etretinate) four years after its sponsor had begun marketing a safer version).

189 See, e.g., Cupp, supra note 44, at 253-54. As the Reporters subsequently explained:

[T]he manufacturer’s first obligation is reasonable design; warnings logically come after, in order to deal with any remaining pockets of hidden risk that cannot reasonably be designed out of the product. With respect to prescription products, this logical sequence is necessarily reversed. Exposure to design-based liability comes into play only as a measure of last resort . . . .

Henderson & Twerski, supra note 19, at 178-79.

190 See Joe Collier & Ike Iheanacho, The Pharmaceutical Industry as an Informant, 360 Lancet 1405, 1405 (2002) (“Although the primary function of drug companies is to develop and market drugs, these companies spend more time and resources generating, gathering, and disseminating information.”); Rebecca S. Eisenberg, The Problem of New Uses, 5 Yale J. Health POL’Y L. & ETHICS 717, 717-18 (2005) (“Drugs are information-rich chemicals that in many respects are more akin to other information products (such as databases) than they are to other chemicals . . . . Creating new molecules has become relatively cheap, but determining which molecules are safe and effective for which therapeutic purposes has remained stubbornly expensive . . . .”); see also Lars Noah, Authors, Publishers, and Products Liability: Remedies for Defective Information in Books, 77 OR. L. REV. 1195, 1212 (1998) (“[D]rug companies are actually engaged in the business of producing and selling information for use by patients and their physicians . . . . [T]he product defectiveness inquiry depends entirely on the information accompanying the product, such as the indications and contraindications for use.”); id. (“The conceptual separation between the product itself and information contained within the product, so evident in cases declining to hold authors and publishers strictly liable, is absent in the prescription drug liability context.”); cf. Feldman v. Lederle Labs., 479 A.2d 374, 385 (N.J. 1984) (noting that “an inadequate warning could constitute a design defect”).

191 Comment k to section 402A had referred separately to proper marketing and proper warnings as prerequisites (along with proper preparation) for exempting sellers of unavoidably unsafe products from strict liability claims. See Swayze v. McNeil Labs., Inc., 807 F.2d 464, 468 (5th Cir. 1987).
restricted distribution. Such claims would represent a hybrid between more traditional defects in design and labeling, challenging a manufacturer’s choice about the appropriate channels for distributing potentially hazardous goods, such as items not appropriate for use by youngsters, in a way that resembles novel (and largely unsuccessful) theories asserted against gun sellers.

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192 See Lars Noah, Too High a Price for Some Drugs?: The FDA Burdens Reproductive Choice, 44 SAN DIEGO L. REV. 231, 236-37 & n.23, 256 & n.100 (2007) (noting that the manufacturer of Accutane has faced claims that it should have taken steps beyond the issuance of stern warnings to both doctors and patients to ensure that women would not become pregnant while using this teratogenic drug, and adding that these lawsuits have failed on other grounds); cf. id. at 239 (wondering whether the FDA could “demand that the manufacturer sell a bundled product (for example, a single pill that combined a teratogen with a hormonal contraceptive?”); Lars Noah, Ambivalent Commitments to Federalism in Controlling the Practice of Medicine, 53 U. KAN. L. REV. 149, 188-91 (2004) (discussing a variety of distribution restrictions on prescription drugs considered by regulatory officials). Congress recently granted the FDA express authority to restrict the distribution of prescription drugs to specially trained physicians. See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901(b), 121 Stat. 823, 930 (to be codified at 21 U.S.C. § 355-1(f)(3)(A)).

193 Some negligent marketing claims relate primarily to issues of product design, while others focus on the nature of the information communicated to users (i.e., advertising), but a third subset of negligent marketing claims—that relate to distribution choices—do not fit as neatly into an existing liability box. See Richard C. Ausness, Tort Liability for the Sale of Non-Defective Products: An Analysis and Critique of the Concept of Negligent Marketing, 53 S.C. L. REV. 907, 909-10, 915-16, 944-46 (2002); see also id. at 939 (“Just a few years ago, it appeared that negligent marketing was about to become a powerful tool in products liability litigation, particularly where the products involved were not ‘defective’ in the traditional sense.”); id. at 954 (“[A] manufacturer’s failure to actively monitor retail sales or to supervise the conduct of distributors and retail sellers seems more like nonfeasance than misfeasance.”); id. at 965 (concluding for a variety of reasons that courts should decline to recognize such claims). Although many of the broader critiques of this theory have more force, the distinctive treatment of medical technologies for purposes of applying other liability rules may justify some willingness to entertain negligent marketing claims. Ausness also mentioned Rx drugs, though focusing primarily on OxyContin. See id. at 915-17, 945 & n.349; see also id. at 916 (making a passing reference to the diet drug combination fen-phen). OxyContin (like the handgun litigation) relates more to criminal misuse, see infra note 203, while fen-phen, which relates to problems of inappropriate off-label prescribing, better matches the type of negligent marketing claim that strikes me as worth considering.

194 See, e.g., Moning v. Alfono, 254 N.W.2d 759, 762 (Mich. 1977) (holding that a jury should resolve negligence claims against the manufacturer, wholesaler, and retailer of slingshots marketed directly to children); id. at 771 (“The issue in the instant case is not whether slingshots should be manufactured, but the narrower question of whether marketing slingshots directly to children creates an unreasonable risk of harm.”); cf. First Nat’l Bank of Dwight v. Regent Sports Corp., 803 F.2d 1431, 1435 (7th Cir. 1986) (rejecting failure-to-warn and negligent marketing claims against the manufacturer of metal-tipped lawn darts sold as appropriate for adults only, but allowing claims for violations of federal regulations prohibiting sales of such products through toy stores and similar retail outlets).

195 See, e.g., Merrill v. Navegar, Inc., 28 P.3d 116, 119 (Cal. 2001); Chicago v. Beretta U.S.A. Corp., 821 N.E.2d 1099, 1148 (Ill. 2004); Hamilton v. Beretta U.S.A. Corp., 750 N.E.2d 1055, 1059 (N.Y. 2001); see also Jean Macchiarelli Eggen & John G. Culhane, Gun Torts: Defining a Cause of Action for Victims in Suits Against Gun Manufacturers, 81 N.C. L. REV. 115, 204-09 (2002). But see Ileto v. Glock Inc., 349 F.3d 1191, 1201-09 (9th Cir. 2003) (allowing a negligent marketing claim to proceed); City of Cincinnati v. Beretta U.S.A. Corp., 766 N.E.2d 1136, 1141 (Ohio 2002) (allowing a municipality to pursue such claims). Some of these lawsuits alleged that manufacturers of certain types of weapons or ammunition should not have sold these products to civilians, instead limiting their distribution to law-enforcement professionals and the military. See, e.g., McCarthy v. Olin Corp., 119 F.3d 148, 152, 156-57 (2d Cir. 1997) (noting, in the course of rejecting such a claim, that the manufacturer of Black Talon® bullets subsequently limited sales to
Although the Products Liability Restatement finds a bright line distinguishing prescription and nonprescription products, which it then uses to justify different rules for the former category (because of the power of differential marketing), pharmaceuticals actually fall along a continuum. For instance, stricter prescription requirements apply to controlled substances and certain teratogens (and the most restrictive access restrictions apply to investigational drugs dispensed to subjects enrolled in clinical trials). Although most people use prescription drugs on an out-patient basis, physicians order the administration of some medications in hospitals and other controlled settings. Conversely, the relatively recent phenomenon of advertising prescription drugs directly to consumers, as well as the advent of Internet prescribing and dispensing, may have made these products more similar to over-the-counter (OTC) drugs.

A few nonprescription drugs, in contrast, now require securing permission from a pharmacist and plaintiffs might argue that other OTC pharmaceuticals also should move “behind-the-counter” (or even to Rx status), but the Restatement reserves the professionals; see id. at 163 (Calabresi, J., dissenting) (“Selling tanks to the armed forces is fine; selling them to the general public is, I would think, clearly negligent.”).

See Henderson & Twerski, supra note 19, at 156, 170-73, 178-79; id. at 168-69 (“[S]uch differentiation in design defect standards based on users is not possible for nonprescription products, which are available to everyone on the open market.”).

See, e.g., Press Release, FDA Approves Entereg to Help Restore Bowel Function Following Surgery, http://www.fda.gov/bbs/topics/NEWS/2008/NEW01838.html (May 20, 2008) (explaining that, in order to minimize risks relative to benefits, this drug will be restricted to inpatient use, only at specially certified hospitals, and patients may receive no more than fifteen doses).

See Chester Chuang, Note, Is There a Doctor in the House? Using Failure-to-Warn Liability to Enhance the Safety of Online Prescribing, 75 N.Y.U. L. REV. 1452, 1483 & n.131 (2000) (imagining the emergence of a new class of “quasi-prescription” drugs, and suggesting that Rx antihistamines might qualify); id. at 1453 (“In an online world where the physician is conspicuously absent, or at best virtual, the learned intermediary doctrine breaks down . . . .”); see also Henderson & Twerski, supra note 19, at 173 n.91 (conceding that, if physicians routinely acquiesced in patient demands for heavily advertised products, “[t]his breakdown of the learned intermediary as a screening device would make marketing of prescription drugs not substantially different from that of nonprescription products”); infra notes 246-50. For more about direct-to-consumer advertising, see infra Part III.B.


See Lars Noah, Treat Yourself: Is Self-Medication the Prescription for What Ails American Health Care?, 19 HARV. J.L. & TECH. 359, 382-83 (2006); id. at 381 (“If an OTC drug with otherwise unassailable labeling and design causes an injury, then the victim might argue that the product should have been made available only under professional medical supervision and never sold directly to consumers.”); see also Howard Latin, “Good” Warnings, Bad Products, and Cognitive Limitations, 41 UCLA L. REV. 1193, 1271 (1994) (“Why should the presence of a ‘good’ warning, no matter how explicit, prevent courts from considering the value of alternative marketing
Some commentators have suggested that drug manufacturers have a duty to cut off supplies to Internet companies that engage in irresponsible online prescribing and dispensing. More controversially, if general practitioners engaged in patterns of dangerous overprescribing, then a plaintiff might claim that the drug manufacturer had a duty to limit access to only some subset of responsible physicians (perhaps only certain specialists or physicians who have registered with the manufacturer after attesting to their knowledge of the risks involved in their strategies in light of the common tendency of people to overuse over-the-counter drugs that provide relief from chronic ailments?).

201. Cf. supra note 15 (explaining that “medical foods” require a prescription). Separately, now that OTC drugs may offer some genuine clinical utility accompanied by non-trivial risks, why not treat these products as “unavoidably unsafe”? See Thomas M. Moore & Scott L. Hengesbach, Comment k: A Prescription for the Over-the-Counter Drug Industry, 22 PAC. L.J. 43, 55 n.57, 61-86 (1990) (arguing that sellers of OTC drugs should receive the same exemption from strict liability claims granted to sellers of prescription drugs); Daniel W. Whitney, Product Liability Issues for the Expanding OTC Drug Category, 48 FOOD & DRUG L.J. 321, 324 (1993) (“It is difficult to fathom how a Rx drug would lose its social utility merely because it is being made available OTC.”). After all, the movement of a product from prescription to nonprescription status does not alter its intrinsic character so much as the means of access and the method of marketing. Cf. Bober v. Glaxo Wellcome PLC, 246 F.3d 934, 939-40, 942 (7th Cir. 2001) (rejecting a consumer fraud claim against the manufacturer of Zantac® for suggesting that two doses of the 75 mg OTC version could not be substituted for the prescribed 150 mg version). The unpredictability of drug response would apply whether or not access requires a prescription, and OTC drugs encounter no less regulatory scrutiny than Rx drugs: indeed, for those that have gotten switched, they have undergone far closer FDA review. See Noah, supra note 200, at 365-66. In some instances, physicians may even “prescribe” OTC products. See infra note 249.

202. See Richard C. Ausness, Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?, 37 WAKE FOREST L. REV. 97, 136 (2002) (forecasting that negligent marketing claims will be brought against manufacturers of prescription drugs when patients suffer injuries as a result of dispensing by unscrupulous Internet pharmacies); Chuang, supra note 198, at 1480-88; cf. Stephanie Feldman Aleong, Green Medicine: Using Lessons from Tort Law and Environmental Law to Hold Pharmaceutical Manufacturers and Authorized Distributors Liable for Injuries Caused by Counterfeit Drugs, 69 U. PITT. L. REV. 245, 265-72 (2007) (suggesting an entirely inapt nondelegable duty theory to hold manufacturers liable for hazardous counterfeiting). Serious practical difficulties would, however, complicate any such effort. See Chuang, supra note 198, at 1460-61 (noting that Pfizer had sought assistance from the Federal Trade Commission to combat online prescribing of Viagra); cf. Ceci Connolly, Pfizer Cats Supplies to Canadian Drugstores, WASH. POST, Feb. 19, 2004, at A10. The FDA once conditioned drug approval on restricted distribution through a single pharmacy. See Aaron Zitmer, Date-Rape Drug OK’d to Treat Sleep Disorder, L.A. TIMES, July 18, 2002, at A12 (GHB); cf. Anna Wilde Mathews & Leila Abboud, FDA Approves Generic OxyContin, WALL ST. J., Mar. 24, 2004, at A3 (“[T]he FDA has never limited any opioid to certain pharmacies, and agency officials say they don’t have the authority to block certain physicians from prescribing a drug.”).

203. Courts generally have rejected negligent marketing claims involving the opioid analgesic OxyContin. See, e.g., Labzda v. Purdue Pharma L.P., 292 F. Supp. 2d 1346, 1355 (S.D. Fla. 2003); see also Philip J. Winerger, Note, Pharmaceutical Overpromotion Liability: The Legal Battle over Rural Prescription Drug Abuse, 93 KY. L.J. 269, 281-94 (2004-2005) (evaluating the prospects for such claims). Imagine, however, that the manufacturer had sold OxyContin without the required legend for Schedule II controlled substances (or, worse yet, without even the Rx legend, which would make it available on OTC shelves alongside analgesics such as acetaminophen and ibuprofen); I assume that—whether called a design defect, informational defect, or negligent marketing claim—such a case would fall under the defectiveness per se rubric. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 4 & cmt. d (1998).
in the use of a product). Such a theory might morph into a design defect claim (viewing the drug product as a package or bundle that includes choices about how patients may secure access to it), which in turn would cast some doubt on the narrow conception of drug designs reflected in section 6(c).

III. INFORMATIONAL DEFECTS

This Part considers alleged defects in the information that accompanies prescription products, especially those advertised directly to consumers. Under the “learned intermediary” rule, manufacturers satisfied their duty to warn of the hazards associated with Rx drugs by communicating risk information to physicians. Accordingly, section 6(d) of the Products Liability Restatement provides as follows:

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204 See Swayze v. McNeil Labs., Inc., 807 F.2d 464, 477 (5th Cir. 1987) (Goldberg, J., dissenting) (“McNeil could have prevented liability by removing, selectively, the [narcotic anesthesia] drug from hospitals that could not ensure that qualified doctors would prescribe [it, as opposed to certified nurse anesthetists who lacked prescribing privileges].”); see also Erik Eckholm & Olga Pierce, Methadone Rises as a Painkiller with Big Risks, N.Y. TIMES, Aug. 17, 2008, at A1 (“Methadone, once used mainly in addiction treatment centers to replace heroin, is today being given out by family doctors, osteopaths and nurse practitioners for throbbing backs . . . and a host of other severe pains. . . . [The FDA is now considering requiring doctors to take special classes on prescribing narcotics.”); cf. In re TMJ Implants Prods. Liab. Litig., 97 F.3d 1050, 1060 (8th Cir. 1996) (Heaney, J., dissenting) (suggesting that the manufacturer of Teflon should have ceased supplying this raw material to a medical device company because it knew of dangers associated with this application); Hunnings v. Texaco, Inc., 29 F.3d 1480, 1485-86 (11th Cir. 1994) (holding that a negligence claim could proceed against the supplier of mineral spirits where it knew that a retailer packaged the chemical in used milk jugs and sold the product without warnings); Mason v. Texaco Inc., 862 F.2d 242, 246 (10th Cir. 1988) (explaining that a “bulk seller [has] the obligation to sell only to knowledgeable and responsible distributors”).

205 See, e.g., Carl Salzman, Mandatory Monitoring for Side Effects: The “Bundling” of Clozapine, 323 NEW ENG. J. MED. 827 (1990) (describing a controversial (and short-lived) system of restricted distribution adopted by the manufacturer of the new antipsychotic Clozaril® (partly in response to liability fears) that included weekly blood testing as a prerequisite for dispensing the drug to schizophrenic patients in order to guard against fatalities caused by agranulocytosis, a side effect reported during clinical trials in less than 2% of subjects); see also Noah, supra note 190, at 1214 (discussing other contexts that involve product bundling). When Celgene created its complex risk management program (S.T.E.P.S.) for Thalomid to guard against the risk of birth defects, it secured a patent on it (and, when Hoffmann-LaRoche had to create a similar program for Accutane, it purchased a license from Celgene). See Doshi, supra note 180, at 641 n.113.

206 See Margaret Gilhooley, When Drugs Are Safe for Some but Not Others: The FDA Experience and Alternatives for Products Liability, 36 HOUS. L. REV. 927, 945-47 (1999); id. at 946 (“The best case for applying a distribution limit, if products liability law were to be extended to recognize a new type of defect, relates to misuse of a drug that poses grave risks not only to the immediate users, but also to the wider public.”). With little explanation, however, this commentator dismissed the possibility:

Limiting the distribution of drugs, however, is too novel to be an appropriate basis for a finding of products liability. It is not clear, for example, how such a responsibility fits into the structure of the Restatement. A limit on distribution goes beyond being a warning, but unlike the typical design defect, it does not relate to a change in the formulation or dose of the drug.

Id. at 945; see also id. at 946-49 (favoring, instead, patient-directed labeling to serve as a counterweight to inappropriate prescribing by physicians).

207 See infra Part III.A.
A prescription drug . . . is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.  

When set alongside the blackletter formulation for design defects, which asked only whether a fully-informed health care professional would prescribe a product to any class of patients, the second clause of this provision imagines a different type of decisionmaking process when suggesting that manufacturers might have a duty to supply information to patients as well. Perhaps this language reflects an understanding of the physician’s primary role as related to product selection and only secondarily concerned with communicating risk information. The scope of section 6(d)(2)’s exception to the learned intermediary rule remains unclear.

The Reporters initially tried to recognize an exception in situations where manufacturers had engaged in direct-to-consumer advertising (DTCA), which would have greatly expanded the duty of pharmaceutical manufacturers to warn patients. The final draft did not

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208 Restatement (Third) of Torts: Prods. Liab. § 6(d) (1998) (omitting parallel reference to “medical device”). The reference to “other” (non-prescribing) health-care providers recognizes that the assessment and treatment of adverse events may occur outside of the prescribing relationship and that manufacturers distribute professional labeling widely (and not only in ways that immediately accompany the particular product). See id. cmt. d. But cf. Kaplan et al., supra note 27, at 66 (“Manufacturers should not be required to warn unascertainable ‘others’ who, because of independent decisions made by doctors, have been enlisted in the treatment of patients.”). Non-physician prescribers may qualify as learned intermediaries. See Walker v. Merck & Co., 648 F. Supp. 931, 934-35 (M.D. Ga. 1986) (treating nurses as learned intermediaries when they administered a vaccine), aff’d mem., 831 F.2d 1069 (11th Cir. 1987); Wyeth-Ayerst Labs. Co. v. Medrano, 28 S.W.3d 87, 92-93 (Tex. Civ. App. 2000) (same, in case of an implanted contraceptive); see also infra note 236 (noting the extension of prescribing privileges).

209 See Restatement (Third) of Torts: Prods. Liab. § 6 cmt. d (1998) (“When prescribing health-care providers are adequately informed of the relevant benefits and risks associated with various prescription drugs and medical devices, they can reach appropriate decisions regarding which drug or device is best for specific patients.”); see also Thomas v. Hoffman-LaRoche, Inc., 731 F. Supp. 224, 229 (N.D. Miss. 1989) (“[T]he physician through education, experience, and specialized training is in the best position to make a benefit/risk analysis in making the determination to prescribe a particular drug for a specific patient.”). One court suggested that the learned intermediary rule would not protect a manufacturer against a claim for failure to warn the general public of a drug recall. See Nichols v. McNeilab, Inc., 850 F. Supp. 562, 564-65 (E.D. Mich. 1993) (distinguishing the notification of a drug withdrawal prompted by safety concerns from the risk information conveyed to patients at the time that a drug is initially prescribed); see also Francesca Lunzer Kritz, Recalls: Who Knew?, WASH. POST, Oct. 22, 2002, at F1 (reporting that patients often do not receive notifications of drug recalls). But cf. Windham v. Wyeth Labs., Inc., 786 F. Supp. 607, 611 (S.D. Miss. 1992) (finding that manufacturer had no duty to warn a patient who had filled a prescription three years earlier of newly acquired risk information).

include this exception, instead explaining that the ALI took no position on the issue and left it for developing case law. 211 As direct advertising of prescription drugs has continued to expand, plaintiffs predictably have urged courts to recognize such an exception to the learned intermediary rule, 212 but so far only a single jurisdiction has taken this step. 213

A. Learned Intermediary Doctrine

In essentially all jurisdictions, manufacturers of prescription drugs satisfy their common law duty to warn by providing precautionary information to physicians and others who act in the capacity of learned intermediaries. 214 Thirty-five years ago the United States Court of Appeals for the Fifth Circuit offered the following oft-quoted justification for this rule:

Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. 215

The physician essentially acts as a proxy, selecting a therapeutic product on the patient’s behalf.

Only in situations where such an individualized decision is unlikely to be made—for example, when individuals receive vaccines through a mass immunization program—would a manufacturer have to provide a warning directly to the patient. 216 A few courts have extended the mass immunization exception to other drugs, such as contraceptives,


212 See Bob Van Voris, Drug Ads Could Spell Legal Trouble: Consumer Campaigns May Result in Greater Liability, NAT’L L.J., July 21, 1997, at B1 (“[L]awyers on both sides of the issue agree that plaintiffs will use the ads to assault the learned intermediary defense.”).

213 See infra Part III.B.1.

214 See, e.g., Mazur v. Merck & Co., 964 F.2d 1348, 1361-64 (3d Cir. 1992); Allison v. Merck & Co., 878 P.2d 948, 958 n.16 (Nev. 1994). With regard to childhood vaccines, however, federal legislation has overridden the mass immunization exception. See 42 U.S.C. § 300aa-22(c) (2006); supra note 166.
for which a health care professional may not make an individualized judgment in prescribing a particular medication.217 Even so, the overwhelming majority of courts do not recognize any exception for contraceptives.218 In 1997, one state supreme court held that FDA-mandated patient package inserts (PPIs) eliminated the learned intermediary rule,219 while several other courts have rejected any such exception.220

The learned intermediary doctrine reflects several related, subsidiary rationales. First, courts do not wish to intrude upon the doctor-patient relationship, and warnings that contradict information supplied by their physician might undermine the patient’s trust in the physician’s judgment.221 Second, physicians may be in a superior position to convey meaningful information to their patients,222 as they must do to satisfy their duty to secure informed consent.223 Third, drug manufacturers

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218 See In re Norplant Contraceptive Prods. Liab. Litig., 955 F. Supp. 700, 704-05 & n.18 (E.D. Tex. 1997) (collecting cases), aff’d, 165 F.3d 374 (5th Cir. 1999); see also Martin v. Ortho Pharm. Corp., 661 N.E.2d 352, 356 (Ill. 1996) (observing that a “majority of courts . . . have held that the FDA regulations concerning contraceptive pharmaceuticals should not serve as a basis to displace or create exceptions to the learned intermediary doctrine”); cf. Doe v. Solvay Pharm., Inc., 350 F. Supp. 2d 257, 272 (D. Me. 2004) (declining to extend the rationales underlying the contraceptive exception to an antidepressant prescribed for the treatment of obsessive-compulsive disorder).

219 See Edwards v. Basel Pharm., 933 P.2d 298, 301 (Okla. 1997) (“When direct warnings to the user of a prescription drug have been mandated by a safety regulation promulgated for the protection of the user, an exception to the learned intermediary doctrine exists . . . .”). The court also held that compliance with the FDA’s PPI requirement would not foreclose an inadequate warning claim. See id. at 301-03; see also Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 658 (1st Cir. 1981) (holding that compliance with FDA labeling requirements would not preclude tort liability).

220 See, e.g., Presto v. Sandoz Pharm. Corp., 487 S.E.2d 70, 73-74 (Ga. Ct. App. 1997); Martin, 661 N.E.2d at 356; Mikell v. Hoffman-LaRoche, Inc., 649 So. 2d 75 (La. Ct. App. 1994); see also In re Norplant Contraceptive Prods. Liab. Litig., 165 F.3d 374, 379 (5th Cir. 1999) (“Why the learned intermediary doctrine should somehow be less applicable when the severity of the side effects encourages the FDA to promote additional labeling escapes us.”).

221 See Brooks v. Medtronic, Inc., 750 F.2d 1227, 1232 (4th Cir. 1984) (“One in a serious medical condition . . . faces unwanted, unsettling and potentially harmful risks if advice, almost inevitably involved and longwinded, from non-physicians, contrary to what the doctor of his choice has decided should be done, must be supplied to him during the already stressful period shortly before his trip to the operating room.”); McKee v. Am. Home Prods. Corp., 782 P.2d 1045, 1055 (Wash. 1989) (suggesting that PPIs “may confuse and frighten the patient”).

222 See Brooks, 750 F.2d at 1232 (noting that “the question turns on who is in a better position to disclose risks?”); Martin, 661 N.E.2d at 357 (“[P]rescribing physicians, and not pharmaceutical manufacturers, are in the best position to provide direct warnings to patients concerning the dangers associated with prescription drugs.”); MacDonald, 475 N.E.2d at 74 (O’Connor, J., dissenting) (“Doctors, unlike printed warnings, can tailor to the needs and abilities of an individual patient the information that that patient needs in order to make an informed decision whether to use a particular drug.”). Professional labeling approved by the FDA may even urge physicians to communicate particular information to their patients. See Noah, supra note 42, at 321 & n.117. Manufacturers may supply PPIs to physicians who directly administer or implant a product. See Humes v. Clinton, 792 P.2d 1032, 1043 (Kan. 1990) (granting summary judgment to IUD manufacturer where physician had neglected to hand out its PPIs in favor of a homemade leaflet).

223 See, e.g., Hutchinson v. United States, 915 F.2d 360, 562-63 (9th Cir. 1990) (holding that doctor was liable for not warning patient of risks involved with the use of asthma medication);
typically lack effective means to communicate directly with patients, making it necessary to rely on physicians to convey the relevant information—unlike OTC products, pharmacists usually dispense prescription drugs from bulk containers rather than as unit-of-use packages in which the manufacturer may have enclosed labeling. Finally, because of the complexity of risk information about prescription drugs, comprehension problems would complicate any effort by manufacturers to translate physician labeling for lay patients. For this reason, even critics of the rule do not suggest that pharmaceutical companies should provide warnings only to patients and have no tort duty to warn physicians.

The learned intermediary rule has important consequences for litigation. When reduced to the question of whether the warning conveyed to a physician or other health care practitioner was adequate, plaintiffs will encounter greater difficulties getting a case to a jury.
Although physicians may have an incentive to shift blame to the drug manufacturer,\(^\text{228}\) normally they will testify that they understood the warnings provided by the company,\(^\text{229}\) as contrasted with a plaintiff’s testimony that the warning communicated to the physician seemed insufficient. Moreover, as contrasted with a consumer-directed warning to which jurors often can apply their own experience, plaintiffs may have to produce expert testimony to support an inadequacy claim.\(^\text{230}\) In some cases, of course, plaintiffs succeed in convincing juries that a warning directed to their physicians was inadequate, either because it failed to mention known risks,\(^\text{231}\) failed to draw sufficient attention to this information,\(^\text{232}\) was diluted by overpromotion of the product,\(^\text{233}\) or was not communicated through the most effective means available.\(^\text{234}\)


\(^{229}\) See, e.g., Hall v. Merck, Sharp & Dohme, 774 F. Supp. 604, 606-07 (D. Kan. 1991); Wooten v. Johnson & Johnson Prods. Inc., 635 F. Supp. 799, 802-04 (N.D. Ill. 1986). Alternatively, physicians may concede that they had learned of the information from other sources, which would mean that any failure to warn did not cause the patient’s injury. See Motus v. Pfizer Inc., 358 F.3d 659, 660-61 (9th Cir. 2004); Ellis v. C.R. Bard, Inc., 311 F.3d 1272, 1283 n.8 (11th Cir. 2002); Eck v. Parke, Davis & Co., 256 F.3d 1013, 1021-24 (10th Cir. 2001) (physician’s testimony that she already knew of the risk and would have selected the drug even with a fuller warning rebutted the heeding presumption); Miller v. Pfizer Inc., 196 F. Supp. 2d 1095, 1126-30 (D. Kan. 2002), aff’d, 356 F.3d 1326 (10th Cir. 2004); id. at 1129 n.108 (noting that the prescribing physician’s consulting relationship with the defendant would not provide the jury with a sufficient basis for disbelieving his testimony); Harden v. Danek Med., Inc., 985 S.W.2d 449, 451 (Tenn. Ct. App. 1998); Noah, supra note 26, at 453; see also id. at 455 (“Courts have . . . declined to impose a duty on product sellers to educate health care providers about information that has appeared in the medical literature.”).

\(^{230}\) See, e.g., Upjohn Co. v. MacMuro, 562 So. 2d 680, 683 (Fla. 1990) (“[T]he adequacy or inadequacy of the warning to inform a physician must, except in the more obvious situations, be proved by expert testimony.”); Wyeth Labs., Inc. v. Fortenberry, 530 So. 2d 688, 692 (Miss. 1988) (“The adequacy of a warning addressed to the medical community may fall into the category of issues requiring expert testimony.”).


\(^{232}\) See, e.g., McNeil v. Wyeth, 462 F.3d 364, 368 (5th Cir. 2006); Thom v. Bristol-Myers Squibb Co., 353 F.3d 848, 853-54 (10th Cir. 2003) (holding that the adequacy of a warning presented a question for the jury where the package insert was “equivocal” in referring to reports of adverse effect as “rare” and only “temporally associated” but for which a “causal relationship . . . had not been established”); Bennett v. Madakasira, 821 So. 2d 794, 805-07 (Miss. 2002).


\(^{234}\) See, e.g., Hoffman v. Sterling Drug, Inc., 485 F.2d 132, 146-47 (3d Cir. 1975); Mahr v. G.D. Searle & Co., 390 N.E.2d 1214, 1232 (Ill. App. Ct. 1979); Richards v. Upjohn Co., 625 P.2d 1192, 1196-97 (N.M. Ct. App. 1980); see also Janssen Pharmaceutica, Inc. v. Bailey, 878 So. 2d 31, 55-59 (Miss. 2004) (noting that plaintiffs had argued “that Propulsid became a victim of label fatigue” by virtue of the five revisions to the package insert—sometimes accompanied by “Dear Doctor” letters—isolated over the course of five years to convey increasingly alarming risk information, and concluding that this presented a question for the fact-finder).
The learned intermediary doctrine has attracted its share of critics who argue, among other things, that the defense reflects an anachronistic and excessively paternalistic model of the physician-patient relationship and fails to take into account changes in the delivery of health care services. In particular, some critics argue that the emergence of managed care organizations has constrained physician autonomy so substantially that prescribing decisions may no longer reflect an informed medical judgment. Even so, in 2004, one of the last remaining jurisdictions not to have ruled on this issue expressly adopted section 6(d), while, in 2007, the West Virginia Supreme Court became the first jurisdiction to reject the learned intermediary rule altogether.

B. Debate over an Advertising Exception

This Section canvasses the arguments made by proponents of an exception to the learned intermediary doctrine in DTCA cases, as reflected in an important decision from the New Jersey Supreme Court, and suggests a number of responses. Until the central feature that defines the marketing of prescription drugs—namely, the requirement that a

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235 See, e.g., Timothy S. Hall, Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace, 35 SETON HALL L. REV. 193, 195-99, 226-34, 261 (2004); Nancy K. Plant, The Learned Intermediary Doctrine: Some New Medicine for an Old Ailment, 81 IOWA L. REV. 1007, 1023-32 (1996) (concluding that “[r]adical changes in the health care system” justify elimination of the learned intermediary doctrine). But see Richard C. Ausness, Learned Intermediaries and Sophisticated Users: Encouraging the Use of Intermediaries to Transmit Product Safety Information, 46 SYRACUSE L. REV. 1185, 1229-35 (1996) (arguing that, although manufacturers are best situated to generate risk information, only physicians and other intermediaries should have the duty to communicate this information to end-users); Walsh et al., supra note 211, at 880 (“The learned intermediary doctrine has proven durable. Its continuing viability is supported by the common sense notion that, in the case of prescription drugs, information is best directed toward medical professionals.”).


237 See Larkin v. Pfizer, Inc., 153 S.W.3d 758 (Ky. 2004) (declining, however, to take any position on possible exceptions).


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medical professional authorize the purchase by a particular patient—is modified,240 the learned intermediary rule does not lose its force simply because a company chooses to promote its product directly to consumers.241 Plaintiffs’ lawyers do their share of tacky (and potentially hazardous) direct advertising to users of prescription products,242 but surely they would not have to fear tort claims brought by patients who discontinued a prescribed (and still net beneficial) course of treatment (or simply became anxious) in response to exaggerated risk information appearing in ads trolling for clients.243

Preliminarily, however, the possibility of recognizing an advertising (or other) exception raises questions about the interrelationship between the design and warning provisions of the Products Liability Restatement.244 If an exception to the learned

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240 Arguments about the reduced role of physicians in health care delivery, if taken to an extreme, may suggest that the existing prescription restrictions no longer make any sense. Perhaps someday patients will purchase any drugs that they would like, whether recommended by a physician, nurse, neighbor, or pharmaceutical company. In the meantime, however, a medical professional will continue to intervene in the decision to prescribe a drug and make the final judgment about its relative risks and benefits for a particular patient. It would constitute professional malpractice to do otherwise. See supra note 223; see also Plant, supra note 235, at 1055-62 (elaborating on the informed consent duties of prescribers).


242 See Bernstein, supra note 40, at 166 & n.204; Chen-Sen Wu, Distributive Justice in Pharmaceutical Torts: Justice Where Justice Is Due?, LAW & CONTEMP. PROBS., Fall 2006, at 207, 223-24; Mary Flood, Drug Doubts Put Lawyers in Motion, HOUS. CHRON., June 10, 2007, at Bus. 1 (reporting that plaintiffs’ attorneys use newspaper and television ads and “case-soliciting Web sites that already look like a pharmacy’s inventory, except that the drugs listed are alleged to cause harm,” and adding that the manufacturer of the latest target (the diabetes drug Avandia®) expressed concern that “lawyer ads could frighten patients into discontinuing their medicine, which could endanger their health!”); id. (noting that one Houston firm’s phone number is “1-800-BAD-DRUG”); Joseph P. Fried, Specialty Lawyers Gear up for Suits over Two Medications, N.Y. TIMES, July 30, 2000, § 1, at 28; see also David Brown, Scientist’s Two Roles in Study May Conflict, WASH. POST, Feb. 21, 2004, at A10 (reporting that the author of a controversial study linking autism to a type of vaccine had failed to disclose his closely related work for a plaintiff’s lawyer done under a grant of nearly $90,000 from a legal aid society). One of my favorites aired during the summer of 2008, from a series of ads run by the firm Ferrer Poirot & Wansbrough on various cable channels, was styled as a “Medical Alert!” and did not focus on any particular drug but instead a class of serious side effects (Stevens Johnson syndrome or toxic epidermal necrolysis) allegedly associated with two dozen (mostly still marketed, and many OTC) pharmaceutical products. One of the firm’s latest TV spots (focusing on the risk of diabetes associated with the atypical antipsychotic drug Seroquel®) helpfully tells prospective clients not to discontinue treatment without first checking with their doctors.


244 Similarly, as a reasonable physician test has begun to displace the traditional custom-based standard of care, courts have had to rethink various subsidiary malpractice doctrines. See Philip G. Peters, Jr., The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium, 57 WASH. & LEE L. REV. 163, 166-68 (2000).
intermediary rule covers a particular case, such as mass immunizations, should that also render inapplicable section 6(c)’s physician-based design defect standard in favor of the more open-ended test of section 2(b)?\textsuperscript{245} How about the far less common contraceptive exception—if section 6(d)(2) would allow a failure-to-warn claim because the learned intermediary has fallen out of the picture, would that also render inapplicable the protective design defect standard of section 6(c)?\textsuperscript{246} The Reporters subsequently considered this difficulty, though only in connection with a possible advertising exception, but they thought that such an “unlikely juncture” lay “far in the future.”\textsuperscript{247}

Separately, if courts increasingly recognized exceptions to the learned intermediary rule that depended on the particulars of the relative degree of consumer and physician involvement in product selection,\textsuperscript{248} then why not work it in the other direction—for instance, when health care professionals select OTC drugs for their patients?\textsuperscript{249} Of course, a categorical rule—as the Reporters preferred for design defects and ultimately (though incompletely) accepted for warning claims—avoids the uncertainty that would attend a case-by-case inquiry into whether a

\textsuperscript{245} Courts following Restatement (Second) § 402A comment k did not do so categorically when finding that a drug had not satisfied one of the prerequisites for this immunity from strict liability design defect claims; instead, the failure, for instance, to supply a proper warning to patients might render comment k’s protection against design defect claims inapplicable in the particular case. Under the Products Liability Restatement, at least as far as prescription drug manufacturers had warned patients adequately in such cases, a design defect claim might offer plaintiffs their only recourse. The mass immunization exception may not, however, provide a good test of this difficulty because public health authorities have made a societal risk-benefit judgment. See supra note 165 and accompanying text.

\textsuperscript{246} Cf. Shanks v. Upjohn Co., 835 P.2d 1189, 1195 n.7 (Alaska 1992) (“In strict liability design cases involving such [atypical prescription] products, it may be appropriate to apply the ‘ordinary consumer expectation’ test rather than the ‘ordinary doctor expectation test.’”).

\textsuperscript{247} See Henderson & Twerski, supra note 19, at 173.

\textsuperscript{248} As happened, for instance, in cases extending the mass immunization exception to other settings involving vaccine administration. See Hall, supra note 235, at 206 & n.55, 209-10; see also id. at 198 (advocating in all cases “a fact-based inquiry to determine whether the drug in question was in fact sold in the absence of an effective intermediary”); id. at 205, 239-54, 261 (same); id. at 220-21, 231, 244 (arguing that § 6(d) represented a move in this direction); id. at 216-19 (objecting to the blanket application of the rule subject only to narrow categorical exceptions). For a new twist on immunizations, see Stephen Smith, Fly-by Flu Shot: No Need to Get out of the Car—Vaccination Is Available at Hospital’s Drive-through, BOSTON GLOBE, Oct. 29, 2008, at B1.

\textsuperscript{249} See, e.g., Ferrara v. Berlex Labs., Inc., 732 F. Supp. 552, 553-55 & n.1 (E.D. Pa. 1990) (applying the doctrine to reject claims for failing to warn of dangerous interaction between the manufacturers of a prescription antidepressant and an OTC decongestant prescribed by the plaintiff’s physician); see also Kelley v. Wiggins, 724 S.W.2d 443, 449-50 (Ark. 1987) (affirming verdict against a clinic for negligently using Sudafed® in high-risk patient); Sharkey v. Sterling Drug, Inc., 600 So. 2d 701, 711 (La. Ct. App. 1992) (crediting a physician’s testimony that he would not have recommended aspirin for a child with flu-like symptoms if the OTC label had included a fuller warning of the risk of Reye’s syndrome); Noah, supra note 42, at 321 & n.117, 338 (noting that the FDA sometimes approves separate professional labeling for OTC drugs); Peter Temin, Realized Benefits from Switching Drugs, 35 J.L. & ECON. 351, 358-59 (1992); Whitney, supra note 201, at 329-30 (arguing that the learned intermediary rule should apply in such cases). But see Mitchell v. VLI Corp., 786 F. Supp. 966, 970 (M.D. Fla. 1992) (declining to apply the learned intermediary rule to an OTC contraceptive sponge that a physician had supplied to his patient).
particular physician-patient encounter passed some threshold for applying the learned intermediary doctrine.250

1. Norplant Litigation

In Perez v. Wyeth Laboratories Inc.,251 the New Jersey Supreme Court adopted an exception to the learned intermediary rule whenever a prescription drug manufacturer has engaged in direct-to-consumer advertising. The case involved Norplant® (levonorgestrel), an implantable long-acting contraceptive product.252 The consolidated lawsuits claimed that the manufacturer had failed to warn patients of a litany of alleged side effects of use and complications associated with removal of the product.253 The trial judge dismissed the complaints,254 but the state supreme court reversed. After taking apparent comfort in the fact that the Products Liability Restatement had left the question to developing case law,255 the majority concluded that DTCA undermined most of the rationales thought to justify the learned intermediary rule.256

Although essentially no one doubts that direct advertising has altered the dynamic between patients and their physicians when considering the use of a drug promoted in this fashion,257 the dissent

250 See supra notes 198-201 and accompanying text (explaining that the use of prescription status as a bright line rule for selecting among design defect standards suffers from both under- and overinclusiveness).
251 734 A.2d 1245 (N.J. 1999).
253 See Perez, 734 A.2d at 1248.
254 See id. at 1249.
255 See id. at 1253; cf. id. at 1267 (Pollock, J., dissenting) (“Given the statutory basis for the learned intermediary doctrine in New Jersey, recourse to the Restatement . . . is gratuitous.”). The majority rejected the argument emphasized by the dissenting opinion that the state legislature had codified the learned intermediary rule. See id. at 1253-54 (majority opinion).
256 See id. at 1255-57, 1263. In the course of its opinion, the majority quoted several passages from my earlier article on the subject, see id. at 1251-52, 1255-56, 1258, but evidently failed to notice that I had concluded that the exception made no sense, citing instead a student note published in the William Mitchell Law Review as supporting its ultimate conclusion, see id. at 1256. Indeed, immediately after quoting my summary of the rationales underlying the learned intermediary rule, the majority offered a brief synopsis that blatantly mischaracterized some of these before explaining that at least three of the four became inapplicable when manufacturers engage in DTCA. See id. at 1255-56. As the dissent briefly explained, all four of the rationales remained pertinent. See id. at 1269 (Pollock, J., dissenting).
257 See Matthew F. Hollon, Direct-to-Consumer Marketing of Prescription Drugs: Creating Consumer Demand, 281 JAMA 382, 383-84 (1999); Richard L. Kravitz et al., Influence of Patients’ Requests for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial, 293 JAMA 1995, 2000 (2005); Steven Pearlstein, Drug Firms Take a Dose of Responsibility for Ads, WASH. POST, Aug. 3, 2005, at D1 (“A study by the Kaiser Family Foundation found that each $1 invested in advertising yields an extra $4.20 in sales.”); FDA Survey Finds Drug Ads
emphasized that, at least with respect to Norplant (a hybrid drug-device product requiring surgical implantation), doctors would continue playing a central role. The majority also never explained how such advertising rendered inapplicable concerns that supplying comprehensive risk information directly to patients might cause them to discontinue needed treatments, much less that a manufacturer could do this in a way reasonably comprehensible to lay persons.


See Perez, 734 A.2d at 1267-68 (Pollock, J., dissenting); see also Jerry Menikoff, Demanded Medical Care, 30 Ariz. St. L.J. 1091, 1109 n.45, 1116 (1998) (“It would be highly unusual for a physician to view her power to write a drug prescription as merely a requirement to make sure that the patient was adequately informed about the drug.”); Steven H. Miles, Informed Demand for “Non-Beneficial” Medical Treatment, 325 NEW ENG. J. MED. 512, 513-14 (1991); Michelle D. Ehrlich, Note, Doctors Can “Just Say No”: The Constitutionality of Consumer-Directed Advertising of Prescription Drugs, 12 HASTINGS COMM. & ENT. L.J. 535, 550, 553-55 (1990) (“[T]he physician—and not the patient/consumer—makes the ultimate decision of what drug a patient will purchase.”); cf. Incollingo v. Ewing, 282 A.2d 206, 218 (Pa. 1971) (“We decline to accept the proposition that a qualified doctor can so easily turn himself into a dupe [by alleging that sales representatives had pressured him into prescribing the drug].”), abrogated on other grounds by Kaczkowski v. Bolubasz, 421 A.2d 1027 (Pa. 1980). The majority belatedly recognized as much. See Perez, 734 A.2d at 1263-64. Nonetheless, it decided as a matter of policy that physicians’ foreseeable intervention (and their failure to convey or act upon risk information that they had received from the drug manufacturer) would not amount to a superseding cause. See id. at 1260-63 (adding, however, that a jury could allocate relative shares of responsibility to these joint tortfeasors). But see Krasnopolsky v. Warner-Lambert Co., 799 F. Supp. 1342, 1346 (E.D.N.Y. 1992) (superseding cause).

Extensive warnings conveyed directly by pharmaceutical manufacturers might make patients lose trust in their physicians or discontinue necessary drug therapies because of undue anxiety about the reported side effects that the physician felt did not deserve mention or emphasis in a particular case—after all, advertisements emphasize benefits and come before the patient visits a physician, while PPIs emphasize risks and reach patients only upon drug dispensing.

Cf. Raymond L. Woosley, Drug Labeling Revisions—Guaranteed to Fail?, 284 JAMA 3047, 3048 (2000) (“In the last 25 years, the package inserts for new drugs have increased in length more than 5-fold. For example, the 2-page package insert for cisapride, when printed in 12-point font on 8.5 x 11 paper, is more than 10 pages long and contains more than 470 facts about the drug.”). For a critique of the Perez decision from the perspective of a practicing physician (enrolled in law school), see Timothy McIntire, Note, Legal and Quality of Patient Care Issues Arising from Direct-to-Consumer Pharmaceutical Sales, 33 U. MEM. L. REV. 105, 127-28, 130-33 (2002); see also id. at 108-09, 134 (emphasizing the difficulty in trying to translate complex risk information for patients); supra note 225.
Moreover, although no one doubts that physicians often fail to engage in meaningful (tailored) discussions with patients about drugs risks, imposing such an obligation on manufacturers may further reduce the incentives of conscientious physicians even to try. Evidently the majority thought that Norplant, like some of the other examples it had cited, did not qualify as a therapeutically important product, echoing suggestions made by some commentators that another exception to the learned intermediary doctrine should apply to “lifestyle” drugs and devices, whether or not directly advertised to consumers.

The majority opinion repeatedly suggested that Wyeth should not enjoy protection from liability for failing to warn patients directly when it has aimed misleading advertisements at them, but it conceded that this characterization assumed that the plaintiffs would manage to prove their allegations at trial. In fact, the plaintiffs may not have seen

262 See Stolberg, supra note 224, at A27 (“In a 1997 survey of 1,000 patients, the F.D.A. found that only one-third had received information from their doctors about the dangerous side effects of drugs they were taking.”).

263 See Perez, 734 A.2d at 1257 (“Further, when one considers that many of these ‘lifestyle’ drugs or elective treatments cause significant side effects without any curative effect, increased consumer protection becomes imperative, because these drugs are, by definition, not medically necessary.”); infra note 266 (discussing the majority’s references to promotional campaigns for seemingly trivial drugs); see also Odgers v. Ortho Pharm. Corp., 609 F. Supp. 867, 878-79 (E.D. Mich. 1985) (oral contraceptives).

264 See, e.g., Kathy A. King-Cameron, Comment, Carving Another Exception to the Learned Intermediary Doctrine: Application of the Learned Intermediary Doctrine in Silicone Breast Implant Litigation, 68 Tul. L. Rev. 937, 969-70 (1994); see also Hall, supra note 235, at 197 & n.10, 229-30, 237, 243, 250 (arguing that the “lifestyle” use of a drug should count as a factor against application of the learned intermediary rule); Susan A. Casey, Comment, Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine, 19 WM. MITCHELL L. REV. 931, 952-55 (1993) (arguing that an advertising exception should exist at least with regard to elective prescription drugs and medical devices promoted to consumers for cosmetic purposes, such as acne treatments and breast implants). For a critique of the suggestion that such a distinct category exists, see supra notes 105-19 and accompanying text.

265 See, e.g., Perez, 734 A.2d at 1257 (“It is one thing not to inform a patient about the potential side effects of a product; it is another thing to misinform the patient by deliberately withholding potential side effects while marketing the product as an efficacious solution to a serious health problem.”); id. (“The question is whether the absence of an independent duty to warn patients gives the manufacturer the right to misrepresent to the public the product’s safety.”); id. at 1261 (declining to “insulate the manufacturer who has engaged in deceptive trade practices”); id. at 1264 (“[W]e must decide if a pharmaceutical manufacturer is free to engage in deceptive advertising to consumers. . . . [The learned intermediary rule] does not confer on pharmaceutical manufacturers a license to mislead or deceive consumers when those manufacturers elect to exercise their right to advertise their product directly to such consumers.”).

266 See id. at 1247-48; id. at 1263 (“acknowledging] that the procedural posture of this case casts defendant’s product in an unfair light”). Elsewhere in the opinion, the majority painted an unfaltering picture of DTCA, citing advertisements involving entirely different pharmaceutical products, indicated for the treatment of allergies, baldness, erectile dysfunction, and excess weight. See id. at 1247, 1251-53, 1260, 1264. It also discussed changes in health care delivery that made it more difficult for physicians to spend time having meaningful discussions with their (increasingly pushy) patients. See id. at 1247, 1255, 1260; see also id. at 1262 n.6 (Internet prescribing). The dissent admonished the majority for going beyond the confines of the record developed in the Norplant cases before the court. See id. at 1268 (Pollock, J., dissenting) (“Through the incorporation of presumed facts, the majority has created a phantom record . . . .”).
any of the allegedly misleading ads, and it also seems implausible that the print ads in major magazines would have failed to comply with the FDA’s relatively clear command that the full prescribing information appear on the next page. What the plaintiffs wanted, however, was not clearer risk information in advertisements that they may not have seen (or remembered); instead, they sought printed warnings to accompany the drugs when later dispensed to them.

If other courts around the country followed New Jersey’s lead in recognizing this exception to the learned intermediary rule, it would have the effect of requiring that manufacturers wishing to engage in DTCA produce and disseminate comprehensive PPIs. No other court has done so to this point, and several courts have rejected the proposed exception. The West Virginia Supreme Court, however, relied heavily on Perez when it recently decided to reject the learned intermediary rule altogether.

267 See id. at 1260 (majority opinion); id. at 1268 (Pollock, J., dissenting); cf. In re Norplant Contraceptive Prods. Liab. Litig., 955 F. Supp. 700, 707-08 & n.45 (E.D. Tex. 1997) (declining to address arguments in favor of an exception because the plaintiffs had not seen any advertisements), aff’d, 165 F.3d 374 (5th Cir. 1999).

268 See Perez, 734 A.2d at 1263 (referring to an agreed statement of facts that seemed to concede as much); cf. id. at 1258 (summarizing the agency’s “brief statement” and other still evolving requirements). The majority referenced ads appearing in Glamour, Mademoiselle, and Cosmopolitan in 1991. See id. at 1248; see also William Green, Consumer-Directed Advertising of Contraceptive Drugs: The FDA, Depo-Provera, and Product Liability, 50 FOOD & DRUG L.J. 553, 555-58 (1995) (describing Upjohn’s print ads for another long-acting contraceptive sold in the early 1990s); id. at 566 (concluding that “the Depo-Provera advertisement appears to comply with section 502(n)’s brief summary requirement”). No doubt the small print did not include disclosures of alleged risks that only later came to light, but, so long as these ads had included the latest prescribing information, they would not have run afoul of agency requirements (or, for that matter, represent inadequate warnings under state law if the risks were unknowable).


270 See State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 908-10 (W. Va. 2007); see also Rimbert v. Eli Lilly & Co., 577 F. Supp. 2d 1174, 1214-24 (D.N.M. 2008) (predicting that the New Mexico Supreme Court would do the same). The Karl case involved Propulsid® (cisapride), and, although serious questions have arisen about promotional efforts for this drug aimed at physicians, it apparently was not heavily advertised directly to patients. See Gardiner Harris & Eric Koli, Lucrative Drug, Danger Signals and FDA, N.Y. TIMES, June 10, 2005, at A1.
2. Satisfying an Expanded Duty to Warn

The Perez majority hastened to add that, as provided by state statute, the defendant would enjoy a rebuttable (or stronger) presumption of adequacy so long as the warnings complied with FDA requirements. This reflects a potentially serious misunderstanding of the intended purpose of the agency’s advertising rules (and it also fails to appreciate the entirely flimsy nature of the FDA’s recent non-rule pronouncements on the subject): these do not attempt to fulfill a risk disclosure function so much as to ensure fair balance. If the plaintiffs had not, in fact, seen any Norplant ads, then compliance with agency requirements designed to prevent misleading advertising could hardly have satisfied the new-found duty to warn patients directly. If extended to broadcast ads, where the

271 See Perez, 734 A.2d at 1259 (“For all practical purposes, absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims.”); id. at 1263 (“The FDA has established a comprehensive regulatory scheme for direct-to-consumer marketing of pharmaceutical products. Given the presumptive defense that is afforded to pharmaceutical manufacturers that comply with FDA requirements, we believe that it is fair to reinforce the regulatory scheme by allowing” these failure-to-warn claims.). In contrast, the dissent argued that this state statute had codified the learned intermediary doctrine without countenancing any exceptions along the lines crafted by the majority. See id. at 1264-67 (Pollock, J., dissenting); see also id. at 1269 (criticizing the majority’s discussion of the compliance defense and proximate causation issues because the parties had not received any opportunity to address these issues).

272 Some commentators also have made this mistake. See, e.g., William A. Dreier, Direct-to-Consumer Advertising Liability: An Empty Gift to Plaintiffs, 30 SETON HALL L. REV. 806, 824-25 (2000); id. at 816-20 (asserting that “FDA standards are minute and definite,” repeatedly citing the agency’s guidance documents); Caroline L. Nadal, Note, The Societal Value of Prescription Drug Advertisements in the New Millennium: Targeted Consumers Become the Learned, 9 J.L. & POL’Y 451, 482-83, 487, 495 & n.229, 498-500, 504-05 (2001) (referring to the FDA’s regulations and guidelines interchangeably); cf. Robert A. Bell et al., Direct-to-Consumer Prescription Drug Advertising and the Public, 14 J. GEN. INTERNAL MED. 651, 654-55, 656 (1999) (finding that many consumers harbor misconceptions about the stringency of the applicable regulatory controls). Although courts grant agencies substantial latitude in interpreting their own regulations, see Lars Noah, Divining Regulatory Intent: The Place for a "Legislative History" of Agency Rules, 51 HASTINGS L.J. 255, 284-90, 294-99 (2000), the FDA’s guidance documents governing DTCA would not pass muster as mere interpretive rules if it ever made a formal attempt to enforce them directly.

273 See Noah, supra note 210, at 175-76. So-called “reminder” and “help seeking” advertisements do not even have to satisfy the fair balance requirement. See Alicia Mundy, Making a Name for Drugs Without Using Their Names: Some Ads Highlight Only Web Addresses So Side Effects Don’t Have to Be Listed, WALL ST. J., Aug. 29, 2008, at B1.

274 Cf. Kaplan et al., supra note 27, at 69 (“Under the draft formulation of the Products Liability Restatement, manufacturers seemingly would be liable if they advertised but failed to warn consumers directly—even if the advertisements were never seen or read by plaintiffs.”). Conversely, if they had seen and relied on genuinely misleading ads, then perhaps the patients could assert a misrepresentation or breach of express warranty claim. See, e.g., Desiano v. Warner-Lambert Co., 326 F.3d 339, 342 (2d Cir. 2003); In re Meridia Prods. Liab. Litig., 328 F. Supp. 2d 791, 811, 818 (N.D. Ohio 2004); Woods v. Gliatech Inc., 218 F. Supp. 2d 802, 810 (D. W. Va. 2002); RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 9 (1998) (recognizing misrepresentation claims); Dreier, supra note 19, at 264. This alternative would provide a more carefully tailored response to a compelling but entirely hypothetical set of facts imagined by the majority. See Perez, 734 A.2d at 1262 (“[W]e must consider as well a case in which a diabetic patient might have been influenced by advertising to request a drug from a physician without being warned by the manufacturer or the physician of the special dangers posed to a diabetic taking the drug. If an overburdened physician does not inquire whether the patient is a diabetic, the question remains whether the manufacturer should be relieved entirely of responsibility.”). Of course, assuming that the manufacturer had
FDA’s “requirements” appear in technically non-binding (and hardly unambiguous) guidance documents, then the compliance defense would offer essentially no protection unless courts understood the manner in which agency expectations operate as de facto requirements. Lastly, of course, only a handful of jurisdictions have recognized an FDA compliance defense.

If courts recognized an advertising exception to the learned intermediary rule (or abrogated it entirely), then pharmaceutical manufacturers would have to find a way of disseminating PPIs, ensure that these inserts contained references to all possible side effects in nontechnical language, and, in the unlikely event that they managed to supplied an adequate warning to the physician, a medical malpractice claim would do so as well. Cf. Ferrara v. Berlex Labs., Inc., 732 F. Supp. 552, 554-55 (E.D. Pa. 1990) (rejecting the plaintiff’s argument that, given the dozens of dangerous interactions with MAO inhibitors, the manufacturer should have supplied patients with an information card); id. at 553 (noting that the plaintiff had secured a malpractice judgment against her physician for having missed this drug interaction warning).

275 See FDA, Consumer-Directed Promotion of Regulated Medical Products; Public Hearing, 70 Fed. Reg. 54,054 (Sept. 13, 2005) (summarizing milestones in the agency’s supervision of the practice); see also Lars Noah, The FDA’s New Policy on Guidelines: Having Your Cake and Eating It Too, 47 CATH. U. L. REV. 113, 140-42 (1997) (criticizing the agency’s practice of not taking definitive positions in guidance documents). At the time that the plaintiffs in Perez used Norplant, “[t]here [were] no regulations that pertain specifically to consumer-directed promotional materials.” FDA, Direct-to-Consumer Promotion; Public Hearing, 60 Fed. Reg. 42,581, 42,582 (Aug. 16, 1995). More than a decade has passed since the FDA announced plans to issue a notice of proposed rulemaking to address the issue. See Noah, supra note 210, at 153; see also id. at 146 & n.21 (explaining the procedural impediments to the issuance of advertising regulations). In 1999, the agency finalized its guideline governing broadcast advertising of prescription drugs. See FDA, Guidance for Industry on Consumer-Directed Broadcast Advertisements, 64 Fed. Reg. 43,197 (Aug. 9, 1999). Five years later, the FDA issued a draft guidance allowing advertisers to satisfy the brief summary requirement by using approved PPIs or highlights from package inserts in consumer-friendly language. See FDA, Draft Guidelines for Industry on Improving Information About Medical Products and Health Conditions, 69 Fed. Reg. 6308 (Feb. 10, 2004); see also id. (“One of the principal objectives of the[se] three [draft] guidances is to encourage prescription drug firms to present risk information in their consumer-directed advertisements using language that is understandable to a lay user.”); Francesca Lunzer Kritz, FDA on Drug Ads: Less Is More, WASH. POST, Feb. 10, 2004, at F1 (noting objections to the brief summary guidance). Congress recently granted the agency greater authority in this area, though only after the FDA issues binding rules. See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901(d)(2), 121 Stat. 823, 939 (to be codified at 21 U.S.C. § 353b(a)) (authorizing advance review of broadcast DTCA); see also id. § 901(d)(6), 121 Stat. at 942 (to be codified at 21 U.S.C. § 352(n)) (eliminating formal rulemaking procedures applicable to drug advertising regulations).

276 See Wash. Legal Found. v. Kessler, 880 F. Supp. 26, 34 (D.D.C. 1995) (anticipating that the FDA would “threaten[] (but never actually initiat[e]) enforcement procedures against companies which failed to comply with the agency’s de facto policy” against the dissemination of information related to off-label uses, which it had announced in a “draft policy statement”); Noah, supra note 57, at 904-05; see also Thomas Ginsberg, Drug Ads Pour in for Review: The FDA Said It Had Seen “A Huge Increase” in Advertising Submitted for Scrutiny Under a Voluntary Industry Program, PHILA. INQUIRER, Feb. 23, 2006, at C1; Melody Petersen, Who’s Minding the Drugstore?, N.Y. TIMES, June 29, 2003, § 3, at 1 (noting complaints that the agency has become less vigilant); Julie Schmit, A Winded FDA Races to Keep up with Drug Ads That Go Too Far, USA TODAY, May 31, 2005, at 1A (reporting that the agency has ordered more corrective advertising). See generally Lars Noah, Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority, 1997 WIS. L. REV. 873.
design such an unassailable warning,\textsuperscript{277} hope that a jury would not decide that continued advertising to consumers diluted the effectiveness of this warning. Even then, providing full risk information will offer only limited assistance to patients unless they receive equally clear information about all of the other products and procedures that might serve the same purpose: a manufacturer’s duty to warn of risks associated with its product generally does not include such a broader duty to educate,\textsuperscript{278} while physicians owe just such a duty when securing informed consent.\textsuperscript{279} Precisely because of the difficult comparative judgments involved, patients must look to physicians for help in making treatment choices.

Extending a parallel suggested previously in connection with the design defect standard,\textsuperscript{280} manufacturers of toys and other goods accessible to young children have a duty to warn their parents.\textsuperscript{281} If manufacturers choose to advertise directly to youngsters, and the kids then whine until their parents purchase inappropriate products, the manufacturers still would owe no duty to warn the kids directly (though, if overpromotion dilutes the force of information already supplied to adult purchasers, then it might well provide the basis for an inadequate warning claim). Although such promotional efforts may deserve

\textsuperscript{277} See Aaron D. Twerski, Liability for Direct Advertising of Drugs to Consumers: An Idea Whose Time Has Not Come, 33 Hofstra L. Rev. 1149, 1153-54 (2005); see also Michael S. Jacobs, Toward a Process-Based Approach to Failure-to-Warn Law, 71 N.C. L. Rev. 121, 149 (1992) (“By scrutinizing closely the seemingly trivial details of type size, warning location, and relative degree of expressed urgency, and by permitting outcomes to hinge on the presence or absence of one or two seemingly innocuous words, courts impose upon manufacturers a duty of virtual perfection, easily breached . . . .”).

\textsuperscript{278} Cf. Graham v. Am. Cyanamid Co., 350 F.3d 496, 514 (6th Cir. 2003) (rejecting claim that OPV manufacturer had a duty to inform physicians that IPV represented the preferred choice); Demmler v. SmithKline Beecham Corp., 671 A.2d 1151, 1154-55 (Pa. Super. Ct. 1996) (rejecting an inadequate warning claim for failure to specify the appropriate therapy in the event that a listed side effect occurred). For a recent proposal to impose such a broader duty, see infra note 302.


\textsuperscript{280} See supra notes 37-41, 194 and accompanying text; see also Marvin M. Lipman, Bias in Direct-to-Consumer Advertising and Its Effect on Drug Safety, 35 Hofstra L. Rev. 761, 762 (2006) (“The only other commercials of this kind are the breakfast-cereal [ads that air during children’s cartoon shows] . . . . In both instances, an intermediary is necessary—in one case a parent who has the money and, in the other case, a physician who has the prescription pad.”); Michael Kirsch, Even If They’re Too Slick and Manipulative, Drug Ads Are Useful, Plain Dealer, Sept. 8, 2000, at 11B (“This is analogous to marketing toys and breakfast cereals to children. Though our youngsters can’t buy them, they have learned how to close the sale. In a similar manner, patients now ask their doctors to sign on to their wonder-drug requests.”); cf. Francesca Lunzer Kritz, What Teens Are Hearing About Drugs: Some Messages Help, Others Are Troubling, Wash. Post, Sept. 9, 2008, at F1 (reporting that some DTCA campaigns target adolescents).

\textsuperscript{281} See, e.g., Metzgar v. Playskool Inc., 30 F.3d 459, 465-66 (3d Cir. 1994); see also Hahn v. Sterling Drug, Inc., 805 F.2d 1480 (11th Cir. 1986); Emery v. Federated Foods, Inc., 863 P.2d 426 (Mont. 1993); M. Stuart Madden, Products Liability, Products for Use by Adults, and Injured Children: Back to the Future, 61 Tenn. L. Rev. 1205, 1214 (1994) (“[A]n adult product with which children may have contact must contain warnings and instructions advising adults on the special risks to children that the product may create.”).
criticism (and efforts at prohibition), presumably no one would argue that recognizing a largely incoherent duty to warn children directly offered a second-best solution to the problem.

By definition, adequate consumer labeling cannot be designed for prescription drugs. Although the FDA increasingly switches Rx drugs to OTC status, products that continue to require prescription labeling reflect the agency’s judgment that professional intervention remains necessary to ensure their safe use. The FDA has in the past mandated PPIs for some drugs to supplement the labeling provided to physicians, and it continues to encourage their broad use, but no one suggests that PPIs should fully replace professional labeling. Direct advertising further encourages active participation by consumers in prescribing decisions, a favorable development that courts should not reward by expanding the tort duties of drug manufacturers and, because consumer-directed warnings inevitably would fall short, discouraging such advertising in the future.

As the United States Supreme Court has observed repeatedly in deciding commercial speech cases, some information is better than none. Drug advertising naturally emphasizes the benefits of a product, but even this may provide valuable information in the prescription drug context if consumers otherwise would leave bothersome conditions


283 See Dunkin v. Syntex Labs., Inc., 443 F. Supp. 121, 123 (W.D. Tenn. 1977) (“[P]rescription drugs are sold on a prescription basis and not over-the-counter because the special expertise of a trained physician is necessary for their safe use. Thus, an effective warning could go only to the medical profession, and not to an untrained patient.”); Peter Temin, The Origin of Compulsory Drug Prescriptions, 22 J.L. & ECON. 91, 103 (1979) (“[T]he FDA assumed that adequate directions for laymen could not be written for some drugs.”); see also supra note 225.

284 See Noah, supra note 200, at 360, 362-63, 371.

285 A number of reasons may exist for prescription labeling, such as the difficulty with self-diagnosis, a product’s margin of safety, and the extent to which dosages need to be carefully titrated for each patient. See id. at 366-68, 375.

286 See Walsh et al., supra note 211, at 881 (“Ironically, preservation of this brightline [learned intermediary] rule would help create the conditions necessary for improved communications between pharmaceutical manufacturers and patients.”).

287 See, e.g., Thompson v. W. States Med. Ctr., 535 U.S. 357, 374 (2002) (“We have previously rejected the notion that the government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.”); see also Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 69 (1983) (holding that a federal law prohibiting unsolicited mailings was unconstitutional when applied to a pharmaceutical company distributing informational pamphlets that encouraged the use of contraceptives); Lars Noah, What’s Wrong with “Constitutionalizing Food and Drug Law”? 75 TUL. L. REV. 137, 143-44 & n.40 (2000); David C. Vladeck, The Difficult Case of Direct-to-Consumer Drug Advertising, 41 LOY. L.A. L. REV. 259 (2007).
untreated. To the extent that advertising fails to highlight harmful attributes of prescription drugs, the FDA can modify its fair balance requirements. The ultimate safeguard, however, must be the physician. So long as prescription drugs continue to require the intervention of a medical professional, courts should focus on the duty of physicians to secure informed consent, while letting regulatory requirements work to supplement rather than supplant the drug information provided to patients.288

IV. MISCELLANEOUS ISSUES

This Part offers a glimpse at various other issues related to the design and informational defect standards that the Products Liability Restatement has announced for prescription drug manufacturers. First, experimental products do not receive distinctive treatment under section 6, and the new Restatement offered only ambiguous guidance about continuing duties to test after approval. Second, generic versions of prescription drugs raise curious questions as to which manufacturer should shoulder responsibility for injuries to patients. Third, prescription medical devices get identical treatment under section 6 notwithstanding fundamental differences from pharmaceuticals, while human tissue products get carved out entirely notwithstanding their similarities to implanted devices. Finally, questions arise about including other parties in the chain of distribution for purposes of imposing liability. Just as the purportedly bright line between prescription and nonprescription has become increasingly blurred,289 the sharp distinction between manufacturers and health care providers imagined by the Reporters may break down over time.

A. Experimental Drugs and the Duty to Keep Testing

The Products Liability Restatement does not separately address investigational products, even though these appeared to be a central concern in the Second Restatement’s comment k to section 402A.290

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288 See Walsh et al., supra note 211, at 880 ("[T]ruthful direct-to-consumer advertising will provide the consumer with useful information without eroding the paramount role of the prescribing physician. In any event, there is little evidence that direct-to-consumer advertising has harmed consumers or foisted medically inappropriate therapies upon them."); Catherine A. Paytash, Note, The Learned Intermediary Doctrine and Patient Package Inserts: A Balanced Approach to Preventing Drug-Related Injury, 51 STAN. L. REV. 1343, 1367-71 (1999) (urging an administrative solution, in particular FDA-mandated PPIs, rather than any judicial modifications of the learned intermediary rule).

289 See supra notes 198-201 and accompanying text.

290 See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965) ("It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk."); Adams v. G.D. Searle & Co., 576 So. 2d 728, 732
Clinical trials of unapproved new drugs occasionally cause serious injury to subjects, but only a few courts have resolved claims for injuries caused by drugs not yet approved by the FDA. The last decade has witnessed growing tort litigation on behalf of subjects injured during clinical trials, though claims against the suppliers of investigational products remain fairly uncommon. Insofar as section 6 turns on differential access rather than deference to FDA approval decisions, it should encompass investigational products accessible only to subjects enrolled in trials and under the strict supervision of clinical investigators, even though the research aims to answer the very questions that lay at the heart of design and informational defect claims (indeed, though subjects may hope to derive some therapeutic benefit from their participation, clinical trials aim primarily to generate scientific information rather than deliver medical treatment).


Claims against sponsors of products subject to the FDA’s investigational device exemption (IDE) have arisen with somewhat greater frequency. See, e.g., Chambers v. Osteonics Corp., 109 F.3d 1243 (7th Cir. 1997) (finding such claims preempted); Martin v. Telectronics Pacing Sys., Inc., 105 F.3d 1090, 1098-101 (6th Cir. 1997) (same); Oja v. Howmedica, Inc., 111 F.3d 782 (10th Cir. 1997) (rejecting preemption defense); Guckin v. Nagle, 259 F. Supp. 2d 406 (E.D. Pa. 2003) (rejecting a manufacturer’s effort to remove on the basis of federal question jurisdiction tort claims filed against multiple parties in state court by a subject injured during a clinical trial of an investigational device).

FDA approval does not entirely remove the experimental aspect of new drugs, and the agency demands that manufacturers conduct postmarket surveillance. The nature and extent of common law duties to engage in postapproval research have, however, received scant attention. Whether resolving a design or informational defect claim, courts may struggle to determine precisely when a seller should have known that its product presented a risk of injury. Pharmaceutical manufacturers generally have no duty to guard against or warn of unknowable risks. According to the Products Liability Restatement, pharmaceutical “manufacturers have the responsibility to perform reasonable testing prior to marketing a product and to discover risks and risk-avoidance measures that such testing would reveal.” Although a few courts resolving products liability claims against sellers of medical technologies

Gina Kolata & Kurt Eichenwald, For the Uninsured, Drug Trials Are Health Care, N.Y. TIMES, June 22, 1999, at A1; supra note 63 (discussing claims by subjects seeking continued access).

See Noah, supra note 279, at 363 (“[P]roduct approval does not define the point at which an investigational intervention passes the threshold into standard therapy. Instead, the research phase continues after licensure, both in the sense that more safety data accumulates and insofar as physicians may improvise when using a product in ways not originally contemplated.”); id. at 394 (“One common misconception is that FDA approval of a medical technology represents the point at which it crosses the line from experimental to standard therapy.”); id. at 394-99 (elaborating); see also id. at 386-94 & nn.134 & 141 (discussing the indistinct line between treatment and research); id. at 400-08 (same). See generally Bernadette Tansey, What FDA Approval Means: Agency Weighs Benefits, Risks Before Drugs Get to Market, S.F. CHRON., Mar. 3, 2005, at C1.

Imagine that a drug company receives a single report from a physician of an unexpected adverse drug event (ADE) in a patient. If the suspected ADE turns out to be spurious, subsequent patients will not suffer that injury or, if they do and attempt to file a lawsuit, patients will lose on causation at trial; if, however, the drug turns out to have caused the injury, plaintiffs often will have stronger evidence of causation by the time of trial even though the far less certain ADE might have served as the trigger for a duty to warn at the earlier time of sale. One would expect courts to require greater substantiation of risks before allowing a design defect (as opposed to a failure-to-warn) claim to proceed. Technologically sophisticated products subject to lengthy premarket review by administrative agencies pose tricky “state-of-the-art” questions. If risk information comes to light late in the agency’s review, sellers generally still can make labeling modifications before sale, but designs become fixed earlier in the R&D process.


Resatement (Third) of Torts: Prods. Liab. § 6 cmt. g (1988); see also id. § 2 cmt. m (“The harms that result from unforeseeable risks—for example, in the human body’s reaction to a new drug, medical device, or chemical—are not a basis of liability. Of course, a seller . . . is charged with knowledge of what reasonable testing would reveal.”); id. § 10 cmt. c (“With regard to . . . prescription drugs and devices, courts traditionally impose a continuing duty of reasonable care to test and monitor after sale to discover product-related risks.”).
have made a similar point, the case law offers essentially no guidance about the contours of a duty to test. One recent article urged the recognition of an expanded obligation to do so but suffered from similar ambiguities about the scope of such a duty.

Drug-drug interactions provide an illustration of the potential difficulties in defining a broader duty to test. Obviously, if a manufacturer discovers a dangerous interaction during clinical trials or postmarket surveillance, then it would have a duty to communicate information about the risk. What if, however, a patient experiences a previously unknown acute drug interaction and argues that the

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300 See, e.g., Kociemba v. G.D. Searle & Co., 707 F. Supp. 1517, 1528-29 (D. Minn. 1989) (“[T]he duty to test is a subpart of the duty to warn.”); Bichler v. Eli Lilly & Co., 436 N.E.2d 182, 188-90 (N.Y. 1982) (allowing plaintiff’s claim that a DES manufacturer could have discovered reproductive toxicity if it had undertaken rodent testing); Collins v. Eli Lilly Co., 342 N.W.2d 37, 52 (Wis. 1984) (same, focusing on postapproval period).

301 See Daniel R. Cahoy, Medical Product Information Incentives and the Transparency Paradox, 82 Ind. L.J. 623, 640-41 & nn.78-81 (2007) (discussing the limited recognition of a common duty to test); Merrill, supra note 3, at 38 (discussing some of the earliest case law on this question); see also Valentine v. Baxter Healthcare Corp., 81 Cal. Rptr. 2d 252, 265 (Ct. App. 1999) (concluding that “imposition of liability for breach of an independent duty to conduct long-term testing, where the causal link to the known harm to plaintiff is the unknown outcome of testing that was not done, would be beyond the pale of any California tort doctrine we can identify” (emphasis omitted)).

302 See George W. Conk, Punctuated Equilibrium: Why § 402A Flourished and the Third Restatement Languished, 26 Rev. Litig. 799, 856-62, 878-80 (2007); id. at 805-06 (“This patient-centered approach emphasizes the ongoing experimental quality of medical products, and a corresponding duty of product stewardship—a duty of ongoing study and product development, a duty of systematic manufacturer surveillance of the actual use of their products after obtaining regulatory approval to market the product.”); see also id. at 879-80; id. at 856 & n.142 (suggesting incorrectly that section 6 relates only to FDA-approved uses); id. at 857 (suggesting incorrectly that the Products Liability Restatement deals with postapproval risks under the forgiving standard for post-sale warnings). Separately, Conk called on sellers to satisfy a broader duty to educate patients, see id. at 872-74, 877-78, which would mean laying out the pros and cons not just of their product but also competing products (and non-product substitutes). He noted that, contrary to recent pronouncements by the FDA, manufacturers may act unilaterally to revise approved labeling in order to communicate new risk information, see id. at 863-64 & n.171, but the agency certainly would never tolerate any of the other additional items that he would want to see included. Another proposal designed to encourage continued testing would recognize a broader duty to disclose (though only to physicians) uncertain risks, for instance when manufacturers have failed to investigate the teratogenic potential of drugs, coupled with awards of limited damages not dependent on proving that the drug actually caused a particular injury. See Berger & Twerski, Informed Choice, supra note 118, at 259, 287-88; see also Susanne L. Flanders, Note, A Tough Pill to Swallow: The Insurmountable Burden in Toxic Tort Claims Against Manufacturers of Children’s Medications, 16 J.L. & Pol’y 305, 308, 315-18, 338-55 (2007) (focusing on (primarily OTC) drugs marketed for use in children, but making broader claims that would include a duty to engage in pediatric testing of prescription drugs marketed solely for use by adults). For my detailed critique of these various proposals, see Lars Noah, Platitude About “Product Stewardship” in Torts: Continuing Drug Research and Education, 15 Mich. Telecom. & Tech. L. Rev. 359 (2009).

303 See, e.g., Garvide v. Osco Drug, Inc., 976 F.2d 77, 81-82 (1st Cir. 1992) (allowing failure-to-warn claim against manufacturer of phenobarbital to proceed where drug allegedly interacted with amoxicillin and caused toxic epidermal necrolysis); Ferrara v. Berlex Labs., Inc., 732 F. Supp. 552, 553-55 (E.D. Pa. 1990) (rejecting failure-to-warn claim against manufacturer of MAO inhibitor because it had warned physicians of dangerous interactions with over forty substances, including a decongestant that the plaintiff’s physician had prescribed).
manufacturer should have tested for it? 304 A strict liability standard that focused on the knowability of this risk seemingly would ask only whether a manufacturer could have checked for the interaction, while a negligence standard would recognize the impracticality of advance testing for every conceivable drug-drug interaction. 305

Package inserts serve, first and foremost, to define for health care professionals the range of uses and users that have undergone rigorous study and FDA review. Assuming that labeling accurately communicates what the seller knows (and does not know) about the safety and efficacy of the prescription product in different user populations, why impose liability when an unexpected injury occurs in a subpopulation not studied (and, therefore, not an indicated use)? 306 A duty to investigate all foreseeable uses to which health care professionals might put an approved drug would be entirely unmanageable, and it would threaten to deprive intended users of a valuable product.

B. Generic Drugs

Generic drug manufacturers might find themselves in a weaker litigating position than their brand-name brethren. For instance, in trying to mount a defense against design defect claims, they may face an evidentiary disadvantage because of their lack of access to the clinical

304 See Bryant v. Hoffman-La Roche, Inc., 585 S.E.2d 723, 728-30 (Ga. Ct. App. 2003) (allowing such a claim to proceed based on testimony from the plaintiffs’ expert witnesses); see also Carl C. Peck et al., Editorial, Understanding Consequences of Concurrent Therapies, 269 JAMA 1550 (1993); D.I. Quinn & R.O. Day, Drug Interactions of Clinical Importance, 12 Drug Safety 393 (1995) (cataloging known interactions); Langreth, supra note 34, at B16 (discussing the discovery of several additional serious interactions shortly after approval of Posicor that led to its withdrawal).

305 See Richard McCormick, Pharmaceutical Manufacturer’s Duty to Warn of Adverse Drug Interactions, 66 Def. Couns. J. 59, 67 (1999) (arguing that application of a strict liability standard in this context would threaten to impose limitless liability); id. at 68 (“If every concurrent use is foreseeable, then manufacturers would be obligated to test for these interactions, increasing the time beneficial drugs would take to go to market and pushing prices beyond the reach of most consumers.”); see also id. at 65 (“[F]ew cases directly consider the manufacturer’s failure to warn of an interaction that it should have discovered prior to marketing.”); cf. Ceci Connolly, Price Tag for a New Drug: $802 Million: Findings of Tufts University Study Are Disputed by Several Watchdog Groups, WASH. POST, Dec. 1, 2001, at A10 (reporting that the figure had more than tripled in the space of a decade, largely because of demands for larger and more complex clinical trials).

306 See Robak v. Abbott Labs., 797 F. Supp. 475, 476 (D. Md. 1992) (“Certainly, no manufacturer need explicitly spell out all of the conditions for which a drug is not indicated.”). Obviously, if a seller knows of widespread off-label pediatric use, it cannot fail to disclose known risks in that foreseeable though unintended user population; similarly, if a seller knows of widespread off-label use for a different condition (or through a different method of administration), then it may have to disclose known risks. See Lars Noah, Constraints on the Off-Label Uses of Prescription Drug Products, 16 J. PROD. & TOXICS LIAB. 139, 159-62 (1994); Kaspar J. Stoffelmayr, Comment, Products Liability and “Off-Label” Uses of Prescription Drugs, 63 U. CHI. L. REV. 275, 299-305 (1996). But why suggest that the seller must comprehensively study safety and efficacy in every conceivable but unintended use or user? Cf. Medics Pharm. Corp. v. Newman, 378 S.E.2d 487, 488-89 (Ga. Ct. App. 1989) (recognizing a duty to test the safety of off-label uses).
trials underlying the NDA for the innovator product,\textsuperscript{307} unless courts decided to apply a more forgiving standard of knowability to manufacturers of generic drugs.\textsuperscript{308} In addition, if section 6(c) does not take cost into account,\textsuperscript{309} then generic drug manufacturers routinely might face a design defect claim after the innovator introduces a new and slightly improved (and more expensive) version of the original.

Sellers of generic drugs may encounter peculiar problems when it comes to off-label uses: if an innovator company receives FDA approval for a new indication, then it may receive three years of additional market exclusivity for that use—this would not prevent the prescribing of the generic version for that new use,\textsuperscript{310} but the labeling for the generic drug will not include any information (including, in all likelihood, risk information) associated with that new use. In the event that a patient suffers an injury while using the generic version (which completely failed to mention risks associated with the new indication approved only for the brand-name version), would a court have any way of finessing this problem? If a physician prescribed the generic version for the new indication after consulting the labeling of the innovator drug, would that insulate the generic manufacturer from a failure-to-warn claim (and might it open the brand-name manufacturer to an inadequate...

\textsuperscript{307} See Eisenberg, supra note 190, at 736-38 (discussing the applicable trade secrecy protections). If the alleged design defect related to the use of a different dosage form or an inactive ingredient not found in the brand-name product, then the supplier of the slightly altered generic version would have generated the necessary bioequivalence data. See Novartis Pharms. Corp. v. Leavitt, 435 F.3d 344 (D.C. Cir. 2006); Zeneca, Inc. v. Shalala, 213 F.3d 161 (4th Cir. 2000); see also Aaron S. Kesselheim et al., Clinical Equivalence of Generic and Brand-Name Drugs Used in Cardiovascular Disease: A Systematic Review and Meta-analysis, 300 JAMA 2514 (2008); Melinda Beck, Inexact Copies: How Generics Differ from Brand Names, WALL ST. J., Apr. 22, 2008, at D1; Melissa Healy, FDA Standards Are Questioned, L.A. TIMES, Mar. 17, 2008, at F7. In addition, generic drug manufacturers would have to abide by any risk labeling changes that the FDA mandates for the brand-name version, see Julie Schmit, Updating Generic-Drug Labels Can Take Months, USA TODAY, Apr. 21, 2005, at 3B, and any failure to do so would support a defectiveness per se claim.

\textsuperscript{308} Courts have not done so. See Foster v. Am. Home Prods. Corp., 29 F.3d 165, 169-70 (4th Cir. 1994) (dictum); id. at 169 (“When a generic manufacturer adopts a name brand manufacturer’s warnings and representations without independent investigation, it does so at the risk that such warnings and representations may be flawed.”); Colacecco v. Apotex, Inc., 432 F. Supp. 2d 514, 543-44 (E.D. Pa. 2006) (dictum), aff’d, 521 F.3d 253 (3d Cir. 2008); id. at 544 (“While it is true that the ANDA process requires generic manufacturers to use the same labeling as the previously approved innovator drug, we cannot agree that this absolves them of liability for the representations made on their own drugs.”); Bell v. Lollar, 791 N.E.2d 849, 855 (Ind. Ct. App. 2003) (“We see no reason to provide greater protection against state law failure to warn claims to generic drugs than to pioneer drugs. . . . Purepac was free to strengthen its label [for a generic version of the Rx drug Tylenol 3] by adding an alcohol warning.”). See generally FDA, Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,955, 17,961 (Apr. 28, 1992).

\textsuperscript{309} See supra notes 86-89 and accompanying text.

\textsuperscript{310} See Sigma-Tau Pharm., Inc. v. Schwetz, 288 F.3d 141, 145-48 (4th Cir. 2002) (holding that the approval of a second indication (protected by a separate exclusivity period) did not prevent the FDA from approving generic versions for only the original (and no longer protected) indication notwithstanding the likelihood of off-label prescribing of the new indication); Eisenberg, supra note 190, at 724, 729-30; see also Bristol-Myers Squibb Co. v. Shalala, 91 F.3d 1493, 1500 (D.C. Cir. 1996) (sustaining the FDA’s authority to approve a generic drug for only a subset of the innovator drug’s labeled indications).
warning claim in the event of any alleged shortcomings in the risk information)?

Even without such differences in labeling, patients who suffer injuries while taking a generic drug sometimes pursue claims against the manufacturer of the innovator product, but courts generally have rejected such efforts to find deeper pockets.\(^{311}\) Even so, to the extent that physicians and patients may rely on representations made by brand-name manufacturers (after all, generic manufacturers generally do little to promote their versions of well-known prescription drugs), use of the generic version would not alter the fact that inadequate warnings accompanying the brand-name drug caused the injury. Indeed, the physician may have prescribed the brand-name product (based on information supplied by the manufacturer of that product), only to have the pharmacist dispense a generic version manufactured by an entirely different company.\(^{312}\)

In rare cases, some courts have allowed victims to sue both brand-name and generic manufacturers when unable to identify the particular source of a drug. Under this “market share” theory, which courts have used almost exclusively in the DES litigation, the imposition of liability sometimes sought to approximate the aggregate risk created by the different suppliers,\(^{313}\) with one jurisdiction going so far as to

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\(^{311}\) See, e.g., Colacicco, 432 F. Supp. 2d at 519-20 & n.2, 538-43 (dictum); Flynn v. Am. Home Prods. Corp., 627 N.W.2d 342, 350 (Minn. Ct. App. 2001); see also Doc 2 v. Ortho-Clinical Diagnostics, Inc., 335 F. Supp. 2d 614, 626-28 (M.D.N.C. 2004) (holding that the company that originally discovered and patented the mercury-based preservative thimerosal, which later was copied by other manufacturers and used in their vaccines and other drug products, owed no duty to warn users); cf. Piscitello v. Hobart Corp., 799 F. Supp. 224, 226 (D. Mass. 1992) (“It would be unfair to impose such an expansive view of tort liability on those whose original [meat grinder] design is mimicked without the designer’s permission.”). Occasionally, the innovator company supplies bulk quantities of drug product to a generic company for labeling, see Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51 (D.C. Cir. 2005), which would simplify the tort issues.

\(^{312}\) See Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 309-17 (Ct. App. 2008) (allowing misrepresentation but not products liability claims against the brand-name manufacturer in such a case); id. at 320-21 (“We hold that Wyeth’s common-law duty to use due care in formulating its product warnings extends to patients whose doctors foreseeably rely on its product information when prescribing metoclopramide, whether the prescription is written for and/or filled with Reglan or its generic equivalent.”); id. at 318-19 (rejecting failure-to-warn claims against the manufacturers of the generic products that injured the plaintiff because her physician had not read or relied upon their labeling!); cf. Miles Labs., Inc. v. Superior Court, 184 Cal. Rptr. 98, 101-03 (Ct. App. 1982) (allowing a claim for failure to warn of risks of use during pregnancy against the manufacturer of a DES product labeled solely for use in male (prostate cancer) patients because it might have been dispensed in place of other DES products labeled for the prevention of miscarriages). But see Foster, 29 F.3d at 167-68, 170-72 (rejecting negligent misrepresentation claims against the manufacturer of the brand-name version of promethazine when a pharmacist had substituted a generic version); Goldych v. Eli Lilly & Co., 2006 WL 2038436, at *1, *6 (N.D.N.Y. July 19, 2006).

prevent exculpation by suppliers that clearly could not have caused a particular plaintiff’s harm. An extension of such risk-contribution notions even in cases where patients can identify the source of the drug as a generic manufacturer might justify imposing some tort liability on the manufacturer of the brand-name version (for causing the injury through a design defect or failure to warn, even if they did not supply the particular dosage unit that ultimately harmed the plaintiff).  

C. Medical Devices

Although comment k to section 402A of the Second Restatement mentioned only prescription drugs and vaccines, several courts have applied it to comparable medical devices. Courts also have applied the learned intermediary rule to such devices, and it makes even more sense to do so in connection with the sale of sophisticated equipment used in the course of treating patients. Consistent with this pattern,
section 6 of the *Products Liability Restatement* drew no distinction between prescription drugs and medical devices.

1. Are Device Designs Different?

For a variety of reasons, design defect claims involving medical devices do not pose nearly the same difficulties that arise with prescription pharmaceuticals. Although the Reporters explained emphatically (and persuasively) that “drug designs are different,” they have not offered a similarly detailed defense of their decision to apply the special design defect standard to medical devices. The Reporters devoted only a single, lengthy (and error-filled) footnote to medical devices. See Henderson & Twerski, *supra* note 19, at 163 n.47. Contrary to what they said, the FDA has no such thing as “Class III drugs,” Class III devices do not invariably require premarket approval (PMA), new drug approval comes under an entirely different provision of the statute (and, even if they have converged in practice, the statutory standards for safety and effectiveness differ for new drugs and Class III devices subject to PMA requirements), and Congress first subjected devices to any sort of premarket scrutiny in 1976 (it did not in that year, as they suggested, gradually start “streamlining” previously applicable requirements). See NOAH, *supra* note 3, at 49-50, 254-56, 269-70, 277-79. Instead, the contours of express federal preemption as a defense to tort claims against medical device manufacturers, which has evolved fitfully and attracted its share of criticism, may better define those contexts where courts should decline to engage in duplicative design defect review—namely, those devices that have undergone full premarket review and approval, at least where the FDA has made a particular judgment about a feature challenged by the plaintiff.
In sharp contrast to prescription drugs, medical devices are built rather than discovered. Innovation in this field tends to be incremental, and the FDA’s premarket screening mechanism accommodates the introduction of new and slightly improved models of medical devices. In addition, devices generally should not present the same unpredictable (and variable) responses encountered with metabolized drugs, though anatomical variation exists (as does variation in the skill of surgeons). In short, the risk-utility standard does not seem nearly as inapt in this context, and perhaps juries can more easily judge the trade-offs made in the course of designing devices. Nonetheless, focusing on the presence of a learned intermediary (and the public policy rationales for limiting the liability of sellers that supply products of value to some patients), the Products Liability Restatement does not differentiate between prescription drugs and medical devices.

A few courts already have discussed the application of section 6(c) to implanted devices, and the new design defect standard has not

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324 See Peter Barton Hutt et al., The Standard of Evidence Required for Premarket Approval Under the Medical Device Amendments of 1976, 47 FOOD & DRUG L.J. 605, 612-13 (1992); Richard A. Merrill, The Architecture of Government Regulation of Medical Products, 82 VA. L. REV. 1753, 1808 (1996) (“[T]he [Medical Device] Amendments were promoted as a new type of regulatory statute, one that would assure careful review of the few high risk technologies but permit less intrusive, less costly regulation of most devices.”); see also Michael VanBuren, Note, Closing the Loopholes in the Regulation of Medical Devices: The Need for Congress to Reevaluate Medical Device Regulation, 17 HEALTH MATRIX 441, 448-60 (2007) (identifying weaknesses in the FDA’s pre- and post-market scrutiny of devices for safety and effectiveness).

325 See, e.g., Hopkins v. Dow Corning Corp., 33 F.3d 1116, 1119, 1126 (9th Cir. 1994) (affirming plaintiff’s verdict based in part on an allegation that the manufacturer had failed to redesign breast implants to reduce the risk of leakage and rupture); Coursen v. A.H. Robins Co., 764 F.2d 1329, 1337-39 (9th Cir. 1985) (Dalkon Shield); Worsham v. A.H. Robins Co., 734 F.2d 676, 681-82 (11th Cir. 1984) (same); Webster v. Pacesetter, Inc., 259 F. Supp. 2d 27, 31-33 (D.D.C. 2003) (finding that plaintiff failed to identify a RAD for the pacemaker lead); Dyer v. Danek Med., Inc., 115 F. Supp. 2d 732, 738-39 (N.D. Tex. 2000) (“Plaintiffs have failed to clearly identify a safer design alternative [for a pedicle screw], which is a prerequisite for a finding of design defect.”); Adams v. G.D. Searle & Co., 576 So. 2d 728, 731-34 (Fla. Dist. Ct. App. 1991) (reversing summary judgment for the manufacturer of an IUD on a design defect claim alleging that the use of a polypropylene withdrawal string was more likely than a polyethylene string to retract into the uterus where it might cause a perforation or pelvic inflammatory disease); Larsen v. Pacesetter Sys., Inc., 837 P.2d 1273, 1286 (Haw. 1992) (pacemaker); Tansy v. Daconcom Corp., 890 P.2d 881, 886 (Okla. 1994).

326 See, e.g., Sita v. Danek Med., Inc., 43 F. Supp. 2d 245, 255-59 & n.9 (E.D.N.Y. 1999) (rejecting plaintiff’s design defect claim against a manufacturer of pedicle screws used in spinal fixation for failing to establish a feasible safer design); id. at 256 n.9 & 258 (making only passing references to § 6(c)); Wheat v. Sofamor, S.N.C., 46 F. Supp. 2d 1351, 1361-62 & n.11 (N.D. Ga. 1999) (declining to predict whether Georgia courts would follow § 6(c), but concluding that, under a risk-utility test, pedicle screws had an appropriate role in securing long bones (as indicated in their labeling) even if not appropriate for plaintiff’s spinal fixation surgery); Gebhardt v. Mentor Corp.,
fared well among those that have squarely addressed the question. For instance, in a case involving an intravenous line that became detached from a catheter, the Illinois Supreme Court found that the plaintiff had satisfied either the consumer expectations or risk-utility test, and it declined to consider adopting section 6(c) because the defendant had not preserved that issue for appeal. A few years later in a case involving a prosthetic hip, an intermediate appellate court in Illinois rejected the new standard, instead applying a modified consumer expectations test that allowed the defendant to introduce evidence of countervailing utilities of the challenged design.

2. Tissue Engineering and Manufacturing Defects

Elsewhere, the Products Liability Restatement expressly excludes human tissue products from coverage, which accurately reflects judicial interpretations of the blood shield statutes found in most states, but it

191 F.R.D. 180, 185-86 & n.2 (D. Ariz. 1999) (holding that the plaintiff’s design defect claim against the manufacturer of an implanted device used to treat gastroesophageal reflux failed under either § 6(c) or § 2(b) of the Products Liability Restatement, and declining to resolve the applicability of § 402A comment k of the Second Restatement); cf. Anderson v. Siemens Corp., 335 F.3d 466, 470-71 (5th Cir. 2003) (declining to apply § 6 to an ICU ventilator with a malfunctioning alarm because it did not qualify as a “prescription” product).


See Mele v. Howmedica, Inc., 808 N.E.2d 1026, 1038-42, 1045-46 (Ill. App. Ct. 2004); id. at 1037-38 (“Even if implantees have no expectation specific to this particular part of the artificial hip, they may have relevant expectations about the safety of the artificial hip as a whole…” The trial court correctly rejected the proposal to assess risks from the standpoint of the ordinary doctor.”). But cf. Rosburg v. Minn. Mining & Mfg. Co., 226 Cal. Rptr. 299, 303-05 (Ct. App. 1986) (allowing expert testimony about the limited life expectancy of a breast implant to rebut the plaintiff’s belief that the device should last a lifetime); Schindler v. Sofamor, Inc., 774 A.2d 765, 766, 775 (Pa. Super. Ct. 2001) (spinal fixation device could not be expected to last forever in case of nonfusion). See generally Kathleen Fackelmann, Hip Implants Get the Active Back in Gear: New Ceramic Joints Can Benefit Aging but On-the-Go Boomers, USA TODAY, June 24, 2003, at 5D (reporting that new ceramic versions should prove to be more durable than older metal and plastic hip implants); Stephen Smith, As Americans Age, So Do Their Implants, BOSTON GLOBE, July 18, 2005, at C1.


See, e.g., Condos v. Musculoskeletal Transplant Found., 208 F. Supp. 2d 1226, 1229 (D. Utah 2002) (“No court has ever applied strict liability to the distribution of human tissue.”); id. at 1229-30 (citing § 19 as further authority, and concluding that the transplantation of processed bone tissue, which allegedly caused recipient to contract hepatitis C, did not constitute a “sale” subject to strict liability); Cryolife, Inc. v. Superior Court, 2 Cal. Rptr. 3d 396, 398, 402-05 (Ct. App. 2003)
fails to recognize the increasingly difficult categorization judgments that FDA officials encounter as the field of regenerative medicine develops. \footnote{331} If, instead, section 6 applied to drug-like blood derivatives and device-like human tissue products, then a separate doctrinal question would arise: are instances of contamination in source material treated as manufacturing defects or design defects? \footnote{332} I assume, for instance, that, after the recent discovery that foreign suppliers of the active ingredient used in heparin surreptitiously had substituted a dangerous material, \footnote{333} the finished good manufacturers would face manufacturing defect claims. \footnote{334}


\footnote{331} See 21 C.F.R. pt. 1271 (2008); Nw. Tissue Ctr. v. Shalala, 1 F.3d 522, 536 (7th Cir. 1993) (invalidating on procedural grounds the FDA’s assertion of its device authority over heart valves recovered from cadavers); Lars Noah, A Postmodernist Take on the Human Embryo Research Debate, 36 CONN. L. REV. 1133, 1146-47 & n.66 (2004); Michael Leachman, Comment, Regulation of the Human Tissue Industry: A Call for Fast-Track Regulations, 65 L.A. L. REV. 443 (2004); Rick Weiss, First Bladders Grown in Lab Transplanted: Breakthrough Shows Promise for Creating Other Human Organs, WASH. POST, Apr. 4, 2006, at A1; see also Noah, supra note 90, at 61 (“If biotechnology rendered untenable the traditional distinction between drugs and biologics, then nanomedicine may do the same to the line separating devices and biologics.”).

\footnote{332} See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19 cmt. c (1998) (assuming that, in the absence of blood shield statutes, such cases involve product contamination and would lead to the imposition of strict liability for manufacturing defects). In contrast, one commentator who focused on HIV contamination of blood factor concentrates used by hemophiliacs treated purported delays in adopting pasteurization and other viral inactivation processes as matters of defective design (and, on that assumption, criticized section 6(c)’s reasonable physician standard for not imposing liability under these circumstances). See Conk, supra note 19, at 1098-101, 1111-14, 1117. But see Henderson & Twerski, supra note 19, at 159-61; id. at 160 (arguing that “the contaminants that caused their harm constituted manufacturing defects”); id. at 161 (distinguishing between “the design of the defendants’ methods of production” and the “products themselves”); id. at 161 (“[P]laintiffs in the blood cases . . . lost because they were unable to establish through credible proof that an alternative method of decontaminating blood was reasonably available at the time of sale.”).

In their response to Conk’s essay, however, the Reporters never attempted to justify the exclusion of blood and tissue products, apart from recognizing the widespread adoption of blood shield statutes. His rejoinder curiously argued that the plaintiffs’ failures in this negligence-based litigation demonstrated that courts have the capacity to engage in risk-utility balancing. See Conk, supra note 21, at 774, 779-81; see also id. at 774-79 (elaborating on the merits of the plaintiffs’ claims, and explaining their litigation failures on other grounds); id. at 772-73 (reiterating his view that these cases involved design rather than manufacturing defects); id. at 780 (conceding that subsequently developed recombinant versions of blood factor concentrates would not have qualified as RADs).


\footnote{334} Cf. Am. Tobacco Co. v. Grinnell, 951 S.W.2d 420, 434 (Tex. 1997) (“Although pesticide residue may be found in many if not all cigarettes, it is not an ingredient American intended to incorporate into its cigarettes. Analyzed in this light, the presence of pesticide residue
D. Links in the Chain of Distribution

Although the title of section 6 refers to a “commercial seller or distributor” of prescription products, section 6(a) covers only a “manufacturer . . . who sells or otherwise distributes.” Section 6(e) further provides as follows:

A retail seller or other distributor of a prescription drug or medical device is subject to liability for harm caused by the drug or device if: (1) at the time of sale or other distribution the drug or medical device contains a manufacturing defect as defined in § 2(a); or (2) at or before the time of sale or other distribution of the drug or medical device the retail seller or other distributor fails to exercise reasonable care and such failure causes harm to persons.335

At the outset, this language leaves open some questions about the liability of entities other than manufacturers and retailers, especially when contrasted with the blackletter language elsewhere in the Restatement that expressly addresses wholesalers as well as component part suppliers.

As for suppliers of inputs used by finished good manufacturers, generally these companies need fear liability only in case of a flaw in what they supplied or a failure to disclose information unknown to the immediate purchaser.337 Nonetheless, when manufacturers of defective medical devices go bankrupt, patients occasionally manage to prevail against raw material suppliers.338 Even though such claims normally could be a manufacturing defect, not a design defect.”); Paul A. Offit, The Cutter Incident, 50 Years Later, 352 NEW ENG. J. MED. 1411 (2005) (describing early litigation over incompletely inactivated polio vaccine). Alternatively, because the finished drug deviated from the specifications of its license, the manufacturers might face a claim of defectiveness per se. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 4(a) (1998).
failed, some suppliers of biomaterials expended substantial resources in defending against these sorts of lawsuits, prompting them to stop supplying raw materials to medical device manufacturers. At the other end of the chain of distribution for prescription drugs and devices, as discussed in the sections that follow, injured patients might try to name physicians, pharmacists, and hospitals.

1. Physicians, Pharmacists, and Compounding

Consistent with the available case law (and the broadly applicable sales-service distinction), the Products Liability Restatement clearly did not mean to treat physicians as retail sellers or other distributors, even though some commentators have advocated extending strict liability to surgeons who implant nonessential medical devices. Instead, tort law uses the less exacting standards of medical malpractice to resolve personal injury claims arising from surgical and medical errors.

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340 For instance, DuPont ultimately prevailed in all of the temporomandibular joint (TMJ) implant lawsuits filed against it for supplying raw materials, but it expended significant resources for its string of victories during the decade that this litigation lasted, paying far more in legal fees than it ever earned on this minor application. See Gary Taylor, A Discovery by DuPont: Hidden Costs of Winning, NAT’L L.J., Mar. 27, 1995, at B1 (reporting one estimate that the company had spent more than $40 million defending itself).


342 See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(e) cmt. h (1998) (explaining that retailers “should be permitted to rely on the special expertise of . . . prescribing and treating health-care providers”). See generally id. § 19(b) (“Services, even when provided commercially, are not products.”).

other medical procedures. Courts have held physicians liable for negligent prescribing decisions, including cases involving inadequate testing for the selection of the best available product for a particular patient, failing to warn of risks, and errors in drug administration. Even compounding or customization, which seem closer to the activities of a manufacturer, may escape strict liability.

344 See, e.g., In re Breast Implant Prod. Liab. Litig., 503 S.E.2d 445, 449 (S.C. 1998) (holding that, though breast augmentation surgery entails the implantation of a device, the service aspect of the transaction predominates); Hoven v. Kelble, 256 N.W.2d 379, 391-93 (Wis. 1977) (declining to impose strict liability for medical services); Noah, supra note 32, at 646-47.


347 See, e.g., Hutchinson v. United States, 915 F.2d 560, 562-63 (9th Cir. 1990) (doctor held liable for not warning patient of risks involved with use of asthma medication); Bowman v. Songer, 820 P.2d 1110, 1113-15 (Colo. 1991) (dermatologist negligent for failing to warn patient of risk of sun exposure during use of topical prescription drug); Tenuto v. Lederle Labs., 687 N.E.2d 1300, 1301-02 (N.Y. 1997) (physician had a duty to warn plaintiff of risk of contracting polio from an infant who had received a polio vaccine); Shadrick v. Coker, 963 S.W.2d 726, 729-30, 734-35, 736-37 (Tenn. 1998) (informed consent doctrine requires physician to tell patient that medical device was not FDA approved); see also Noah, supra note 279, at 364-70. Physicians also may have duties to warn former patients when new risk information comes to light about a previously prescribed drug or implanted medical device. See, e.g., Harris v. Raymond, 715 N.E.2d 388, 394-95 (Ind. 1999); Tanuz v. Carlberg, 921 P.2d 309, 312, 316 (N.M. Ct. App. 1996). In some jurisdictions, third parties involved in traffic accidents with a person driving under the influence of a sedating medication may have a claim against the patient’s physician in case of a failure to warn of this side effect. See, e.g., Burroughs v. Magee, 118 S.W.3d 323, 324-25 (Tenn. 2003) (holding, however, that the third party could not assert a claim for negligent prescribing). But see Lester ex rel. Mavrogenis v. Hall, 970 P.2d 590 (N.M. 1998).


Pharmacists have a limited duty of care in connection with dispensing drugs and supplying information.\textsuperscript{350} In addition, pharmacists may face tort liability for mistakes in compounding drugs,\textsuperscript{351} and the \textit{Products Liability Restatement} appears to treat them as within the chain of distribution for limited purposes,\textsuperscript{352} but they generally escape strict liability because courts regard them as providers of a service rather than sellers of a product.\textsuperscript{353} In fact, courts have rejected products liability claims against pharmacies even when they engage in large-scale compounding operations,\textsuperscript{354} even though the FDA treats such activity as akin to commercial drug manufacturing.\textsuperscript{355}

\textsuperscript{350}See, e.g., Fagan v. AmerisourceBergen Corp., 356 F. Supp. 2d 198, 213 (E.D.N.Y. 2004) (“[S]ince there is an allegation that the label on the Epogen was facially defective [and indicative of counterfeiting], the instant case does not involve a latent defect; but rather a patent defect, for which [the mail-order pharmacy] may be held liable for failing to discover upon reasonable inspection.”); Harco Drugs, Inc. v. Holloway, 669 So. 2d 878 (Ala. 1995) (pharmacist should have double-checked prescription because it was illegible and an oncologist normally would not have prescribed a cardiology drug); Lou v. Smith, 685 S.W.2d 809 (Ark. 1985) (pharmacist who altered prescription to correct an assumed prescribing error held liable after a child suffered a severe reaction to the drug). When a pharmacist dispenses the wrong drug, the wrong dosage, or with the wrong label, he or she may be liable for negligence if the error harms the patient. In these circumstances, no matter how well-trained and careful a pharmacist may be, the processing error itself usually suffices to prove negligence. See, e.g., Forbes v. Walgreen Co., 566 N.E.2d 90, 91 (Ind. Ct. App. 1991) (pharmacist liable for dispensing incorrect medication); Walter v. Wal-Mart Stores, Inc., 748 A.2d 961, 967-68 (Me. 2000) (same); see also Eric M. Grasha, Note, \textit{Discovering Pharmacy Error: Must Reporting, Identifying, and Analyzing Pharmacy Dispensing Errors Create Liability for Pharmacists?}, 63 OHIO ST. L.J. 1419 (2002); Christopher Rowland, \textit{CVS Faces Pharmacy Reviews: Settlement with State Comes After Scores of Prescription Errors}, BOSTON GLOBE, Feb. 10, 2006, at C1 (reporting that “pharmacies typically experience a 3 percent error rate”). A presumption of negligence in the case of processing errors differs, however, from strict liability for dispensing a product with a manufacturing defect that the pharmacist could not have detected.


\textsuperscript{352}See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(e) (1998) (manufacturing defects). Courts that reject strict liability claims against pharmacists seem, however, to do so without limitation, which would mean excluding responsibility for manufacturing defects as well. See Ashworth v. Albers Med., Inc., 395 F. Supp. 2d 395, 407-08 (S.D. W. Va. 2005) (rejecting claims against pharmacy that unknowingly dispensed counterfeit drug); Fontanez v. Parenteral Therapy Assoc., 974 So. 2d 1101, 1105 (Fla. Dist. Ct. App. 2007) (“[T]he imposition of strict liability on a pharmacist simply dispensing a prescription drug would improperly convert retail pharmacists into insurers of the safety of the manufactured drug.”). Furthermore, the line between included manufacturing defects and excluded design defects may become particularly blurry in the context of pharmacy compounding operations.


\textsuperscript{354}See Scherrer v. Stewart’s Plaza Pharmacy, Inc., 79 P.3d 922 (Utah 2003). But cf. Fontanez, 974 So. 2d at 1106 (allowing a breach of warranty claim); id. at 1105 ("[T]he risk of harm associated with the use of a drug which somehow became contaminated during the compounding
Again, as with other health care professionals, some have argued that pharmacists should face strict liability claims (after all, they do not differ markedly from retailers that simply sell products in sealed containers).\textsuperscript{356} Pharmacies and other businesses that sell OTC drugs and devices face the same threat of products liability as any other retailer of consumer goods.\textsuperscript{357} Indeed, pharmacies may have greater flexibility than manufacturers when it comes to regulating consumer access to nonprescription products,\textsuperscript{358} which might make them more vulnerable to negligent marketing claims if they fail to adopt necessary safeguards.\textsuperscript{359}

In the last decade, online prescribing and dispensing have become increasingly common. Aside from the difficulties that Internet sales of prescription drugs present for regulatory officials,\textsuperscript{360} and the possibility that manufacturers might have a duty to limit such modes of distribution,\textsuperscript{361} this phenomenon may justify rethinking the traditional process should be borne by the one best able to implement procedures to prevent the contamination, not by a consumer who is powerless to protect himself or herself.


\textsuperscript{356} See, e.g., Furrow, supra note 47, at 404-13; see also Rhonda L. Rundle, \textit{Getting Your Drugs from a Vending Machine}, WALL ST. J., June 21, 2005, at D1 (discussing efforts to use ATM-like kiosks to dispense prescription refills).


\textsuperscript{358} Before Congress legislated in this area, concerns about methamphetamine prompted some retailers to place OTC cough-cold products containing the meth precursor pseudoephedrine behind the counter. See Margaret Webb Pressler, \textit{Retailers Restrict Some Cold Medicines: Ingredient Can Be Used to Make Meth}, WASH. POST, May 14, 2005, at A1. Retailers also have begun to limit access to other OTC cough-cold products in response to problems with teenagers purchasing them to get high. See Rebecca Dana, \textit{Household Medicine Abused by the Young: Trend Alarms Activists, Officials}, WASH. POST, Oct. 8, 2004, at A1; cf. Annys Shin, \textit{Speeding up Safety}, WASH. POST, May 3, 2008, at D1 (“The rush to banish [bisphenol A] is an example of how businesses have learned to respond quickly when their customers become alarmed. Major retailers and manufacturers have been taking their own measures because of a regulatory system that has not kept up with changes in the marketplace . . . .”). Only once before has the manufacturer of an OTC drug created a “behind-the-counter” system of distribution. See Francesca Lunzer Kritz, \textit{Over the Counter but Not Easy to Reach}, WASH. POST, Oct. 8, 2002, at F3 (Mucinex®).

\textsuperscript{359} See Nora Lockwood Toohrer, \textit{Meth Suits Target Cold Medicine Makers and Sellers}, LAWYERS WKLY. USA, Feb. 27, 2006; see also supra note 199 and accompanying text (discussing “behind-the-counter” status).


\textsuperscript{361} See \textit{supra} note 202 and accompanying text.
view that physicians and pharmacists offer predominantly professional services and, therefore, lie outside of the chain of distribution.\textsuperscript{362} Similarly, if an exception to the learned intermediary rule applies (e.g., mass immunization, contraceptives, DTCA),\textsuperscript{363} then it seemingly would undermine the professional-status rationale underlying the exclusion of doctors and pharmacists from the chain of distribution for such drugs.

2. Will Pharmacogenomics Change Everything?

These issues may take on greater importance in the future as medical product development and use undergo fundamental changes. The improved understanding of the human genome promises advances in personalized medicine. “Pharmacogenomics” refers to the science of utilizing information about genetic variations to facilitate drug development and to create optimal patient treatments.\textsuperscript{364} Moreover, because human beings exhibit a great deal of variation, better understanding of individual differences presents an opportunity for physicians to tailor drugs to suit their patients’ individual genetic quirks and minimize the risk of side effects.\textsuperscript{365} To the extent that pharmacogenomics blurs the line between manufacturing and compounding, courts may have to revisit the sales-service distinction as it applies to pharmaceutical products.

Even if pharmacogenomics never results in complete customization of drug therapy, it may affect the resolution of products liability litigation against pharmaceutical manufacturers. For instance, this research may help to identify subgroups of patients for whom reasonable physicians would prescribe a certain drug in the face of a

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\textsuperscript{363} See supra notes 244-47 and accompanying text (asking whether a different design defect standard would apply in such circumstances).

\textsuperscript{364} See Jeffrey L. Moe, Commercialization Considerations for Individualized Diagnostic and Drug Therapies Resulting from Pharmacogenomics, 66 LA. L. REV. 103 (2005); Lars Noah, The Coming Pharmacogenomics Revolution: Tailoring Drugs to Fit Patients' Genetic Profiles, 43 JURIMETRICS J. 1 (2002); Symposium, Pharmacogenomics, 46 JURIMETRICS J. 237 (2006); Andrew Pollack, A Special Drug Just for You, at the End of a Long Pipeline, N.Y. TIMES, Nov. 8, 2005, at F1.

\textsuperscript{365} See Barbara J. Evans, What Will It Take to Reap the Clinical Benefits of Pharmacogenomics?, 61 FOOD & DRUG L.J. 753 (2006); Yusuke Nakamura, Editorial, Pharmacogenomics and Drug Toxicity, 359 NEW ENG. J. MED. 856 (2008); Gina Kolata, A Tale of Two Drugs Hints at Promise for Genetic Testing, N.Y. TIMES, July 11, 2006, at F1; Ron Winslow & Anna Wilde Mathews, New Genetic Tests Boost Impact of Drugs: Cancer Screens, Moves by FDA Help Launch Era of Personalized Medicine, but Strategy Is Still Young, WALL ST. J., Dec. 21, 2005, at D1; see also Andrew Pollack, F.D.A. Urges Genetic Test Before Giving AIDS Drug, N.Y. TIMES, July 24, 2008, at C3 (reporting the addition of a black box warning in the labeling for abacavir with instructions to screen for a particular gene variation found in approximately five percent of patients because they may suffer severe allergic reactions); id. (“The labels of several other drugs, like the blood thinner warfarin and the cancer drug irinotecan, also recommend [genetic] tests aimed at avoiding side effects or helping to adjust the dose.”).
plaintiff’s allegations of defective design. Conversely, it may expand the limited duty to warn of allergic reactions. Historically, such claims rarely succeeded, either because the manufacturer could not have known of the risk of allergic reactions, or because a warning would not have altered the consumer’s decision to use a product if they did not know of their susceptibility. Pharmacogenomics may eliminate both of these obstacles to recovery in drug products liability cases. For instance, in a class action lawsuit premised on a failure-to-warn theory, the plaintiff’s allegations were that the manufacturer of a vaccine against Lyme disease should have recommended that patients first get a genetic test for the HLA-DR4+ allele, which occurs in thirty percent of the population and produces an autoimmune reaction in response to an outer surface protein found on the vaccine. As pharmacogenomic research reveals more such genetic variations, drug companies can expect to encounter an expansion in this sort of litigation.

3. Hospitals and SUDs

Finally, hospitals that supply defective drugs or devices to patients generally need not fear strict liability claims, and the Products

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367 Drug manufacturers have an obligation to warn when they should have known that an appreciable number of hypersensitive individuals may suffer serious injury. See, e.g., Basko v. Sterling Drug, Inc., 416 F.2d 417, 430 (2d Cir. 1969); see also RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(c) cmt. k (1998) (“A warning is required when the harm-causing ingredient is one to which a substantial number of persons are allergic.”); Marcia Anne Mobilia, Allergic Reactions to Prescription Drugs: A Proposal for Compensation, 48 ALB. L. REV. 343, 346-49 (1984).


Liability Restatement does not appear to treat them as retail sellers or other distributors who might face liability for manufacturing defects under section 6(e),\(^{372}\) though some commentators have suggested that hospitals should qualify as links in the chain of distribution.\(^{373}\) Hospitals may face negligence claims for supplying flawed devices,\(^{374}\) for failing to supply state-of-the-art equipment,\(^{375}\) and for failing to monitor drug therapy.\(^{376}\) For the most part, however, courts refuse to treat hospitals as members of the chain of distribution on the notion that they provide a service (indeed, even more so than retail pharmacies, they look like sophisticated purchasers rather than mere retailers). Courts do not care that hospitals nowadays generate itemized bills that charge for everything used by a patient (often with a substantial mark-up),\(^{377}\) may enter into exclusive (and lucrative) purchasing agreements with particular wholesalers and manufacturers (almost the way an automobile dealership does),\(^{378}\) and may have the clout to influence manufacturers’ design choices. Moreover, hospitals have the expertise to select and inspect drugs and devices—and patients presumably depend on hospitals

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\(^{372}\) See Restatement (Third) of Torts: Products Liability § 20 cmt. d (1998) (“In the overwhelming majority of jurisdictions, hospitals are held not to be sellers of products they supply in connection with the provision of medical care, regardless of the circumstances.”).

\(^{373}\) See, e.g., Rachel B. Adler, Comment, Device Dilemma: Should Hospitals Be Strictly Liable for Retailing Defective Surgical Devices?, 5 ALB. L.J. SCI. & TECH. 95, 103-10, 124-30 (1994). Commentators have made the same argument in connection with injuries caused by drugs administered within a hospital. See Furrow, supra note 47, at 393-404; see also id. at 424, 434 (suggesting that managed care organizations also should face products liability claims to the extent that they create restricted drug formularies).


\(^{377}\) See, e.g., Hector v. Cedars-Sinai Med. Ctr., 225 Cal. Rptr. 595, 600-01 (Ct. App. 1986) (noting that hospital had added a surcharge of 85%, but declining to impose strict liability for supplying a defective pacemaker).

\(^{378}\) See United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 236-37 (3d Cir. 2004) (reversing summary judgment for defendant in False Claims Act lawsuit where surgeon alleged that the manufacturer of orthopedic implants had offered kickbacks to hospital chain for purchasing products that would get billed to Medicare); In re Cardiac Devices Qui Tam Litig., 221 F.R.D. 318, 323 (D. Conn. 2004) (allowing an action initiated by a manufacturer’s sales representative against more than 100 hospitals that had received payments for services to patients enrolled in clinical trials of numerous different investigational devices not eligible for Medicare reimbursement); Reed Abelson, Possible Conflicts for Doctors Are Seen on Medical Devices, N.Y. TIMES, Sept. 22, 2005, at A1; Mary W. Walsh, Senate Panel Weighs Tighter Rules for Hospital Suppliers, N.Y. TIMES, Sept. 15, 2004, at C4.
to exercise that expertise—to say nothing of their active role in storage and handling.

In the early 1980s, because of concerns about the difficulty of sterilizing increasingly sophisticated medical devices and surgical instruments after use (and no doubt also to promote repeat sales), manufacturers began to label these devices as “disposable” or “single-use devices” (SUDs). Many hospitals responded, however, by reusing certain SUDs in order to cut costs. This practice became widespread and can have frightening results. For example, some hospitals reused surgical instruments after operations on patients with Creutzfeldt-Jakob disease, but, because ordinary sterilization procedures do not destroy the prions that cause this fatal condition, subsequent patients may have been exposed.379 The FDA now regulates hospitals engaged in reprocessing in the same manner as original equipment manufacturers.380 Such reprocessing and reuse of SUDs might, of course, make hospitals vulnerable to negligence claims,381 but why not apply rules of products liability in such cases (even if that meant the more forgiving rules governing used products)?382

V. CONCLUSION

At least the medical technology industry got its own blackletter rules this time around. In contrast to some of the other special provisions in the Products Liability Restatement (e.g., food), section 6 has attracted substantial attention. Given the expansion in litigation concerning drugs

379 See Alec Klein, Reused Devices, Surgery’s Deadly Suspects: Patients May Be Exposed to Rare Brain Disease from Prior Operations, WASH. POST, Dec. 30, 2005, at A3 (“Over the past five years, dozens of patients in at least four U.S. hospitals have been potentially exposed to the disease because their surgeons reused medical instruments first used on patients who had the rare brain disorder . . . .”).
381 See Emil P. Wang, Regulatory and Legal Implications of Reprocessing and Reuse of Single-Use Medical Devices, 56 FOOD & DRUG L.J. 77, 93-95 (2001) (explaining that the duty of care “includes efforts to establish and maintain appropriate reprocessing protocols and to insure that reuse of the device is safe and presents no increased risk of harm or injury to the patient”).
382 See Janice M. Hogan & Thomas E. Colonna, Products Liability Implications of Reprocessing and Reuse of Single-Use Medical Devices, 53 FOOD & DRUG L.J. 385, 395 (1998) (“For health care entities with in-house reprocessing, however, the quasi-manufacturing role may increase the likelihood that claims for strict liability would be permitted.”); id. at 393-94 (discussing earlier case law involving used consumer goods). See generally RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 8 (1998).
and medical devices, it has the potential to have a substantial practical impact; it also raises intriguing doctrinal questions and provides some interesting contrasts with the core of products liability. Unfortunately (whether from a failure to appreciate some of the tricky regulatory or medical practice issues, a narrow focus on only one of the subsections, or a preoccupation with taking sides), much of the published literature has done a poor job of grappling with the genuinely difficult questions presented by section 6. This Article has tried to explore those issues and offer an overview of the interrelationships between different facets of this special provision.
Design Defect Ghosts

David G. Owen†

I. INTRODUCTION

Ghosts haunt design defect law across the land. Design defectiveness lies at the heart of products liability law, yet courts and legislatures around the nation, and increasingly the globe, disagree on how the fundamentally important concept of a design defect should be defined. Both textual and conceptual ghosts from times gone by continue to frustrate efforts to apply modern principles to this field of law. Halting progress toward sound liability tests for unsafe design is visible here and there, but movement toward workable design defect definitions remains slow and tortured.

How design defects should be defined was the most explosive issue in the entire politically-charged Restatement (Third) of Torts: Products Liability project. When the Reporters (Professors Aaron Twerski and James Henderson, Jr.) offered their definition of design defect early in the Third Restatement project, most observers viewed it as a strange and radical departure from the straight-forward formulation of strict products liability in tort in section 402A of the Restatement (Second) of Torts. Yet, from the time the American Law Institute (ALI) approved section 402A in 1964 (and promulgated it in 1965), courts and lawyers struggled to apply its “strict” liability principles beyond manufacturing defects, a context where such principles comfortably grounded liability determinations, to the then-emerging context of design safety, where section 402A’s consumer expectations test proved increasingly inadequate. In addition to ingeniously diverting commotion away from the strict liability versus negligence debate that lay beneath, the Third Restatement Reporters’ functional, negligence-based definition of design defect reflected how courts and lawyers around the nation increasingly were framing and litigating this central issue of products liability law.

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1 See David G. Owen, Products Liability Law § 8.1, at 495 (2d ed. 2008) [hereinafter Owen, Products Liability Law].
2 See id. § 1.4; Geraint Howells & David G. Owen, Products Liability Law in America and Europe, in Handbook of Research on International Consumer Law ch. 9 (forthcoming 2009).
Since the *Products Liability Restatement* was published in 1998, courts have tried to decide how much of the new *Restatement* to adopt and, in particular, the extent to which the section 2(b) definition of design defect should displace decades of section 402A jurisprudence. As one might expect, some courts have found the *Third Restatement* persuasive authority for redefining design defectiveness, while others have rejected it as inconsistent with their developed products liability jurisprudence, sometimes grounded in a reform statute and often constructed around *Restatement (Second) of Torts* section 402A. Yet, there can be no doubt that the words and concepts of section 2(b), even as this section emerged in its initial draft in 1993, began to frame the debate over how the notion of design defectiveness should be formulated for the 21st century.

First among design defect issues highlighted by the *Third Restatement* was whether the idea of a defective product should continue to be conceived as a unitary concept, as in section 402A of the *Second Restatement*, or whether instead the product defect idea should be splintered into three separate pieces, with design defect lying at the center. More fundamentally, the *Third Restatement* redefined design defect in principles of reasonableness and fault, based on a balance of the foreseeable costs and benefits of an untaken design precaution, in contrast to the widespread judicial characterization of design defect liability as “strict,” a characterization drawn from section 402A of the *Second Restatement* which grounded products liability broadly in terms of consumer safety contemplations.

Impedimenta to adoption of the *Third Restatement*’s formulation of design defectiveness abound. Obstacles to acceptance of *Products Liability Restatement* section 2(b) include various textual ghosts left over from section 402A of the *Second Restatement*—notably, questions about the very idea of “strict” liability; whether the linchpin section 402A phrase, “defective condition unreasonably dangerous,” is a one-pronged test or two; and how courts misinterpret comment j to section 402A as allowing manufacturers to escape responsibility for safe designs by providing warnings of a product’s dangers. A number of conceptual ghosts also linger, including whether consumer safety expectations should remain the sole test of design defectiveness, whether such expectations should provide an independent, alternative test to risk-

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3 Liability for selling a defective product may rest on “(b) a design defect if the foreseeable risks of harm presented by the product could have been reduced by the adoption of a reasonable, safer design . . . .” *Restatement (Third) of Torts: Products Liability* § 101(2) (Preliminary Draft No. 1, 1993).


5 See Part III.B.1.
utility, or whether instead they should be blended somehow with risk-utility, and what to do with the Wade-Keeton “prudent manufacturer” hindsight test. In addition, other perplexing ghosts have frustrated courts attempting to frame a risk-utility test appropriate for design decisionmaking, including whether large numbers of conceivably relevant design factors (like the Wade factors) should regularly be considered, and whether a risk-utility test should be formulated in “macro-balance” terms (weighing the product’s risks against its utility) or “micro-balance” terms (weighing the costs and benefits of some particular untaken design feature).

Resolution of these and other design defect perplexities has been retarded in many states by various barriers: the inertia of a developed jurisprudence of section 402A under the Second Restatement, products liability legislation in many states, and perceptions of the Third Restatement as an ideologically driven reform effort to rein in products liability law. Despite these obstacles, the Products Liability Restatement has served to focus debate in a manner that appears to be helping calm the unsettled design defect waters in a number of jurisdictions around America. If in fits and starts, courts and legislatures in various states continue to mature and clarify their law with helpful guidance from section 2(b) of the Restatement (Third) of Torts: Products Liability.

II. DESIGN DEFECTS IN THE THIRD RESTATEMENT

Restatement (Third) of Torts: Products Liability articulates the fundamental liability principles in just two sections, 1 and 2. Grounding the Third Restatement, section 1 provides the overarching general principle of modern products liability law—that commercial enterprises are liable for harm caused by defects in products that they sell:

§ 1. Liability of Commercial Seller or Distributor for Harm Caused by Defective Products

One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.

8 See Part III.B.2.
9 See Part III.C.
10 See, e.g., Green v. Smith & Nephew AHP, Inc., 629 N.W.2d 727, 751 n.16 (Wis. 2001) (citing journal articles for this proposition); see also Potter, 694 A.2d at 1331-32; Delaney v. Deere & Co., 999 P.2d 930, 945 (Kan. 2000).
Had the Restatement stopped here, it would have left Restatement (Second) of Torts § 402A effectively unchanged, addressing the concept of product defect monolithically in a manner that is strict. Instead, the Reporters followed the groundswell of jurisprudential development around the nation by splintering the idea of product defect into its three constituent parts—manufacturing defects, design defects, and warning defects. Section 2 thus defines each separate type of defect, including design defects in subsection 2(b), which provides that a product:

(b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe . . . . 12

Rather than defining liability strictly, as the Second Restatement had done, and rather than returning to explicit negligence doctrine, the Reporters for the Third Restatement focused on the type of proof lawyers and courts had increasingly been relying upon to determine whether or not a product is defective: whether the defendant reasonably could have adopted an alternative design that would have prevented the plaintiff’s harm. 13 Reducing the rather cumbersome Restatement language to its essentials, the design defect liability standard of section 2(b) may be translated as follows:

A design is defective if its foreseeable risks of harm could have been avoided by a reasonable alternative design, the omission of which renders the product not reasonably safe. 14

The “foreseeability” and “reasonableness” requirements of section 2(b) effectively reset the liability standard to one of negligence—a rather remarkable retreat from the explicitly “strict” standard of liability of Restatement (Second) of Torts section 402A that most courts for decades have boldly purported to apply to design defect cases. Instead, section 2(b) bases liability for design defects on the reasonableness-balancing-negligence concepts that ground the law of tort. 15 Many, perhaps most, courts have come to employ a “risk-utility” test for ascertaining whether the dangers of a product design are

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12 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) (1998).
13 For an extended discussion of this point, see RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 Reporters’ Note, cmt. d (1998). The discussion here draws from OWEN, PRODUCTS LIABILITY LAW, supra note 1, § 5.9, and David G. Owen, Products Liability Law in America, 11 DANNONE RESPONSABILITA 1065 (1999).
acceptable or excessive, a determination normally based on a cost-benefit analysis of a manufacturer’s decision to forego a safety improvement that the plaintiff claims was necessary to render the design reasonably safe, as further explored below. This reasonable safer design concept lies at the heart of the Third Restatement’s definition of design defectiveness in subsection 2(b).

Consumer expectations remain entitled to important respect in evaluating design defect claims under section 2(b), but the comments to section 2 unceremoniously relieve consumer expectations of their elevated status as the exclusive, determining test of liability under section 402A. Instead, the Third Restatement, following the implicit (if usually unspoken) approach of many courts, relegates consumer expectations to the balancing calculus. Despite complaints at the time that this fundamental definitional change eviscerated the basis of section 402A, the Third Restatement’s shift in section 2(b) from “strict” liability to negligence-like balancing principles, though conceptually monumental, merely did “restate” what most courts themselves had long been doing if rarely saying.

Prior to the Third Restatement, it had been an open secret for many years that while purporting to apply “strict” liability doctrine to design cases, courts in fact were applying principles that look remarkably like negligence. As today, most courts then based design defect determinations on risk-utility principles of balance, reasonableness, and foreseeability. Except for a very small number of aberrant decisions, courts widely have rejected efforts to make manufacturers guarantors of a product’s design safety, requiring only that manufacturers design their products as safe as they are reasonably able to do, by methods that are

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17 “[A]lthough consumer expectations do not constitute an independent standard for judging the defectiveness of product design, they may substantially influence or even be ultimately determinative on risk-utility balancing in judging whether the omission of a proposed alternative design renders the product not reasonably safe.” Restatement (Third) of Torts: Prods. Liab. § 2 cmt. g (1998).

18 See id. § 2 cmt. f.

reasonably available and reasonably likely to be effective.20 This is negligence, pure and simple, in fact if not in name. Consequently, by grounding liability for design defects in principles of negligence, the Third Restatement truly “restates” the law—no doubt quite differently from how most courts have stated (and still proclaim) the law to be, but in fact quite closely to how most courts functionally have applied the law in litigation.

Prior to the Third Restatement, a number of state legislatures had already defined design defect in untaken precaution terms.21 Since that time, the Products Liability Restatement’s section 2(b) definition of design defect has influenced a number of courts and legislatures reconsidering their definitions of defective design, particularly with respect to whether they should allow or require proof of a “reasonable alternative design,” as the Third Restatement puts it, commonly called a “RAD.”22 In 2002, the Iowa Supreme Court most boldly followed the Third Restatement’s recommendations by formally adopting the section 2(b) functional definition of design defect, rejecting doctrinal labels such as “negligence” and “strict liability” in the process.23 Ohio’s path toward the Third Restatement’s design defect approach has been convoluted, to say the least. One year after adopting the consumer expectations test,24 the Ohio high court switched to a Barker v. Lull Engineering Co.25 two-pronged test (without the shift in burden of proof).26 Thereafter, the Ohio legislature adopted the two-pronged test, later dropped the consumer expectations prong,27 and finally, following the Third Restatement approach, included consumer expectations as a factor in the risk-utility

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20 See Owen, Products Liability Law, supra note 1, § 5.3.

21 See, e.g., LA. REV. STAT. ANN. § 9:2800.56 (enacted in 1988) (providing that a product is unreasonably dangerous in design if (1) the claimant’s harm would have been prevented by an alternative design, and (2) the burden of which was outweighed by the likelihood and gravity of the harm it prevented); N.J. STAT. ANN § 2A:58C-3(a)(1) (enacted in 1987) (providing that the unavailability of a feasible alternative design is a defense to design defect liability); WASH CODE § 7.72.030(a) (enacted in 1981) (providing that a design is not reasonably safe if the burdens of a feasible alternative design were outweighed by the risks it would have prevented); see also MISS. CODE ANN. § 11-1-63(f) (enacted in 1993) (providing that a claimant must prove that the product failed to function as expected and a feasible design alternative design would have prevented the harm without impairing its usefulness); TEX. CIV. PRAC. & REM. CODE ANN. § 82.005(a)-(b) (enacted in 1993) (requiring a plaintiff to prove that an alternative design was feasible and would have prevented the harm).

22 Most courts and statutes speak instead of a “feasible” alternative design. For statutes, see supra note 21.

23 Wright v. Brooke Group Ltd., 652 N.W.2d 159, 166-70 (Iowa 2002). “[W]e prefer to label a claim based on a defective product design as a design defect claim without reference to strict liability or negligence.” Id. at 169.


balance of considerations.\textsuperscript{28} In addition, the Ohio statute now specifically provides that a design is not defective if a feasible alternative design was not available.\textsuperscript{29}

While some jurisdictions have expressly relied upon the Third Restatement’s RAD approach for defining design defects, others have rejected the section 2(b) formulation as imposing unnecessary obstacles to recovery for injured plaintiffs.\textsuperscript{30} “Thus, . . . 2(b) increases the burden for injured consumers not only by requiring proof of the manufacturer’s negligence, but also by adding an additional—and considerable—element of proof to the negligence standard.”\textsuperscript{31} As will be seen below, however, the untaken precaution (RAD) approach of the Products Liability Restatement, though much maligned, is entirely sound. That is, the Third Restatement is entirely correct in characterizing a design as defective if a manufacturer failed to adopt a reasonable alternative design that would have avoided the plaintiff’s harm, since the RAD approach reflects how lawyers and courts routinely frame and litigate design defect cases in courtrooms across the nation.\textsuperscript{32}

The question here, then, is why more courts have not explicitly adopted Restatement (Third) of Torts: Products Liability section 2(b) as a formal definition for design defects. As explained below, the answer may be found, at least in part, by various design defect ghosts from several decades of jurisprudence on Restatement (Second) of Torts section 402A,

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\begin{itemize}
\item \textsuperscript{28} See OHIO REV. CODE ANN. § 2307.75(B)(5) (2004).
\item \textsuperscript{29} See id. § 2307.75(F).
\item \textsuperscript{30} Our research of state court cases decided since the Restatement (Third)’s initial definition of design defect in 1993 revealed decisions relying explicitly and substantially on section 2(b) in ten states—six by common law (California, Iowa, Kentucky, New Mexico, New York, and Rhode Island), plus four with prior risk-utility statutes (Mississippi, New Jersey, Texas, and Washington)—compared to nine states rejecting it, often due to its RAD requirement (Connecticut, Florida, Illinois, Kansas, Maryland, Missouri, New Hampshire, Pennsylvania, and Wisconsin). While Illinois has expressly refused to adopt section 2(b), we note the inscrutability of that decision, Mikolajczyk v. Ford Motor Co., 901 N.E.2d 329 (Ill. 2008), which concludes that “both the consumer-expectation test and the risk-utility test may be utilized in a strict liability design defect case to prove that the product is ‘unreasonably dangerous.’ . . . When both tests are employed, consumer expectation is to be treated as one factor in the multifactor risk-utility analysis.” Id. at 360. In Bugosh v. I.U. North America, Inc., 942 A.2d 897 (Pa. 2008), the Supreme Court of Pennsylvania granted review to decide whether it should replace section 402A of the Restatement (Second) of Torts with section 2 of the Restatement (Third) of Torts.
\item \textsuperscript{31} Green v. Smith & Nephew AHP, Inc., 629 N.W.2d 727, 751-52 (Wis. 2001); see also Mikolajczyk, 901 N.E.2d at 346 (holding that to add a RAD requirement, “that would so fundamentally alter the law of product liability,” was for legislature); Delaney v. Deere & Co., 999 P.2d 930, 945 (Kan. 2000) (“The Third Restatement’s requirement that a plaintiff produce a reasonable alternative design has been harshly criticized.”); Vautour v. Body Masters Sports Indus., Inc., 784 A.2d 1178, 1184 (N.H. 2001) (“Thus, the rigid prerequisite of a reasonable alternative design places too much emphasis on one of many possible factors that could potentially affect the risk-utility analysis.”).
\item \textsuperscript{32} The count of twenty-five jurisdictions requiring proof of RAD by Professors Twerski and Henderson is broader than our survey of decisions substantially informed by section 2(b) itself. Their compilation usefully reveals how widely courts apply some form of RAD approach. See James A. Henderson, Jr. & Aaron D. Twerski, Manufacturers’ Liability for Defective Product Designs: The Triumph of Risk-Utility, 74 BROOK. L. REV. 1061 (2009) (presenting a state-by-state compilation of standards for design defect); see also supra note 16.
\end{itemize}
such as the Wade-Keeton “hindsight” test, the Wade liability factors, and the formulation of the risk-utility test in “macro-balance” terms.

III. DESIGN DEFECT GHOSTS

That the Third Restatement requires plaintiffs to prove an alternative design is the primary reason most courts offer for rejecting section 2(b), as just discussed. Other objections, often unspoken, explain more fundamentally why more courts have not adopted this commonsense formulation. In short, section 402A of the Second Restatement and its enormous body of consumer protection jurisprudence casts a long shadow over the law of design defectiveness across the nation, a formidable ancestry which section 2(b) of the Third Restatement appears explicitly to repudiate in certain fundamental ways. Within this shadow lurk a number of persistent ghosts, to which the inquiry now will turn.

A. Textual Ghosts

Three textual aspects of Restatement (Second) of Torts section 402A continue to haunt design defect jurisprudence in a manner that retards judicial adoption of the language and principles of the Third Restatement. The first is the fundamental issue of whether liability for design defects is strict, or whether it actually is based on negligence; the second involves how a product with unacceptable design dangers should be characterized—as “defective,” as containing “a defective condition unreasonably dangerous to the user or consumer,” or somehow else; and the third is how properly to interpret a sentence in comment j to section 402A which says that warnings of danger render a product not defective.

1. “Strict” Liability versus Negligence

Section 402A of the Second Restatement of Torts, promulgated in 1965, applies a principle of “strict liability” to manufacturers and other sellers for physical harm caused by defects in products they sell. Strict liability is suggested, of course, by the black letter of section 402A(1) itself, which states simply: “One who sells any product in a defective condition unreasonably dangerous to the user or consumer . . . is subject to liability . . . .” More plainly, the strictness of liability is formally announced (also in black letter) in section 402A(2), which declares in no uncertain terms that the liability rule of subsection (1) “applies although
(a) the seller has exercised all possible care . . .,” and the rule is explicitly declared to be “strict” in comment a.\textsuperscript{33}

With a gusto unmatched in the annals of the \textit{Restatements of the Law},\textsuperscript{34} courts and legislatures across the land embraced section 402A and the bold new doctrine it proclaimed—“strict” liability in tort for physical harm caused by defective products.\textsuperscript{35} Tort law has probably never witnessed such a rapid, widespread, and altogether explosive change in the rules and theory of legal responsibility.\textsuperscript{36} If ever a Restatement reformulation of the law were accepted uncritically as divine,\textsuperscript{37} surely it was section 402A of the \textit{Restatement (Second) of Torts}.

Notwithstanding the rapid and widespread acceptance and application of “strict” liability doctrine to design defect litigation across the nation, and eventually over much of the world, American courts in time broadly came to understand that principles of reasonableness were necessary to resolve the difficult issues of balance between product usefulness, safety, cost, practicality, and information dissemination inherent in such cases. Whether one calls this method for determining liability “strict” or “twerski,” it is at bottom negligence. And, once one further recognizes that responsibility in such cases must be limited by principles of foreseeability, as many courts have done, then the liability standard is plainly negligence, and nothing more. Increasingly, in other words, whatever “strictness” there ever was in a manufacturer’s design responsibility has drained away. Yet most courts, while often acknowledging the application of negligence principles in such cases, insist on calling liability “strict,” on calling a pig a mule.\textsuperscript{38}

At the time the \textit{Third Restatement} process was begun, some commentators argued that the new \textit{Restatement} should preserve the form and language of the \textit{Second Restatement}’s “strict” products liability doctrine as echoed in thousands of courtrooms and written decisions over three decades.\textsuperscript{39} Others thought that doctrine should follow practice,

\begin{itemize}
\item \textsuperscript{33} “The rule is one of strict liability, making the seller subject to liability to the user or consumer even though he has exercised all possible care in the preparation and sale of the product.” \textit{RESTATEMENT (SECOND) OF TORTS} § 402A cmt. a (1965).
\item \textsuperscript{34} At the June 8, 1993 meeting of the Consultative Group on the \textit{Restatement (Third) of Torts: Products Liability}, the Director of the ALI, Geoffrey Hazard, reported that section 402A had been cited in judicial opinions more than any other section of any \textit{Restatement}.
\item \textsuperscript{35} See \textsc{Owen}, \textit{Products Liability Law}, supra note 1, § 5.3.
\item \textsuperscript{36} See \textsc{William L. Prosser}, \textit{The Fall of the Citadel (Strict Liability to the Consumer)}, 50 MINN. L. REV. 791, 793-94 (1966) (characterizing the adoption of strict products liability in the early 1960s as “the most rapid and altogether spectacular overturn of an established rule in the entire history of the law of torts”).
\item \textsuperscript{37} On the divinity of section 402A, see James A. Henderson & Aaron D. Twerski, \textit{A Proposed Revision of Section 402A of the Restatement (Second) of Torts}, 77 CORNELL L. REV. 1512, 1513 (1992) (observing that section “402A has achieved the status of sacred scripture”).
\item \textsuperscript{38} See \textsc{Owen}, \textit{Defectiveness Restated}, supra note 14, at 749.
suggesting that the liability rule in design and warning cases formally be returned to the law of negligence. 40 Perhaps not unwisely, in view of the undiluted passion of the warring camps, the Reporters decided to ignore the conventional doctrinal labels of “strict liability” and “negligence” and instead defined liability “functionally” according to the required proof.41 Yet courts in most jurisdictions, due to the strong pull of decades of jurisprudence rooted in section 402A, even if increasingly applying principles of negligence, continue to purport to apply a rule of “strict” liability for harm caused by defects in design.42

In design defect litigation, a number of important issues are bound up in the question of whether liability is based on negligence or is truly “strict.” One issue is how courts and legislatures choose to define the “test” for design defectiveness—that is, whether design defect is defined in terms of risk-utility (a negligence formulation) or consumer expectations (a strict liability formulation).43 Another important but less frequent issue concerns the role of state-of-the-art evidence in design defect litigation, which involves the question of whether a design may be considered defective because of the development of technology after the product was designed that was not reasonably available at the time of design. The proper role for state-of-the-art evidence involves numerous complex issues all circling back to whether modern products liability law should be grounded on principles of reasonableness or should in fact be considered “strict.” Most courts and legislatures addressing the issue take the position that later-developed safety technology does not render an accident product’s earlier technology defective.44 How design defect tests should be formulated is a fundamentally important issue further explored as a “conceptual ghost,” below.

2. “Defective Condition Unreasonably Dangerous”

Another textual ghost that continues to interfere with clear judicial thinking about design defect formulations is the focus of section 402A on whether a product is in a “defective condition unreasonably dangerous” to the user or consumer.45 Too many courts have become
entangled, understandably, in this prolix language. The history of this clumsy phrase is just one part of section 402A’s tortuous path from conception to completion, and there is widespread understanding that this bulky liability phraseology really means just one thing—that a product is more dangerous than it properly should be. Today, most courts, almost all commentators, and the Third Restatement capture that single concept in a single word: “defective.”

Notwithstanding general agreement that “defective” best characterizes a product that is unacceptably dangerous, some courts still attribute more meaning to the language of section 402A than it deserves. Thus, many courts and even some legislatures nominally divide section 402A’s “defective condition unreasonably dangerous” language into two separate elements, “defective” and “unreasonably dangerous,” and a fair number of jurisdictions ambiguously suggest two separate elements. Yet it is difficult to find a case where a court in such a jurisdiction explicitly addresses the differences between the two elements, perhaps because the comments to section 402A define both

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46 The phrase resulted from Dean Prosser’s overreaction to the ALI Council’s complaint that the “dangerous condition” language he initially proposed was over-broad. See id. § 5.8.
47 See, e.g., McAlpine v. Rhone-Poulenc Ag. Co., 16 P.3d 1054, 1058 (Mont. 2000), quoting Dean Werdner Page Keeton of Texas, an Adviser for the Second Restatement:

It is unfortunate perhaps that Section 402A of the Restatement (Second) of Torts provides that as a basis for recovery it must be found that the product was both “defective” and “unreasonably dangerous” when as a matter of fact the term “unreasonably dangerous” was meant only as a definition of defect. The phrase was not intended as setting forth two requirements but only one.

W. Page Keeton, Product Liability and the Meaning of Defect, 5 ST. MARY’S L.J. 30, 32 (1973). McAlpine held that the trial court erred in instructing the jury that liability depended on the product having been in a “defective condition unreasonably dangerous,” rather than only in a “defective condition,” because the full Restatement phrase could mislead the jury into thinking that liability was based on two requirements rather than just one. McAlpine, 16 P.3d at 1059.


49 Some jurisdictions do so quite explicitly. See, e.g., Pilcher v. Suttle Equip. Co., 223 S.W.3d 789, 794 (Ark. 2006) (plaintiff has burden of proof that product “was not only in a ‘defective condition’ but was also ‘unreasonably dangerous’”); Halliday v. Sturm, Ruger & Co., 792 A.2d 1145, 1150 (Md. 2002) (“[F]or a seller to be liable under § 402A, the product must be both in a ‘defective condition’ and ‘unreasonably dangerous’ at the time it was placed on the market.”); Williams v. Bennett, 921 So. 2d 1269, 1274 (Miss. 2006) (state’s products liability statute provides that “in a design defect claim, a manufacturer is not liable unless the design of the product is both defective and unreasonably dangerous”); Haase v. Badger Mining Corp., 682 N.W.2d 389, 395 (Wis. 2004) (strict liability in tort requires proof that product was (1) defective, and (2) unreasonably dangerous).

50 Some jurisdictions state that a defect must “make” or “render” the product unreasonably dangerous. See, e.g., Moss v. Batesville Casket Co., 935 So. 2d 393, 402 (Miss. 2006) (plaintiff must prove defect and also that defect made product unreasonably dangerous); Rainbeault v. Takeuchi Mfg. (U.S.), Ltd., 772 A.2d 1056, 1063 (R.I. 2001) (plaintiff must prove defect and that “defect rendered the product unreasonably dangerous”) (quoting Crawford v. Cooper/T. Smith Stevedoring Co., 14 F. Supp. 2d 202, 211 (D.R.I. 1998)).
phrases congruently, as dangerous beyond a consumer’s expectations.\textsuperscript{51} In states that have legislated products liability doctrine, some statutes use terminology suggesting a two-pronged liability standard\textsuperscript{52} while others ground liability more simply in terms of a product’s being “defective,” “unreasonably dangerous,” or some other single phrase without the burden of a second prong.\textsuperscript{53} Even courts in some jurisdictions whose legislatures adopted section 402A statutorily\textsuperscript{54} have avoided the trap of dividing the “defective condition unreasonably dangerous” concept into two separate elements.\textsuperscript{55} and there simply is no good reason to perpetuate a linguistic error grounded in a \textit{Restatement} that has now been superseded.

3. Comment j

That the three types of defect beget distinct and largely independent obligations would seem to be so obvious today as to be beyond dispute. Yet a sentence in one comment to section 402A, comment j, can be read quite literally to mean that a manufacturer who provides a warning—\textit{any} type of warning, no matter how deficient—eludes altogether the separate duty of safe design.\textsuperscript{56} Some courts still are haunted by this widespread misreading of comment j.\textsuperscript{57}

\textsuperscript{51} See \textit{Restatement (Second) of Torts} § 402A cmts. g & i (1965).
\textsuperscript{52} See, e.g., ARK. CODE ANN. § 4-86-102 (2001) (“The product was supplied . . . in a defective condition that rendered it unreasonably dangerous . . . .”); GA. CODE ANN. § 51-1-11(b)(1) (2000) (manufacturer subject to liability if product was “not merchantable and reasonably suited to the use intended”); MISS. CODE ANN. § 11-1-63(a)(ii) (West 2008) (“The defective condition rendered the product unreasonably dangerous . . . .”); N.D. CENT. CODE § 28-01.3-06 (2006) (“a defect or defective condition in the product which made the product unreasonably dangerous to the user or consumer”). Indiana’s curious statute adopts the “defective condition unreasonably dangerous” language of section 402A. IND. CODE § 34-20-2-1 (West 1976), and then defines “defective condition” as a condition (1) “not contemplated by . . . consumers,” and (2) that is “unreasonably dangerous.” IND. CODE § 34-20-4-1. Cf. TENN. CODE ANN. § 29-28-105(a) (2000) (“A manufacturer or seller of a product shall not be liable for any injury to a person or property caused by the product unless the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.”) (emphasis added).
\textsuperscript{55} See, e.g., McAlpine v. Rhone-Poulen Ag Co., 16 P.3d 1054, 1058 (Mont. 2000) (“[A] plaintiff is not required to show that a product is defective and also that it is unreasonably dangerous because establishing that a product is unreasonably dangerous is merely a means of proving that it is defective.”); see also McCathern v. Toyota Motor Corp., 23 P.3d 320, 329-32 (Or. 2001) (statutory consumer expectations test is sole standard for assessing whether product is in a “defective condition unreasonably dangerous” to user).
\textsuperscript{56} For a fuller discussion of this issue, see OWEN, \textit{PRODUCTS LIABILITY LAW}, supra note 1, § 6.2, from which this section draws.
\textsuperscript{57} See infra note 62.
Comment j to section 402A basically sets forth, in a largely noncontroversial manner, a product seller’s duty to warn of foreseeable hazards, but it concludes with this curious language:

Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in [a] defective condition, nor is it unreasonably dangerous. 58

This ambiguous language can be read literally, as several courts have done, to mean that any warning, no matter how inadequate, satisfies every duty of whatever type that a product seller has. Yet that would be quite preposterous, for it would allow a manufacturer of metal household fans to substitute a warning on the base of such a fan (“Watch out!”) for the fan’s protective cage.

For decades, the meaning of this curious sentence of comment j lay shrouded in the mists of history. Yet research has revealed that its actual meaning is far more limited than suggested above—that it really only means that sellers of inherently dangerous products like certain foods, alcohol, tobacco, and prescription drugs, in addition to supplying them free of impurities, need only warn consumers of any unavoidable, latent dangers such products foreseeably may contain. 59 This narrow interpretation has been shown to be correct because of the purpose of comments i, j, and k, all of which allay concerns that inherently hazardous but useful products like those just mentioned might give rise to liability under section 402A’s new, “strict” standard of liability for the harmful consequences of their unavoidable risks.

Although a handful of decisions have misinterpreted comment j as negating the general duty of safe design, 60 a great majority of courts, some explicitly rejecting comment j on this point, 61 hold that the separate forms of defect give rise to separate obligations that may independently support a products liability claim. 62 Thus, except in certain limited

58 RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (1965).
62 Even critics of the Third Restatement’s rejection of the warnings-trump-design approach acknowledge that the Third Restatement position is widely embraced by the courts. See, e.g., Richard C. Ausness, When Warnings Alone Won’t Do: A Reply to Professor Phillips, 26 N. KY. L. REV. 627, 638 (1999).
contexts, it is abundantly clear that a manufacturer is subject to liability for a product’s manufacturing defects, no matter how clear the product’s warnings or how perfect its design; for warning defects, no matter how perfect the product’s manufacture or how impeccable its design; and for design defects, no matter the precision of its manufacture or the abundance of its warnings. This latter point may be the most important, because of the lingering, perverse effects of comment j’s long tentacles in a number of jurisdictions.

“Decisively” repudiating the “primitive” interpretation of comment j that would accord warnings the power to override a manufacturer’s other safety responsibilities, the Third Restatement declares in no uncertain terms that the law does not permit a manufacturer to hide behind a warning in an attempt to insulate itself from its independent duty of safe design:

In general, when a safer design can reasonably be implemented and risks can reasonably be designed out of a product, adoption of the safer design is required over a warning that leaves a significant residuum of such risks. . . . Warnings are not . . . a substitute for the provision of a reasonably safe design.

The courts have quite colorfully expressed the same idea. For example, the Michigan Supreme Court has observed that “[a] warning is not a Band-Aid to cover a gaping wound, and a product is not safe simply

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because it carries a warning.” And the United States Court of Appeals for the District of Columbia Circuit has ruled that “[i]t is thus not correct that a manufacturer may . . . merely slap a warning onto its dangerous product, and absolve itself of any obligation to do more.” More succinctly, warnings do not trump design.

B. Conceptual Ghosts

Behind the textual ghosts of section 402A hide some conceptual ghosts, embedded in the design defect jurisprudence of many states, whose shadows continue to frustrate the adoption of the Third Restatement’s test for design defectiveness: (1) the consumer expectations test; (2) the Wade-Keeton test; and (3) over-broad formulations of the risk-utility test, including the Wade liability factors.

1. Consumer Expectations

How consumer expectations should figure in evaluating the sufficiency of a product’s design has bedeviled courts and commentators for at least half a century, and it remains one of the most problematic conceptual ghosts of section 402A. Resolving this issue appropriately, the Third Restatement relieves consumer expectations of its exalted place under the Second Restatement as the sole determinant of liability and relegates it to a mere factor in the risk-utility balance. Despite the correctness of the Third Restatement’s approach, judicial progression toward this ideal has been agonizingly slow and disorderly, and most courts and legislatures still have a long way to go in figuring out the proper role for consumer expectations in design defect litigation.

a. Source of Consumer Expectations Standard

Prior to the development of strict products liability in tort, courts applying strict liability in warranty drew from the law of contracts, grounded in the protection a purchaser’s expectations predictably generated by a product’s appearance and a manufacturer’s representations, express and implied. When William Prosser, the Reporter for the Restatement (Second) of Torts, searched for a foundation for the new doctrine of strict products liability in tort, it was only natural

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70 Rogers v. Ingersoll-Rand Co., 144 F.3d 841, 844 (D.C. Cir. 1998).
71 The consumer expectations test still plays a prominent role as a liability standard for design defectiveness in roughly half the states by common law (e.g., Connecticut, New Hampshire, Wisconsin) or statute (e.g., North Dakota, Ohio, Tennessee). See Owen, Products Liability Law, supra note 1, §§ 5.6, 8.3, and 8.6. A related standard, at least in name, exists in Europe. See id. § 1.4. See generally Douglas A. Kysar, The Expectations of Consumers, 103 Colum. L. Rev. 1700 (2003); Jerry J. Phillips, Consumer Expectations, 53 S.C. L. Rev. 1047 (2002).
that he would turn to the same consumer expectations basis of the warranty law cases that provided the sole authority (until Greenman v. Yuba Power Products, Inc.73) for the new tort doctrine. And as they began to apply section 402A to design defect cases, it was natural for the courts to adopt the warranty-based definition of liability provided in that section’s comments which define “defective condition” and “unreasonably dangerous” as dangerous beyond a consumer’s contemplations.74 Accordingly, most courts applying section 402A in the 1960s and early 1970s reasonably concluded that design defectiveness under section 402A should be tested according to the warranty-based standard of product safety gauged by “consumer expectations.”75

b. Problems with Consumer Expectations

It was not long, however, before the frailties of the consumer expectations standard in the design defect setting began to reveal themselves. Though measuring the adequacy of a design’s safety against consumer expectations was conventionally thought more protective of plaintiff interests than the risk-utility standard, courts in fact have applied the consumer expectations test most frequently to deny recovery in cases involving obvious design hazards.76 Obvious dangers—such as the risk to human limbs from an unguarded power mower or industrial machine—are virtually always contemplated or expected by the user or consumer, who thereby is necessarily unprotected by the consumer expectations test, no matter how probable or severe the likely danger or how simple and inexpensive the means of avoiding it. In such cases, the buyer got what he or she paid for, or the user engaged a danger that he or she expected, so that the risk of injury is placed on the buyer or user who chose to accept it, or on a third-party victim who had no say in the matter at all. The failure of the consumer expectations test to deal adequately with the obvious danger problem profoundly weakens the usefulness of the test as the sole basis for determining defects in design.

Another significant limitation on the usefulness of consumer expectations as a liability standard in design cases is the problem of identifying whose expectations should control in cases where the buyer or user controls the safety of other persons, such as children, patients, employees, or bystanders. In such cases, the foreseeable victims of dangerous designs depend solely upon the actions of other, imperfect humans, and the consumer expectations test relieves manufacturers of responsibility for failing to adopt simple design improvements to protect

73 377 P.2d 897 (Cal. 1963).
74 See supra note 53.
75 See generally Owen, PRODUCTS LIABILITY LAW, supra note 1, § 5.6 (explaining early development of consumer expectations test).
the types of persons they know to be ultimately placed at risk. Finally, there is the problem of vagueness in a consumer’s expectations concerning most complex designs, a problem further discussed below. All of these problems are resolved by the Third Restatement’s definition of design defect in risk-utility terms, a definition which allows for consideration of consumer expectations without giving it veto power over liability for design dangers for which manufacturers otherwise fairly should be responsible.

c. Partial Restrictions on Consumer Expectations

Although the consumer expectations test has now widely lost its status as the sole determinant of a product’s design defectiveness, this test continues to exert a heavy hand in many states. The shadow that the consumer expectations ghost has cast upon American products liability jurisprudence is best illustrated by its evolution in California—the state that generated Greenman v. Yuba Power Products, Inc., the only tort authority for section 402A, but also a state that, ironically, never adopted section 402A. In Barker v. Lull Engineering Co., the California Supreme Court in 1978 adopted a two-pronged design defect test which allowed a plaintiff to prevail on either of two standards, consumer expectations or risk utility. This approach has logical appeal because it protects the essential interests furthered by each test: contract law’s protection of the expectations of buyers and sellers in their private bargains, and tort law’s protection of the public welfare by requiring sellers to accord due respect to the safety interests of persons foreseeably endangered by defective products.

While Barker’s embrace of the risk-utility test and commensurate shift away from consumer expectations as the sole test was a laudable development, the retention of a dominant role for consumer expectations continued to haunt California’s courtrooms over time. In 1994, in Soule v. General Motors Corp., the California high court sharply restricted the consumer expectations prong to cases involving “simple” products or mechanisms (such as an unguarded fan), cases where expert testimony might not be necessary or appropriate. In all other design defect cases, such as most automotive crashworthiness cases (like Soule), plaintiffs were restricted to using the risk-utility test.

77 See supra text accompanying notes 15-16.
78 377 P.2d 897 (Cal. 1963).
79 573 P.2d 443 (Cal. 1978). For an expanded narrative of the California cases, see Vetri, supra note 11, at 1415-23.
80 Id. at 455-56.
81 Two years before Barker, the explicitly two-pronged approach was proposed in John E. Montgomery & David G. Owen, Reflections on the Theory and Administration of Strict Tort Liability for Defective Products, 27 S.C. L. REV. 803, 843-45 (1976).
82 882 P.2d 298 (Cal. 1994).
83 Id. at 308.
Soule’s simple versus complex product distinction had an initial appearance of genius in seeming to put each of the two design defect tests to its highest use, and a number of courts have followed this approach. Yet, Soule’s approach suffers from its retention of even a narrow, “simple-product” role for the consumer expectations test. A risk-utility test which retains consumer expectations as a factor (the approach of Third Restatement section 2(b)) fairly resolves just about any case where the facts and circumstances of an accident are knowable. In the small set of cases where knowledge of why an accident occurred is unavailable, the widely available “malfunction doctrine” provides plaintiffs with a fair and simple method for recovery in appropriate cases.

Soule’s primary example of a “simple product” case appropriate for the consumer expectations test is Campbell v. General Motors Corp., where a bus passenger was thrown from her seat during a sharp turn. The court there held that the consumer expectations test properly allowed a design defect claim without expert testimony, based on the absence of a grab bar in easy reach of the injured passenger’s seat, because jurors could decide the issue on the basis of common experience. This is true, of course, but the case could have been decided just as easily, and on a more principled risk-utility basis, had the plaintiff introduced evidence of where and how, precisely, grab bars should have been installed on this particular model bus.

The Soule court’s other examples of cases appropriate only for consumer expectations include cars that “explode while idling at stoplights,” that “roll over and catch fire in two-mile-per-hour collisions,” or new cars that suffer steering or brake failures. Putting aside the implausibility of some of these hypotheticals, and acknowledging that the consumer expectations test could reasonably resolve such simple product cases, the consumer expectations test is hardly necessary for this purpose in the great majority of states which subscribe to the malfunction doctrine mentioned above. In short, while the Soule court nicely explains why the risk-utility test is the only practical and principled way to resolve design defect problems in complex design cases, such as the automotive crashworthiness issues there involved, it fails to make a convincing case for retaining Barker’s consumer expectations prong for use in any type of case.

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85 On the malfunction doctrine, see Restatement (Third) of Torts: Prods. Liab. § 3 (1998); Owen, Products Liability Law, supra note 1, § 7.4.
86 649 P.2d 224, 225 (Cal. 1982).
87 Id. at 232-33.
88 Soule, 882 P.2d at 308 n.3.
89 Id. at 309.
Another problem with the Soule court’s relegation of simple product design cases to the consumer expectations test is that it unreasonably dooms plaintiffs to lose most such cases for the simple reason that the dangers in such “simple” cases typically are obvious to consumers, a problem addressed above. This was the conclusion of the Illinois Supreme Court in Calles v. Scripto-Tokai Corp., which recently addressed the Soule simple-product issue in a case where a young child used a utility lighter to set a deadly fire. The trial court in Calles granted summary judgment to the lighter’s manufacturer on the defendant’s argument that a lighter without a child-proof safety mechanism was a simple product, restricting the plaintiff to the consumer expectations test which required a ruling for the defendant. Reversing, the Supreme Court refused to limit its Barker-like two-pronged design defect test with Soule’s mandated use of the consumer expectations prong in simple-product cases.

While restricting plaintiffs to the consumer expectations test in simple-product cases may be justifiable in autonomy terms of promoting personal responsibility, courts unanimously crossed that policy bridge years ago by rejecting the patent danger rule in design defect cases in favor of social utility. In short, while California beneficially progressed away from the consumer expectations standard toward risk-utility in Barker and then further in Soule, it so far has stopped short of recognizing the virtue of the Third Restatement’s adoption in section 2(b) of a unitary risk-utility standard which folds consumer expectations into its family of factors.

Other courts, often haunted by the false yet widespread view of some plaintiffs’ lawyers that the consumer expectations test is more plaintiff-friendly than risk-utility, have moved away from consumer expectations to risk-utility by simply redefining “consumer expectations” in risk-utility terms. Potter v. Chicago Pneumatic Tool Co. is a prominent example of this approach. This case was brought by workers at a shipyard against the manufacturers of pneumatic hand tools for

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90 864 N.E.2d 249, 256-57 (Ill. 2007).
91 Id. at 254.
92 “[T]he dangers associated with a product that is deemed ‘simple’ are, by their very nature, open and obvious. . . . [T]he adoption of a ‘simple product’ exception is nothing more than the adoption of a general rule that a manufacturer will not be liable for open and obvious dangers.” Id. at 258-59.
93 Compare id., with id. at 265-66 (Karmeier, J, specially concurring).
94 See OWEN, PRODUCTS LIABILITY LAW, supra note 1, § 10.2.
95 See also Mikolajczyk v. Ford Motor Co., 901 N.E.2d 329, 360 (Ill. 2008) (reaffirming both its consumer expectations and risk-utility tests for use in design defect cases, but stating ambiguously: “When both tests are employed, consumer expectation is to be treated as one factor in the multifactor risk-utility analysis”).
96 694 A.2d 1319 (Conn. 1997).
97 Judge Wisdom first hinted at this approach in Welch v. Outboard Marine Corp., 481 F.2d 252, 254 (5th Cir. 1973).
injuries from excessive vibration of the tools. 98 Although the consumer expectations test was well established in Connecticut, the court was nevertheless troubled by the vagueness problem in consumer expectations concerning the safety of complex designs. 99 Following jurisdictions like Washington “that have modified their formulation of the consumer expectation test by incorporating risk-utility factors into the ordinary consumer expectation analysis,” 100 the Potter court reformulated its consumer expectations test in risk-utility terms. That is, particularly with complex products, Potter reasoned that consumers reasonably expect manufacturers to make fair and reasonable risk-utility decisions in designing their products. 101 While there is virtue in the Potter court’s adoption of risk-utility principles for evaluating a product’s design safety, a redefinitional approach adopted by a number of other courts, 102 this type of judicial sleight of hand muddies products liability jurisprudence. It would be far better if such courts would admit that they are abandoning the consumer expectations test for the many reasons the risk-utility test is preferable for judging the safety of a product’s design.

2. The Wade-Keeton Test

In fixing responsibility on manufacturers for defects in design, courts and commentators have always sought to avoid absolute liability, recognizing that the concepts of design safety and design danger are matters of degree involving trade-offs between a product’s usefulness, cost, and safety. The idea of a design defect, in other words, has long been understood to rest on the idea of reasonable balance. 103 Because negligence itself is grounded on reasonableness and balance, one is led to inquire whether and how negligence and strict liability may differ in design defect litigation. Accordingly, in the 1960s, products liability scholars began to search for a way to define strict liability for selling products with defects in design (and warnings) in a manner that distinguished the strict liability standard from mere negligence.

Other than Dean Prosser, the two most prominent tort law scholars in the 1960s who shared a special interest in products liability law were Dean Page Keeton of the University of Texas and Dean John Wade of Vanderbilt University. As modern products liability law was

98 Potter, 694 A.2d at 1324-25.
99 Id. at 1333.
100 Potter, 694 A.2d at 1333. The Potter court’s reference is to Seattle-First Nat’l Bank v. Tabert, 542 P.2d 774 (Wash. 1975), probably the first court explicitly to use this redefinitional, blended approach.
101 Potter, 694 A.2d at 1334.
103 See, e.g., Owen, Defectiveness Restated, supra note 14, at 754-61.
just beginning to emerge in the 1960s, the two deans, both Advisers to the American Law Institute’s Restatement (Second) of Torts, which was then in progress, offered separate versions of a similar definition of product defectiveness that distinguished negligence-based responsibility from liability called “strict” in a fundamental way. At the time, courts and commentators were just beginning to feel their way around the new precept of holding manufacturers of defective products “strictly” accountable for injuries to remote consumers.104 Little thought was being devoted to how the new field might be divided up, for purposes of the standard of liability, according to different types of defect. Thus, as with most other scholars of the day, the search by Deans Keeton and Wade for an appropriate “test” of strict liability was a search for a single liability standard that would embrace most products liability problems of the day.

The test developed by Deans Keeton and Wade, which in time became known as the “Wade-Keeton” test,105 quite simply was a negligence test stripped of scienter.106 That is, both scholars proposed defining defectiveness in terms of whether a manufacturer or other seller with full knowledge of a product’s dangerous condition would be negligent in selling it in that condition. By requiring a seller to know its product’s risks, commensurately relieving an injured plaintiff of the burden of proving the foreseeability of those risks, this test imposes on the seller “constructive knowledge” of any dangers its products may possess.107

In 1961, Dean Keeton authored a little article in the Texas Law Review in which he first articulated a liability test for product defects that was truly strict.108 He there proposed that a product should not be considered defective “if a reasonable man with full knowledge of all the properties and the danger therein, would continue to market the product because the utility of its use outweighs the danger.”109 In numerous other articles, from 1963 to at least 1980, Dean Keeton recommended and refined his test of design defectiveness.110 In his later articles, he emphasized that a design’s risks should be determined at the date of trial,

104 See OWEN, PRODUCTS LIABILITY LAW, supra note 1, §§ 5.2-5.4.
109 Id. at 210. “This is close to a negligence test but not the same” because “excusable ignorance of a defect or the properties of a product is immaterial . . . .” Id. In his full discussion, Dean Keeton mistakenly confuses the negative and positive formulations of the standard.
110 See infra note 120.
which of course imposes constructive knowledge on the manufacturer at the time of first design and sale: “A product is defectively designed if the magnitude of the danger in fact of the design as it is proved to be at the trial outweighs the utility of the design.”

Dean John Wade, in a 1965 article in which he cited both of Dean Keeton’s Texas articles, offered a similar strict liability test for ascertaining whether a product is unreasonably dangerous: “assuming that the defendant had knowledge of the condition of the product, would he then have been acting unreasonably in placing it on the market?” Further, Dean Wade remarked, “[i]f the test is equivalent to that of whether a reasonable prudent man would put it on the market if he knew of the dangers of this particular article, then the elements for determining negligence are relevant. We have here again the problem of balancing the utility of the risk against the magnitude of the risk.” In his famous 1973 article in the Mississippi Law Journal, Dean Wade restated his version of the test:

The simplest and easiest way [to define defectiveness] is to assume that the defendant knew of the dangerous condition of the product and ask whether he was then negligent in putting it on the market or supplying it to someone else. In other words, the scire is supplied as a matter of law, and there is no need for the plaintiff to prove its existence as a matter of fact. Once given this notice of the dangerous condition of the chattel, the question then becomes whether the defendant was negligent . . . . Another way of saying this is to ask whether the magnitude of the risk created by the dangerous condition of the product was outweighed by the social utility attained by putting it out in this fashion.

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111 W. Page Keeton, Products Liability—Design Hazards and the Meaning of Defect, 10 CUMB. L. REV. 293, 314-15 (1979). In this article, Dean Keeton noted that his test: differs from negligence primarily because, as proposed, the danger in fact as proven at trial determines whether a product is good or bad. . . . When the negligence of the defendant is in issue, it is perceivable danger at the time the product was designed that is the basis for weighing danger against utility. Therefore, a clear difference between proof of negligence and proof of defect as a basis for recovery is apparent.

Id. In a footnote, Dean Keeton pointed out that the difference between the two tests was the requirement for negligence that the danger be foreseeable, whereas, under his “strict” liability test, “it is irrelevant that the defendant did not know or had no reason to know of the danger.” Id. at 315 n.87.

112 John W. Wade, Strict Tort Liability of Manufacturers, 19 SW. L.J. 5 (1965). The article arose out of a products liability symposium the year before in Dallas, Texas where both deans presented papers.

113 Id. at 12-13 n.45.

114 Id. at 15.

115 Id. at 17.

116 Wade, supra note 106.

117 Id. at 834-35. Dean Wade also recommended how the jury might be instructed on this test:

A [product] is not duly safe if it is so likely to be harmful to person [or property] that a reasonable prudent manufacturer [supplier], who had actual knowledge of its harmful character would not place it on the market. It is not necessary to find that this defendant
Just why the “Wade-Keeton” test was labeled precisely as it was is shrouded in the mists of time, but its name is surely backwards. Not only does it appear to have been invented by Dean Keeton in 1961, four years before Dean Wade first proposed it, but Dean Keeton spread the theory far and wide. Dean Wade, who appears to have borrowed the idea for the test from Dean Keeton, may have offered the test in the law journals merely twice, in 1965 and 1973. By contrast, Dean Keeton proposed and explained the test in law journals and his products liability casebook at least a dozen times, from 1961 at least to 1980.

Be that as it may, a number of courts, themselves searching for a way to distinguish strict liability design claims (and warning claims) from those in negligence, picked up quite early on the Wade-Keeton hindsight test. By the 1980s, however, courts and commentators had begun to question the fairness and logic of imposing strict liability for design defectiveness, and the only other truly strict test of products liability, the consumer expectations test, had already begun its decline. Recognizing the problems in forcing truly strict liability on manufacturers for dangers in design, Dean Wade and Dean Keeton, in the early 1980s, both repudiated the test that bore their names: Dean Wade claimed that he never meant what he had said, and Dean Keeton admitted that he no longer believed what he had said. The Products Liability Restatement, adopting a negligence-like risk-utility standard of liability, based on risks that are foreseeable at the time of sale, explicitly rejects the Wade-Keeton test and notes with pith: “The idea has not worn

had knowledge of the harmful character of the [product] in order to determine that it was not duly safe.

Id. at 839-40.

118 The dual origins of the test were noted at least as early as 1974, see Phillips v. Kimwood Mach. Co., 525 P.2d 1033, 1036 n.6 (Or. 1974), and the “Wade-Keeton” moniker appeared in print no later than 1978. See Cepeda v. Cumberland Eng’g Co., 386 A.2d 816, 829 (N.J. 1978); see also Birnbaum, supra note 19, at 619 n.125.

119 For citations to these articles, see OWEN, PRODUCTS LIABILITY LAW, supra note 1, § 8.7 nn.11, 13, 14 & 16.

120 See, e.g., Dorsey v. Yoder Co., 331 F. Supp. 753, 759-60 (E.D. Pa. 1971), aff’d, 474 F.2d 1339 (3rd Cir. 1973) (stating test for strict products liability in tort as “whether a reasonable manufacturer would continue to market his product in the same condition as he sold it to the plaintiff with knowledge of the potential dangerous consequences the trial just revealed”) (emphasis omitted) (citing W. Page Keeton, Manufacturer’s Liability: The Meaning of “Defect” in the Manufacture and Design of Products, 20 SYRACUSE L. REV. 559, 568 (1969)); see also Phillips, 525 P.2d at 1036, where the court formulated the test as follows:

A dangerously defective article would be one which a reasonable person would not put into the stream of commerce if he had knowledge of its harmful character. The test, therefore, is whether the seller would be negligent if he sold the article knowing of the risk involved. Strict liability imposes what amounts to constructive knowledge of the condition of the product.

Id.


122 See W. P. KEETON et al., PROSSER AND KEETON ON TORTS 697-98 n.21 (5th ed. 1984).
well with time.”123 Most courts focusing on the state-of-the-art issue have agreed, rejecting the hindsight test and limiting a manufacturer’s responsibility to risks that are foreseeable.124

Despite the rejection of the Wade-Keeton test by the scholars who gave it birth, some courts continued to adopt the test after its “official” demise in the early 1980s,125 and others have continued rotely to restate the test,126 and even proudly to reaffirm allegiance to it while knowing it has died.127 While one state legislature reversed the judicial adoption of the Wade-Keeton test,128 another affirmatively adopted it,129 and one wonders at its staying power in scattered decisions across the nation. The ghost of the Wade-Keeton test continues to haunt judicial halls, but its time has come and gone.

C  Risk-Utility Ghosts

1. Principles of Risk-Utility Balancing

The purpose of any design liability test, of course, is to separate bad products from good, to hold accountable manufacturers of products designed with excessive risks, and to protect manufacturers of products designed with risk of unforeseeable danger.

123 See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 Reporters’ Note, cmt. m (1998).
124 While the Wade-Keeton test sometimes arises in design defect cases, it more often arises in the warning context. See, e.g., Powers v. Taser Int’l, Inc., 174 P.3d 777, 779-84 (Ariz. Ct. App. 2007) (declining to extend Arizona’s hindsight test from design to warning defect cases, and holding by implication that the duty to warn extends only to foreseeable risks); Vassallo v. Baxter Healthcare Corp., 696 N.E.2d 909, 924 (Mass. 1998) (silicone breast implants; duty to warn limited to foreseeable risks); see also OWEN, PRODUCTS LIABILITY LAW, supra note 1, § 10.4.
125 See, e.g., Sternhagen v. Dow Co., 935 P.2d 1139, 1144, 1147 (Mont. 1997) (adopting Wade-Keeton constructive knowledge test for strict products liability, and holding that “knowledge of any undiscovered or undiscoverable dangers should be imputed to the manufacturer”).
127 See Brooks v. Beech Aircraft Corp., 902 P.2d 54, 63 (N.M. 1995) (recognizing that the Wade-Keeton test is now a misnomer, but reaffirming it where the facts did not show a true advancement in the technological state of the art):

[In] those hypothetical instances in which technology known at the time of trial and technology knowable at the time of distribution differ—and outside of academic rationale we find little to suggest the existence in practice of unknowable design considerations—it is more fair that the manufacturers and suppliers who have profited from the sale of the product bear the risk of loss.

The standard New Mexico jury instruction applies the Wade-Keeton test. See id. at 62.
128 In 1979, the Oregon legislature abolished the Wade-Keeton test, which that state’s Supreme Court had adopted in Phillips v. Kimwood Mach. Co., 525 P.2d 1033 (Or. 1974), by legislatively adopting section 402A of the Restatement (Second) of Torts, including its comments which define defectiveness in consumer contemplation terms. See Or. REV. STAT. § 30.920 (2007).
that are safe enough. The immense basket of complexities involved in deciding how properly to design a product, and in judicially reviewing such decisions after a product accident—a basket that includes such diverse considerations as consumer preferences for utility, cost, and safety; engineering constraints; expense; and human physical and psychological characteristics—suggests the need for a liability test that is subtle, intelligent, and robust. Put otherwise, determining whether a product design is safe enough, or whether instead it should include more safety, involves a sophisticated balance of such factors as engineering technology, cost, the magnitude of the risk, the extent to which a design change might reduce the risk, the effect of such a change on the product’s utility, and the ability of consumers to perceive and control the risk themselves.

As previously addressed, rather than resting on the sole pillar of consumer expectations, the quality of any particular design decision is usually best determined by a broad, evaluative balance of the costs and benefits of a particular untaken precaution.

Principles of equal freedom, utilitarianism, and economic efficiency inherent in the tort law system of corrective justice support the use of cost-benefit balancing precepts to test the propriety of design decisionmaking, and such balancing precepts also reflect simple common sense. Nearly all reasoned decisions reflect a weighing of the advantages and disadvantages expected to flow from a contemplated course of action, and product design decisions are no different. A responsible member of society contemplating action will weigh the expected costs and benefits to others as well as to himself, as reflected in Learned Hand’s celebrated $B < P \times L$ formula in United States v. Carroll Towing Co. In the products liability context, a manufacturer fairly may be charged with maximizing not only profits but also consumer welfare, which is comprised of product usefulness, desirability, affordability, and

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131 To say nothing of other factors such as aesthetics, reliability, durability, ease and cost of operation, maintenance, and repair.
133 See supra text accompanying note 80.
134 See generally Owen, Moral Foundations, supra note 15, at 479.
135 See, e.g., Letter from Benjamin Franklin (Sept. 19, 1772) (suggesting, as an aid to rendering difficult decisions, that one list and consider “all the reasons pro and con” and contemplate “where the balance lies”), reprinted in EDWARD M. GRAMLICH, BENEFIT-COST ANALYSIS OF GOVERNMENT PROGRAMS 1-2 (1981); see also Oliver Wendell Holmes, Jr., The Path of the Law, 10 HARV. L. REV. 457, 474 (1897) (advising that “for everything we have to give up something else, and we are taught to set the advantage we gain against the other advantage we lose”).
136 159 F.2d 169, 173 (2d Cir. 1947) (expressing the concept algebraically as negligence being implied if $B < P \times L$, where $B$ is the burden or cost of avoiding accidental loss, $P$ is the probability of loss absent $B$, and $L$ is the expected magnitude or cost of such loss). For a considered review of the origins of risk-benefit analysis in early American tort law and its path into modern products liability law, see Michael D. Green, Negligence = Economic Efficiency: Doubts >, 75 TEX. L. REV. 1605 (1997).
safety to consumers and third parties. Testing the propriety of a manufacturer’s design decisions on a cost-benefit basis thus draws from principles of reasonableness, optimality, and balance, which support both the negligence and strict liability standards for judging the quality of product design decisions.

2. Judicial Confusion in Risk-Utility Formulations

While courts increasingly comprehend that ascertaining design defectiveness in products liability cases requires some kind of “risk-utility” balancing, they do not seem to understand just what that balance should entail. In case after case, courts uphold verdicts rooted in risk-utility proof and argument—on the balance of the costs and benefits of some untaken design precaution—without focusing closely on just how that balance properly should be formulated. And when most courts and commentators do attempt to define the balance, to state with some precision just what should be balanced against what, they quickly lose themselves, conceptually and linguistically, in a tangled thicket of “risks” and “benefits” and “costs” and “utility.” Balancing bedlam, that is, defines the interior of modern design defect jurisprudence.

Section 2(b) of the Restatement (Third) of Torts: Products Liability rests squarely on risk-utility balancing, as seen above, in defining design defect in terms of whether, on balance, some safer alternative design was better than the manufacturer’s chosen design. Yet, except in one Reporters’ Note, the Third Restatement does not focus closely on how a proper design defect balancing test should be formulated. A comment to section 2(b) states broadly that the risks and benefits of the chosen and alternative designs should somehow be compared and adopts the popular “grab-bag” approach, throwing into the balance nearly everything in sight.

138 See Owen, Defectiveness Restated, supra note 14, at 753-61 (explaining the principles of reasonableness, optimality, and balance and the practical equivalence of negligence and strict liability in the design defect context).
139 See, e.g., Sperry-New Holland v. Prestage, 617 So. 2d 248, 255 (Miss. 1993) (stating that risk-utility has become the “trend in most federal and state jurisdictions” and adopting the risk-utility standard for design defect cases).
140 See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmts. a, b, c, d, e & f (1998) (explaining the liability rule to be a risk-utility balancing test).
141 See id., § 2 Reporters’ Note, cmt. f[1].
142 Comment f provides in part:

A broad range of factors may be considered in determining whether an alternative design is reasonable and whether its omission renders a product not reasonably safe. The factors include, among others, the magnitude and probability of the foreseeable risks of harm, the instructions and warnings accompanying the product, and the nature and strength of consumer expectations regarding the product. The relative advantages and disadvantages of the product as designed and as it alternatively could have been designed may also be considered. Thus, the likely effects of the alternative design on production costs; the effects of the alternative design on product longevity, maintenance, repair, and esthetics;
Just what should be balanced against what in design defect cases? Should all the risks of the manufacturer’s chosen product design, viewed in the aggregate, be balanced against all of that same design’s aggregate utility? Or is the proper balance between the aggregate risks and utility of the alternatively designed product the plaintiff claims ought to have been adopted? Does the true balance require a comparison of the risks and utility of the chosen design, on the one side, against the risks and benefits of the proposed alternative design, on the other? Or should courts more narrowly balance the incremental risks (or costs) and utility (or benefits) resulting solely from altering the design in the particular manner proposed by the plaintiff? Balancing questions like these penetrate to the very heart of design defect decisions, but few courts have focused on the definitional confusion, much less attempted to unravel the mysteries inside conflicting formulations of the balancing equation.143

Surveys of judicial opinions applying the risk-utility test to design defect determinations reveal a vast disparity of definition.144 From court to court, and from judge to judge, definitions of the risk-utility test vary widely. Even within the same opinion, it is not unusual for a single judge to enunciate the test in two, three, or even more different ways,145 demonstrating the definitional problem and the need for definitional focus. The existence of such disparity surrounding the central products liability issue hardly inspires confidence in the “law” and surely is a cause for despair by those bound to govern their conduct according to its precepts.

3. “Factoritis”

3. The Disease

Appellate courts too often open a Pandora’s box by formulating the risk-utility calculus far too widely, in a scatter-shot manner that leaves no risk-utility stone unturned.146 Such approaches open the balancing calculus to the sky by listing large numbers of possibly relevant “factors” that a risk-utility calculation might contain. Courts infected with this temptation invariably contract an insidious disease that might fairly be labeled “factoritis.”

Id. § 2 cmt. f.

For elaboration, see Owen, Risk-Utility Balancing, supra note 16, and Owen, Toward a Proper Test for Design Defectiveness, supra note 4, from which this discussion draws.

See, e.g., RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 Reporters’ Note, cmt. d (1998); Owen, Risk-Utility Balancing, supra note 16; Vargo, supra note 16.

See, e.g., Nichols v. Union Underwear Co., 602 S.W.2d 429, 434 (Ky. 1980) (Lukowsky, J., concurring) (defining risk-utility in four separate ways).

This section draws from OWEN, PRODUCTS LIABILITY LAW, supra note 1, § 8.4.
Banks v. ICI Americas, Inc.\textsuperscript{147} is a good example. There, in adopting a risk-benefit test for evaluating design defectiveness, the Georgia Supreme Court observed that “no finite set of factors can be considered comprehensive or applicable under every factual circumstance, since such matters must necessarily vary according to the unique facts of each case.”\textsuperscript{148} Pertinent to the “reasonableness” of a manufacturer’s chosen design are “[s]uch diverse matters as competing cost trade-offs, tactical market decisions, product development and research/testing demands, the idiosyncrasies of individual corporate management styles, and federal and other regulatory restrictions . . . .”\textsuperscript{149} The court offered a “non-exhaustive list of general factors,” including:

the usefulness of the product; the gravity and severity of the danger . . . ; the likelihood of that danger; the avoidability of the danger, i.e., the user’s knowledge of the product, publicity surrounding the danger, or the efficacy of warnings, as well as common knowledge and the expectation of danger; the user’s ability to avoid danger; the state of the art . . . ; the ability to eliminate danger without impairing the usefulness of the product or making it too expensive; and the feasibility of spreading the loss in the setting of the product’s price or by purchasing insurance.\textsuperscript{150}

The court then listed the “[a]lternative safe design factors” also pertinent to the issue: “the feasibility of an alternative design; the availability of an effective substitute for the product which meets the same need but is safer; the financial cost of the improved design; and the adverse effects from the alternative.”\textsuperscript{151} Finally, the court set forth “benefit factors” that may also be considered in the balancing test: “the appearance and aesthetic attractiveness of the product; its utility for multiple uses; the convenience and extent of its use, especially in light of the period of time it could be used [safely]; and the collateral safety of a feature other than the one that harmed the plaintiff.”\textsuperscript{152}

No doubt many (perhaps most) factors in this long list\textsuperscript{153} should be considered by manufacturers making fully informed decisions on how to design their products. And most of the listed factors are legitimate issues in different kinds of design cases confronting courts over time. But such a wide and open-ended “catalogue of factors” provides little help for adjudicating the design defect issue in particular cases,\textsuperscript{154} and a practicable “test” for design defectiveness must be framed far more

\textsuperscript{147} 450 S.E.2d 671 (Ga. 1994). The Georgia court is not alone in succumbing to the temptation to list a broad range of risk-utility factors. A recent example is Calles v. Scripto-Tokai Corp., 864 N.E.2d 249, 260-61 (Ill. 2007).

\textsuperscript{148} Banks, 450 S.E.2d at 675.

\textsuperscript{149} Id.

\textsuperscript{150} Id. at 675 n.6.

\textsuperscript{151} Id.

\textsuperscript{152} Id.

\textsuperscript{153} Thirty-three, by my count.

\textsuperscript{154} For an effort, see Moore v. ECI Management, 542 S.E.2d 115, 120 (Ga. Ct. App. 2000), applying the multi-factor risk-utility test to a washer/dryer design defect claim.
narrowly in terms of the costs and benefits of a particular untaken precaution normally at issue in a design defect case.

b. The Wade Factors

Over-broad formulations of risk-utility analysis for design defect decisionmaking are traceable to a widely quoted set of liability factors proposed in an early, influential article written by Dean John Wade,\textsuperscript{155} On the Nature of Strict Tort Liability for Products.\textsuperscript{156} Dean Wade proposed that a court consider the following list of factors:

1. The usefulness and desirability of the product—its utility to the user and to the public as a whole.
2. The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.
3. The availability of a substitute product which would meet the same need and not be as unsafe.
4. The manufacturer’s ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
5. The user’s ability to avoid danger by the exercise of care in the use of the product.
6. The user’s anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.
7. The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.\textsuperscript{157}

Searching for guidance in the murky sea of design defectiveness, appellate courts quickly grasped onto the Wade factors for use in design defect cases.\textsuperscript{158} However, while courts across the continent have authoritatively \textit{quoted} these six or seven\textsuperscript{159} factors for decades,\textsuperscript{160} only infrequently do courts actually try to \textit{apply} the factors in assessing whether a particular product was defective in design. Even more rarely has an application of these factors actually \textit{helped} a court determine

\begin{itemize}
\item Indeed, the \textit{Banks} court’s “non-exhaustive list of general factors,” \textit{see supra} notes 147-150 and accompanying text, is largely a restatement of Dean Wade’s seven factors.\textsuperscript{156}
\item \textit{Wade}, \textit{supra} note 106, at 837-38.
\item \textit{Id.}\textsuperscript{157}
\item \textit{See, e.g.}, Cepeda v. Cumberland Eng’g Co., 386 A.2d 816, 826-27 (N.J. 1978), \textit{overruled in part on other grounds} by Suter v. San Angelo Foundry & Mach. Co., 406 A.2d 140 (N.J. 1979); Roach v. Kononen, 525 P.2d 125, 129 (Or. 1974) (“We agree that these factors should be considered by a court before submitting a design defect case to the jury. Also, proof of these factors bears on the jury’s determination of whether or not a given design is defective.”).
\item For an inspired reduction of the Wade and other factors, see Montgomery & Owen, \textit{supra} note 81, at 818, which propose four elegantly crafted factors.\textsuperscript{159}
\item Some courts leave out the seventh factor, loss-spreading, as discussed below.\textsuperscript{160}
\end{itemize}
design defectiveness; more typically, a court attempting to apply the factors has become ensnared in one of their many traps.

Despite some early favorable commentary on the Wade factor approach, commentators now view most of the Wade factors as problematic. The first factor, the utility of the product, has been criticized on political grounds for allowing courts to second-guess the market as to the desirability of different kinds of products. In particular, this factor seems to reflect "the fallacy that ‘essentials’ provide utility whereas ‘luxuries’ do not." Factor two, on the other hand, which embraces the \( P \times L \) (risk of harm) side of the Hand formula discussed above, is vital to intelligent cost-benefit decisionmaking.

The third factor, the availability of a substitute product, is difficult to interpret. If it is read narrowly to mean the availability of a substitute design feature, then it properly introduces the necessarily central question in design defect analysis of the availability of a feasible and otherwise reasonable alternative design feature, a crucial issue previously examined. If, on the other hand, this factor is interpreted literally, as Dean Wade probably intended, the availability of substitute "products" falls victim to the flaw infecting the first factor by inviting a judge or jury to engage in social engineering of the highest, and most dubious, order. Factor four, the manufacturer’s ability to eliminate the risk without unduly sacrificing price or utility, properly raises the relevant issues of the costs and benefits of altering the chosen design to eliminate the risk. Indeed, factors two and four together form the heart of proper cost-benefit analysis in design defect litigation.

Factors five and six raise important issues on the proper allocation of responsibility for product accidents between manufacturers and users. Factor five, the user’s ability to avoid the risk, importantly introduces the issue of consumer responsibility into the matrix. Its only fault lies in its tendency to mislead courts, and especially juries, into

161 For an unusual example of a decision astutely applying the factors, see Monahan v. Toro Co., 856 F. Supp. 955 (E.D. Pa. 1994).
163 See, e.g., Montgomery & Owen, supra note 81, at 895.
165 Viscusi, supra note 164, at 582.
166 See id. at 583.
167 See Owen, Products Liability Law, supra note 1, § 8.5.
confusing the proper issue of how users generally may act, on the one hand, with the improper issue of whether the particular plaintiff behaved appropriately in using the particular product in the manner that led to the accident, on the other. The sixth factor, the user’s awareness of the danger and avoidance techniques, is similarly problematic. Its most reasonable interpretation appears to be subjective, which then introduces a plaintiff’s conduct into the prima facie case of design defectiveness, rather than leaving it as an affirmative defense where it normally belongs. If, on the other hand, this factor is interpreted with some strain as a broader inquiry into the extent to which consumers generally may be expected to comprehend a product’s dangers, it would fit nicely with (though should precede) factor five.

The final Wade factor, number seven, is especially problematic as a factor for design liability decisionmaking. As a rationale for a generalized doctrine of strict tort liability for manufacturers, “loss-spreading” (“insurance” by another name) has been viewed in recent decades with increasing skepticism. If the strict products liability litigation system is to serve as a substitute for private and social insurance, it must force people to buy types and levels of insurance against product accidents that many neither need nor want, and at excessive cost. By so requiring consumers to pay higher prices for products as a form of product accident insurance, loss-spreading may be seen as both unfair and inefficient. Poor people pay regressively unfair premiums for this form of insurance, or “taxes” when the tort system substitutes for social welfare insurance. Moreover, the litigation method for determining whether particular accidents are covered by the system (whether a product is “defective,” whether jurisdiction is proper, whether any defenses apply, etc.) is exceedingly time-consuming, enervating, and expensive. For the most serious accidents, where a victim’s compensation needs are immediate and immense, it may take five or even ten years to complete the litigation compensation process.

168 See, e.g., Johansen v. Makita U.S.A., Inc., 607 A.2d 637, 645-46 (N.J. 1992) (trial court should have instructed jury “to not consider evidence concerning plaintiff’s lack of care in deciding the question of design defect,” because the fifth factor pertained only to users generally, not to particular plaintiff’s conduct). While irrelevant to duty, the propriety of a particular user’s conduct may well be relevant to the misconduct defenses.


170 See, e.g., Owen, Moral Foundations, supra note 15, at 484-93.

171 See, e.g., Viscusi, supra note 164, at 584-91.

172 George Priest explains that the level of insurance “premiums” manufacturers add to product prices regrettably penalizes the poor who stand to gain far less in damages for lost earnings than wealthy victims who pay the same premium for much higher coverage. See, e.g., George L. Priest, The Current Insurance Crisis and Modern Tort Law, 96 YALE L.J. 1521, 1558-60 (1987).

173 See, e.g., Mesman v. Crane Pro Servs., Div. of Konecranes, Inc., 409 F.3d 846 (7th Cir. 2005) (Ind. Law), Mesman v. Crane Pro Servs., 512 F.3d 352 (7th Cir. 2008) (on appeal after
And in the end, the victim may lose the case and end up with no compensation whatsoever. In short, design defect liability is a poor means for society to spread the losses that result from product accidents.

As a factor for helping assess whether particular products are defective, loss-spreading is even more seriously flawed, because it always points toward liability: a finding of design defectiveness resulting in a judgment for the plaintiff always spreads the plaintiff’s loss, at least among the shareholders of the manufacturer. Yet products liability law self-consciously limits a manufacturer’s liability to designs that are defective in order to distinguish between products whose design dangers are acceptable from those that are not, as previously discussed. Including loss-spreading, or any other factor that always weighs on the same side of the scales, can only subvert the process of fair and rational adjudication of design defectiveness. As a result, this seventh, loss-spreading factor sometimes is excluded from the list as inappropriate.

It is understandable that in the early days of modern products liability courts looked for guidance to the Wade factors, which had an aura of logic, fairness, and common sense. Indeed, modern products liability law has absorbed the best aspects of Dean Wade’s factors in a variety of ways. But the design defect jurisprudence of recent years has moved well beyond the place it was when Dean Wade conceived it at the time section 402A was just getting off the ground. Even from the start, courts have done little more than pay lip service to the Wade factors, which now are well past their prime. Typically, courts recite the factors and then move on to a far narrower and appropriate cost-benefit analysis of some particular design feature offered by the plaintiff as a safer alternative. In short, by ridding risk-utility formulations of “catalogues of factors,” design defect definitions are cured of the insidious “factoritis” disease.
4. Perils of Macro-Balancing

Worse, perhaps, than factoritis has been a disturbing long-term trend among appellate courts to articulate risk-utility definitions in a manner that is not only contrary to logic, but contrary to how courts and juries actually make design defect determinations.\(^{178}\) Probably most appellate courts defining risk-utility have articulated a global type of balance for determining the adequacy of a design’s safety, an evaluative method that might be characterized as “macro-balancing.” Under this approach, the defect question is framed in terms of a comparison between a product’s entire bundle of risks and the product’s entire bundle of utility. That is, the balance of good and bad in a product is examined in the aggregate: if the product’s aggregate risk exceeds its aggregate social utility, it is defective; if its aggregate utility exceeds its aggregate risk, the product is nondefective.\(^{179}\)

Although courts rarely endorse this form of global balancing explicitly,\(^{180}\) the manner in which they generally describe the risk-utility test strongly suggests this interpretation. Thus, a global balance is asserted when a court refers to “balancing the overall risk and utility of a product,”\(^{181}\) and a global balance appears contemplated when a court states that design defect determinations require “balancing the utility of the product against the risks involved in its use.”\(^{182}\) Unfortunately, courts widely use these and other macro-balance risk-utility formulations to define design defectiveness.\(^{183}\)

Defining design defectiveness in macro-balance terms poses a variety of problems, not the least of which is that this form of definition fails to state the issue as it ordinarily is litigated in courtrooms across the nation. This situation presents a fundamental jurisprudential problem

\(^{178}\) This problem is explored in Owen, Risk-Utility Balancing, supra note 16, and Owen, Toward a Proper Test for Design Defectiveness, supra note 4.

\(^{179}\) The widespread notion that a product’s aggregate social utility and aggregate risk may have some relevance to design defectiveness may find its roots in two of Dean Wade’s famous seven factors, discussed above: “(1) The usefulness and desirability of the product—its utility to the user and to the public as a whole;” and “(2) The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.” Wade, supra note 106, at 837.


\(^{181}\) Penick v. Christensen, 912 S.W.2d 276, 283 (Tex. App. 1995) (emphasis added); see also Denny, 662 N.E.2d at 736 (ascertaining defectiveness “requires a weighing of the product’s dangers against its over-all advantages”).


\(^{183}\) See Banks v. ICI Ams., Inc., 450 S.E.2d 671, 673 (Ga. 1994) (finding that an “exhaustive review of foreign jurisdictions and learned treatises” reveals “a general consensus regarding the utilization in design defect cases of a balancing test whereby the risks inherent in a product design are weighed against the utility or benefit derived from the product”). Commentators have not been immune from this disease, also sometimes speaking loosely in macro-balance terms. See, e.g., W. Page Keeton et al., Prosser & Keeton on the Law of Torts § 99, at 699 (W. Page Keeton ed., 5th ed. 1984) (“Under [the ‘danger-utility test’] approach, a product is defective as designed if, but only if, the magnitude of the danger outweighs the utility of the product.”).
because the liability standard announced by the appellate courts contravenes the law as it actually is applied. The issue normally litigated is not whether an accident-producing product was globally good or bad for society. Instead, the question typically at issue is whether the manufacturer might have avoided the accident (and possibly others) by changing the product’s design in some manner that was relatively inexpensive, that did not unduly diminish the product’s usefulness, and that did not introduce excessive new dangers which the chosen design did not possess. These litigated issues also involve a balance, of course, but one far narrower than that contemplated by the macro-balance formulations often articulated by appellate courts in their design defect risk-utility definitions.

5. A Reasoned Micro-Balance Approach

To distinguish the narrow courtroom balance from its mischievous big sister, macro-balance, one might label the former, proper approach a “micro-balance.” The micro-balance scales care not about the overall risk, utility, or quality of a product but seek only to evaluate the marginal costs and benefits of adopting the particular alternative design feature proposed by plaintiff in order to determine whether its omission may be viewed as having rendered the product defective. Thus, micro-balancing—not macro-balancing—is revealed to be the form of risk-utility balancing actually and properly used by lawyers and trial judges in the litigation of design defect cases.

As with negligence determinations, the risk-utility micro-balance involved in design defect determinations focuses on the costs and benefits of adopting the particular alternative design feature proposed by the plaintiff—not a global macro-balance of all risks and benefits of either the chosen or the alternative design. Thus, if the plaintiff frames the issue in terms of the defectiveness of an outboard

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184 When confronting this issue head on, usually in the context of inherent risks (sometimes characterized as “product category” liability), courts almost always refuse to adjudicate the global desirability of a product in relation to its detriments, viewed as a whole. See Owen, Products Liability Law, supra note 1, § 10.3.


186 In the terms of the Restatement (Third) of Torts: Products Liability, the test is whether the omission of “a reasonable alternative design . . . renders the product not reasonably safe.” Restatement (Third) of Torts: Prods. Liab. § 2(b) (1998).


188 Insightfully explained in Grady, supra note 4, at 139.
motor not equipped with a propeller guard, the proper inquiry concerns the balance of costs and benefits that would result from adding such a guard—not the risks and benefits of outboard motors generally, without such guards, and certainly not the broader risks and benefits of power boats propelled by outboard motors. Similarly, a plaintiff’s proposed design feature might involve removing some hazardous feature of the product, such as a dangerous hood ornament on a car. Here, the only pertinent costs and benefits would concern the removal of the hood ornament from the car—not the broader risks and benefits of cars with sporty, but dangerously sharp, hood ornaments. This proper form of micro-balancing analysis describes quite well how design defect cases are actually litigated in the trial courts, but it does not comport at all with how most appellate courts define the balance.

6. Formulating a Proper Cost-Benefit Test

Just as courts and commentators have spared no ink in illustrating the variety of ways in which design defects may be defined incorrectly, so too are there a multitude of ways to define a test correctly. To fall into the “good” definitional pot rather than the “bad” pot requires that a liability formulation build properly upon micro-balance principles by framing the liability issue in terms of the marginal precaution costs and marginal safety benefits that should follow a move from the chosen to the alternative design. Such a “bare-bones” definition might look something like the following:

A product is defective in design if the safety benefits of an alternative design would have exceeded its costs.

A more robust test might look something like this:

A product is defective in design if the safety benefits of an alternative design were foreseeably greater than the resulting costs, including any diminished usefulness or diminished safety.

And a softer, more flexible formulation might be phrased along these lines:

A product is defective in design if it was not designed with reasonable safety, such that the safety benefits of an alternative design were foreseeably greater than the resulting costs, including any diminished usefulness or diminished safety.

There plainly is no single “proper” way to define a micro-balance test,191 but each of these formulations offers an appropriate micro-balance standard for assessing design defectiveness in most cases.192 Each of these risk-utility (or “cost-benefit”)193 formulations reflects and builds upon the liability definition of the Third Restatement, and any formulation that applies similar cost-benefit, micro-balance principles should provide a coherent frame for design defect determinations.

IV. CONCLUSION

It is now sixteen years since the Reporters first offered their definition of design defects in Restatement (Third) of Torts: Products Liability section 2(b), a definition the ALI formally promulgated one decade in the past. Resting squarely on risk-utility—on a comparison of the costs and benefits of a “reasonable design alternative”—the formulation of design defect in section 2(b) consigns consumer safety expectations to a heap of contingent factors that may be relevant in particular situations. While a number of legislatures and courts have accepted some version of this untaken precaution method for evaluating design safety, many courts so far have rejected the Third Restatement’s explicit risk-utility approach to design defect determinations. Why more courts have not embraced section 2(b)’s commonsense untaken precaution view of design defectiveness may be explained in terms of a large number of textual and conceptual ghosts still lurking in the shadows after decades of section 402A jurisprudence, ghosts which may be expected to continue to haunt design defect decisions across the land for years to come.

191 Indeed, the very concept of a “perfect” test is surely rubbish.
192 Similar formulations are examined in Owen, Toward a Proper Test for Design Defectiveness, supra note 4.
193 For an explanation of why the “cost-benefit” term is preferable to “risk-utility,” see id. at 1692-97.
Post-Sale Duties

THE MOST EXPANSIVE THEORY IN
PRODUCTS LIABILITY

Kenneth Ross & Professor J. David Prince†

I. INTRODUCTION

Manufacturing, designing, and selling safe products does not totally satisfy a product manufacturer’s legal duties. A few U.S. courts, starting in 1959, held that manufacturers have a duty to warn product users when they learn of risks in their product after sale even if the product was not defective when sold.¹ A number of courts, on the other hand, held that there was no such duty.²

In the 1990s, the American Law Institute (“ALI”) considered the status of products liability law in the United States. This culminated in the publication of the Restatement (Third) of Torts: Products Liability (“Restatement (Third)”).³ The Institute had to decide whether enough precedent existed to support a section on the “post-sale duty to warn” in this enunciation of products liability law.

The law professors who served as the drafters of the Restatement (Third) (“Reporters”), considered all of the cases through 1997, and despite a split of authority, felt there was sufficient support in case law and common sense to support a “post-sale duty to warn in the

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¹ Cover v. Cohen, 461 N.E.2d 864, 871 (N.Y. 1984) (“Although a product [may] be reasonably safe when manufactured and sold and involve no then known risks of which warning need be given, risks thereafter revealed by user operation and brought to the attention of the manufacturer or vendor may impose upon one or both a duty to warn.” (citations omitted)); see also Comstock v. Gen. Motors Corp., 99 N.W.2d 627, 634 (Mich. 1959); Walton v. Avco Corp., 610 A.2d 454, 459 (Pa. 1992).

² Williams v. Monarch Mach. Tool Co., 26 F.3d 228 (1st Cir. 1994) (no post sale duty to warn if product was reasonably safe at the time of sale); see also Romero v. Int’l Harvester Co., 979 F.2d 1444, 1449 (10th Cir. 1992); Carrizales v. Rheem Mfg. Co., 589 N.E.2d 569, 579 (Ill. App. Ct. 1991).

This proposed inclusion resulted in widespread debate. The plaintiff-oriented members of the Institute wanted this section included while some of the defense-oriented members wanted it omitted or severely limited. Post-sale duty to warn was ultimately included in the final Restatement (Third).

The Restatement (Third) and supporting case law require manufacturers or product suppliers, in certain instances to provide post-sale warnings or possibly to recall or repair products. In analyzing possible post-sale liability, it is important that manufacturers and product suppliers be aware of the factors that may trigger a post-sale duty under the common law. In addition, manufacturers and product suppliers need to be very familiar with post-sale duties imposed on them by U.S. agencies and, if the product is sold outside the U.S., by foreign government agencies. Armed with this knowledge, they can establish procedures to identify the existence of the duty and implement appropriate post-sale remedial measures to prevent or limit exposure based on post-sale conduct.

This Article provides an overview of the Restatement (Third)’s post-sale duty sections. In addition, it discusses relevant case law and the impact of the Restatement (Third) on developing case law. Part II provides a background of the post-sale duty sections of the Restatement (Third). Parts III-IX look back to case law prior to the Restatement (Third) and analyze how courts at that time dealt with post-sale duty issues including negligence standards, post-sale knowledge, defect timing questions, identification of product users, the duty to inform of safety improvements, and the duty to recall. Part X examines case law decisions that post-date the Restatement (Third)’s drafting, divided according to whether the court accepted, rejected, or adopted some variation of the Restatement sections. And lastly, Part XI provides a brief discussion of regulatory post-sale duties.

II. RESTASTATEMENT (THIRD): SECTIONS 10, 11, AND 13

The Restatement (Second) of Torts: Products Liability “Restatement (Second)” added section 402A in 1965 to adopt newly-developed common law rules making product manufacturers strictly liable for harms caused by defective products. But section 402A did not contain post-sale duty provisions. According to section 388 of the Restatement (Second), warnings were required only if a risk associated

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4 See James A. Henderson, Jr. & Aaron D. Twerski, The Politics of the Products Liability Restatement, 26 Hofstra L. Rev. 667 (1998), for a general discussion of the process by which the Reporters and the American Law Institute decided which sections to include.
5 Id.
7 Id. §§ 10-11, 13.
8 RESTATEMENT (SECOND) OF TORTS 2D § 402A (1965).
with a product was known or should have been known at the time of sale.\textsuperscript{9} The post-sale duty section in the Restatement (Third) was truly new when written, not merely a revision of section 388. It provides as follows:

\section*{§ 10. Liability of Commercial Product Seller or Distributor for Harm Caused by Post-Sale Failure to Warn}

(a) One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller’s failure to provide a warning after the time of sale or distribution of a product if a reasonable person in the seller’s position would provide such a warning.

(b) A reasonable person in the seller’s position would provide a warning after the time of sale if:

\begin{enumerate}
  \item the seller knows or reasonably should know that the product poses a substantial risk of harm to persons or property; and
  \item those to whom a warning might be provided can be identified and can reasonably be assumed to be unaware of the risk of harm; and
  \item a warning can be effectively communicated to and acted on by those to whom a warning might be provided; and
  \item the risk of harm is sufficiently great to justify the burden of providing a warning.\textsuperscript{10}
\end{enumerate}

The Reporters considered post-sale warnings to be the “most expansive area in the law of products liability” and a “monster duty.”\textsuperscript{11} However, the Reporters felt that section 10 limited this monster duty by requiring the plaintiff to prove all four factors before they would be allowed to pursue this claim.\textsuperscript{12}

Section 10 does not include a duty to do anything other than warn.\textsuperscript{13} However, since there was case law holding that, in certain narrow instances, a manufacturer may have a duty to recall or retrofit a product, the ALI decided to also deal with this precedent.\textsuperscript{14} Given the great burden of any post-sale activities, especially recall, the Institute included a section severely limiting the duty to recall a product.\textsuperscript{15} Section 11 of the Restatement (Third) provides as follows:

\section*{§ 11. Liability of Commercial Product Seller or Distributor for Harm Caused by Post-Sale Failure to Recall Product}

\textsuperscript{9} Id. § 388.
\textsuperscript{10} \textit{Restatement (Third) of Torts: Prods. Liab.} § 10 (1998).
\textsuperscript{11} JAMES A. HENDERSON, JR. & AARON TWERSKI, TEACHER’S MANUAL FOR PRODUCTS LIABILITY: PROBLEMS AND PROCESS 159 (6th ed. 2008).
\textsuperscript{12} Id.
\textsuperscript{13} \textit{Restatement (Third) of Torts: Prods. Liab.} § 10 (1998), cmt. a.
One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller’s failure to recall a product after the time of sale or distribution if:

(a) (1) a governmental directive issued pursuant to a statute or administrative regulation specifically requires the seller or distributor to recall the product; or

(2) the seller or distributor, in the absence of a recall requirement under Subsection (a)(1), undertakes to recall the product; and

(b) the seller or distributor fails to act as a reasonable person in recalling the product.\(^\text{16}\)

Section 11 basically provides that the seller or distributor is not liable for a failure to recall the product unless the recall is required by statute or regulation or the seller or distributor voluntarily undertakes to recall the product and does so negligently.\(^\text{17}\) The main reason for including section 11 was to make it clear that section 10 does not include a duty to recall the product. However, section 11 also included the so-called “Good Samaritan” doctrine where liability can attach for a negligent recall, even if it is voluntary.\(^\text{18}\)

The last section pertaining to the post-sale duty to warn is section 13.\(^\text{19}\) This section, which concerns a successor’s liability for a failure to issue a post-sale warning, states in part:

§ 13. Liability of Successor for Harm Caused by Successor’s Own Post-Sale Failure to Warn

(a) A successor corporation or other business entity that acquires assets of a predecessor corporation or other business entity, whether or not liable under the rule stated in § 12,\(^\text{20}\) is subject to liability for harm to persons or property caused by the successor’s failure to warn of a risk created by a product sold or distributed by the predecessor if:

(1) the successor undertakes or agrees to provide services for maintenance or repair of the product or enters into a similar relationship with purchasers of the predecessor’s products giving rise to actual or potential economic advantage to the successor, and

(2) a reasonable person in the position of the successor would provide a warning.\(^\text{21}\)

The section further states that a reasonable person in the successor’s position would provide such a warning if the four conditions in section 10 are met.\(^\text{22}\)

\(^{16}\) Id.

\(^{17}\) Id.

\(^{18}\) Id. §§ 11(a)(2)-11(b) & cmt. c (1998).

\(^{19}\) Id. § 13.

\(^{20}\) Id. § 12. Section 12 provides for liability for a successor manufacturer even if a predecessor manufacturer sold the product in a defective condition. Id.

\(^{21}\) Id. § 13.

\(^{22}\) Id.
Case law supported the inclusion of section 13 into the Restatement (Third)’s post-sale duty sections and emphasizes the same important factors for finding successor liability.23

III. DISTINGUISHING POST-SALE DUTY FROM TIME-OF-SALE DUTY

In examining case law prior to publication of the Restatement (Third), it became apparent to the Reporters that there was great confusion by juries, judges, and scholars.24 Many of the cases reviewed were unclear as to whether the jury or judge believed that the product was defective when sold or whether the product only became defective after sale.

If it was defective when sold, then it was judged under section 402A (or now section 2 of the Restatement (Third)).25 Since the Restatement (Second) did not have a post-sale duty section, courts that discussed this new theory of liability simply assumed that the defect became known after sale without considering whether it was defective when sold.26

The Restatement (Third) makes it clear that this post-sale duty is independent of a time-of-sale defect and therefore selling a defective product can result in claims of time-of-sale defect and also post-sale failure to warn.27 In addition, the Restatement (Third) makes it clear that if the product was defective when sold, the manufacturer cannot be absolved of liability by issuing a post-sale warning for harms caused before any warning is issued.28

While the Restatement (Third) is generally viewed as favorable to product manufacturers and sellers, section 10 clearly establishes a cause of action that creates opportunities for plaintiffs to argue for further discovery of post-sale actions and greater admissibility of post-sale accidents, thereby providing a greater chance of an award of punitive damages.29

23 Sherlock v. Quality Control Equip. Co., 79 F.3d 731, 734 (8th Cir. 1996) (“The critical element required for the imposition of the duty is a continuing relationship between the successor and the predecessor’s customers for the benefit of the successor.”); Patton v. TIC United Corp., 77 F.3d 1235, 1240 (10th Cir. 1996) (“[A] ‘successor entity’ . . . may incur a duty to warn if it has knowledge of the defective condition of the predecessor’s product, and has a ‘more than casual’ relationship with the customers of the predecessor entity that is an ‘economic benefit’ to the successor.” (quoting Stratton v. Garvey Int’l, Inc., 676 P.2d 1290, 1294 (Kan. Ct. App. 1984))).

24 Henderson & Twerski, supra note 4, at 669.


26 Hodder v. Goodyear Tire & Rubber Co., 426 N.W.2d 826, 835 (Minn. 1988).


28 Id.

29 Researchers analyzing punitive damage cases have found almost 75% of such awards to be based on the failure of a manufacturer to take appropriate post-sale actions. Michael Rustad, In Defense of Punitive Damages in Products Liability: Testing Tort Anecdotes with Empirical Data, 78 IOWA L. REV. 1, 66 (1992).
In addition, by stating that a manufacturer cannot cut off liability no matter how effective the post-sale warning program, this section almost creates absolute liability for injuries sustained by a product defect that was known after sale and where the manufacturer undertakes a less than reasonable post-sale warning program.\textsuperscript{30} Plaintiffs can now argue that a program that was not successful in warning them was not reasonable. And, arguably, when it comes to post-sale programs, the manufacturer or product supplier can always do more.

IV. A CAUSE OF ACTION BASED ON POST-SALE DUTY SOUNDS IN NEGLIGENCE

While synthesizing years of judicial consideration of post-sale issues, section 10 still raises many questions that have been and will be litigated for years.\textsuperscript{31} One aspect of section 10, however, is clear: A cause of action based on post-sale duties must sound in negligence, since the reasonableness of a product supplier’s conduct is the focus of the post-sale inquiry.\textsuperscript{32}

According to section 10(b), a seller can only be subject to post-sale duties if a “reasonable” person would have supplied such a warning.\textsuperscript{33} The four factors of section 10(b) are fact-based, making the reasonableness of supplying a post-sale warning the key to establishing a post-sale duty.\textsuperscript{34}

Judging post-sale conduct through the lens of negligence is consistent with case law prior to the adoption of the Restatement (Third).\textsuperscript{35} Actual or constructive knowledge of a post-sale risk is necessary to impose a post-sale duty.\textsuperscript{36} Also, negligence is the correct legal theory when a manufacturer’s conduct is at issue,\textsuperscript{37} and as such, application of a post-sale duty depends on the reasonableness of the manufacturer’s conduct.\textsuperscript{38} Consequently, a product supplier cannot be strictly liable for post-sale conduct under section 10.

V. ACQUISITION OF POST-SALE KNOWLEDGE

Section 10, by confirming the existence of post-sale duties in the law, created an affirmative duty for product suppliers to exercise

\textsuperscript{30} \textit{Restatement (Third) of Torts: Prods. Liab. § 10 cmt. j (1998).}
\textsuperscript{31} \textit{See infra} Parts III and X.
\textsuperscript{32} \textit{Restatement (Third) of Torts: Prods. Liab. § 10 cmt. b (1998).}
\textsuperscript{33} \textit{Id. § 10(a).}
\textsuperscript{34} \textit{Id. § 10(b).}
\textsuperscript{35} \textit{See id § 10 cmt. b (1998).}
\textsuperscript{38} \textit{Crowston v. Goodyear Tire & Rubber Co.,} 521 N.W.2d 401, 409 (N.D. 1994).
reasonable care to learn of post-sale problems with their products. Section 10(a) bases a post-sale duty, in part, on suppliers who know or reasonably should know that their products pose a substantial risk of harm to persons or property.\textsuperscript{39} In addition, comment c states that the general duty of reasonable care may require manufacturers to investigate when reasonable grounds exist for the seller to suspect that a hitherto unknown risk exists.\textsuperscript{40}

However, comment c to section 10 also makes it clear that, except for prescription drugs and medical devices,\textsuperscript{31} “constantly monitoring product performance in the field is usually too burdensome” and will not support a post-sale duty.\textsuperscript{42} Despite this language, plaintiffs have tried to use section 10 and comment c to impose a broader duty on product suppliers to establish systems to obtain information from the field. The failure of a manufacturer to set up a system to gather post-sale information and then claim a lack of knowledge, may appear unreasonable to a jury, especially when one could be set up with little effort and expense.

Many courts, however, reflected concerns similar to those raised in the Restatement (Third) about imposing too heavy of a burden on manufacturers to monitor field performance. In \textit{Patton v. Hutchinson Wil-Rich Manufacturing Company}, the Kansas Supreme Court held that plaintiffs who allege post-sale duty claims must prove that manufacturers “acquired knowledge of a [post-sale] defect.”\textsuperscript{43} The case did not, however, impose an affirmative duty on suppliers to take reasonable steps to learn of post-sale problems that were not brought to their attention. This is consistent with earlier opinions.\textsuperscript{44}

The language in section 10 could be used to argue that the scope of other manufacturers’ and suppliers’ legal duties are extended by requiring reasonable affirmative actions to learn of post-sale product risks. Regardless of the legal duty, affirmatively trying to learn of post-sale risks is a beneficial activity for enhancing product safety and preventing accidents.

\textsuperscript{39} \textit{RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 10(a) (1998)}.
\textsuperscript{40} \textit{Id.} § 10 cmt. c.
\textsuperscript{31} Long-standing case law requires prescription drug and medical device manufacturers to keep themselves informed of scientific developments and provide the medical profession with information about the risks of drugs already on the market. This affirmative duty for drug and device manufacturers is consistent with the language in section 10 and may also be imposed by the Code of Federal Regulations for other products. \textit{See}, \textit{e.g.}, \textit{Tinnerholm v. Parke Davis & Co.}, 285 F. Supp. 432, 451 (S.D.N.Y. 1968); \textit{Baker v. St. Agnes Hosp.}, 421 N.Y.S.2d 81, 85 (N.Y. App. Div. 1979).
\textsuperscript{42} \textit{RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 10 cmt. c (1998)}.
\textsuperscript{43} \textit{Hutchinson Wil-Rich Mfg.}, 861 P.2d at 1314.
VI. EXISTENCE OF THE DEFECT: A QUESTION OF TIMING

Section 10(a) obviously contemplated that knowledge of a risk or defect acquired by a supplier must be obtained after the sale. The section is less clear about when the defect must actually come into existence. Comment a to section 10 explains that a post-sale duty may be imposed “whether or not the product is defective at the time of original sale.” The Institute acknowledged in comment a that imposing a post-sale duty, even if the product was not defective when sold, was relatively new. It was quick to point out, however, that the requirement that the plaintiff prove section 10’s four factors should prevent “unbounded” and onerous post-sale burdens on product sellers.

The position of section 10—that it is immaterial whether the defect existed at the time of sale—contrasts with many decisions where courts have refused to impose post-sale duties when products were not defective when sold.

VII. PRODUCT USERS: CAN THEY BE IDENTIFIED?

Section 10(b) requires proof that people to whom a post-sale warning should be provided can be identified before a post-sale duty is triggered. This case-specific inquiry depends on a number of factors including the type of product, the number of units sold, the number of potential users, the availability of records, and the available means of tracing product users. Comment e makes it clear that when no records identifying the customers are available, a post-sale duty does not arise.

These factors formed the basis for the Wisconsin Supreme Court’s holding that the manufacturer of a sausage stuffing machine had a duty to provide users with information about a new safety by-pass valve. The machines were sold to a limited market where the manufacturer knew all of the product’s owners. The Wisconsin court made it clear, however, that it was not crafting an absolute post-sale duty for all manufacturers to warn of safety improvements year after year since many products are mass-produced and tracing users to warn of safety improvements would place an undue burden on manufacturers.
Similarly, the North Dakota Supreme Court held that it would be difficult to require the manufacturer of mass-produced tire rims to trace individual users if the rims were not unique or sold to a specialized group of customers.\(^{56}\) While recognizing the problem of providing individual notice to the original purchasers, this court nevertheless held that the defendant had a duty to warn foreseeable product users about dangers which were discovered after the product was originally sold.\(^{57}\)

An interesting question remains as to how far a manufacturer must go to identify its customers. What would a reasonable manufacturer concerned about safety do? Establishing a “traceability” system before the product is sold is the most effective way to find customers. However, such systems take planning, considerable effort, and substantial cost.\(^{58}\) The question of whether a particular defendant’s actions are “reasonable” will be case-specific and decided by the jury. The ALI continually stresses in comments to section 10 that this duty should not be “unbounded” and onerous and that courts need to be careful before imposing such a duty.\(^{59}\)

The federal government has jurisdiction over many products and Congress recently “raised the bar” in this area. In August 2008, the President signed the Consumer Product Safety Improvement Act,\(^{60}\) which contains several new provisions to enhance the identification and tracking of children’s products.\(^{61}\) The federal government already mandates customer tracking for products such as car seats\(^{62}\) and medical devices.\(^{63}\)

**VIII. DUTY TO INFORM OF SAFETY IMPROVEMENTS**

Manufacturers should always strive to improve the safety of their products. But does the manufacturer have a duty to inform prior customers of each safety improvement made in similar products manufactured after the sale of the less safe product? Prior to the drafting

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\(^{57}\) Id. at 409; see also Hodder v. Goodyear Tire & Rubber Co., 426 N.W.2d 826, 832 (Minn. 1988) (holding tire rim manufacturer had a post-sale duty to instruct and warn, so that potential users of its product would be apprised of safety hazards which, at an earlier time, were not fully appreciated).

\(^{58}\) PROD. SAFETY AND LIAB. PREVENTION INTEREST GROUP, AMERICAN SOCIETY FOR QUALITY, THE PRODUCT RECALL PLANNING GUIDE (2d ed. 1999).

\(^{59}\) RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 10 cmts. a & d (1998). There are also several federal guidelines, as well as industry guidelines, describing what might be considered a reasonable program. For a recent example of an industry produced guideline, see PROD. SAFETY AND LIAB. PREVENTION INTEREST GROUP, supra note 58.


\(^{62}\) 49 C.F.R. § 588.5-6 (2007).

of Restatement (Third), some courts found it reasonable to impose a duty to inform purchasers of safety improvements when:

1. There is a continuing relationship between the manufacturer and the purchaser;
2. The market is limited; and
3. The cost of providing notice of the safety improvement is negligible.64

Most courts prior to 1998, however, found that there was no post-sale duty to inform customers of safety improvements when the original product had been properly designed and manufactured.65

Section 10 did not foreclose the imposition of a post-sale duty to inform about safety improvements but made it clear that the four factors in that section must be met.66 However, it said that “in most cases it will be difficult to establish each of the four section 10 factors that are a necessary predicate for a post-sale duty to warn if the warning is merely to inform of the availability of a product-safety improvement.”67

It is certain that plaintiffs have tried to use a manufacturer’s post-sale warning of a product safety improvement to argue that the original product, without the safety improvement, was defective at the time of sale. However, any attempt to use the improvement as evidence of a time-of-sale defect will generally run afoul of evidentiary rules that preclude the introduction of “remedial measures” evidence.68

A manufacturer must carefully consider whether it is reasonable and prudent to notify prior customers of safety improvements. The manufacturer should perform the kind of analysis that is done under section 10 in deciding whether a duty arises in the first place. If the manufacturer’s post-sale improvement significantly improves safety and the manufacturer can easily find its customers, the manufacturer should consider informing its prior customers about the safety improvement.

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64 Bell Helicopter Co. v. Bradshaw, 594 S.W.2d 519 (Tex. Civ. App. 1979) (holding a duty to retrofit where manufacturer assumed duty to notify users of safety improvements), overruled in part by Torrington Co. v. Stutzman, 46 S.W.3d 829 (Tex. 2000); Kozlowski v. John E. Smith’s Sons Co., 275 N.W.2d 915, 923-24 (Wis. 1979) (holding a duty to inform users of machine of post-sale safety improvements where users were traceable).
67 Id. § 10 (Reporter’s Note to cmt. a).
68 Rule 407 of the Federal Rules of Evidence provides that evidence of measures taken after an injury “is not admissible to prove negligence, culpable conduct, a defect in a product, a defect in a product’s design, or a need for a warning or instruction.” FED. R. EVID. 407. Most state rules of evidence also bar the introduction of such evidence to prove a time-of-sale defect.
IX. **POST-SALE DUTY TO RECALL**

Section 11 set forth a limited duty to recall a defective product. Comment a made it clear that this duty is different from the post-sale duty in section 10. This comment also says that improvements in product safety do not trigger a duty to recall or retrofit a product because that would discourage manufacturers from making safer products.

This limited duty is based mostly on a government directive specifically requiring the manufacturer to recall an imminently hazardous product. The Michigan Supreme Court declined an invitation to impose a common law duty to recall or repair in a negligent design claim where a plaintiff alleged that a manufacturer knew or should have known of a defect at the time of sale. While Michigan required a warning in such circumstances, the court concluded that “the duty to repair or recall is more properly a consideration for administrative agencies and the Legislature.”

However, the Restatement (Third) incorporated the “Good Samaritan” or “volunteer” rule that one who undertakes a rescue must act reasonably so as not to put the rescued party in worse shape than before. This rule, in the context of products liability, comes from the belief that voluntary recalls are typically undertaken in the anticipation that a government agency will require one anyway.

This belief by the ALI and some courts may be correct in a general sense. However, there are many voluntary recalls, retrofits, or even post-sale warning programs that are done to enhance safety and would not constitute a post-sale duty under section 10. With this doctrine incorporated into the Restatement (Third), it is likely, though impossible to prove for certain, that only those manufacturers who undertook truly voluntary programs were prepared to do so in a way that would not be considered negligent. This determination is difficult and case-specific.

Hopefully, more manufacturers will “do the right thing” and try to improve the safety of their products and try to anticipate what might be considered reasonable. Unfortunately, the fact that an accident happened means, by definition, that the post-sale remedial program was arguably ineffective for the injured party.

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70 Id. cmt. a (“The duty to recall or repair should be distinguished from a post-sale duty to warn about product hazards discovered after sale.”).
71 Id.
72 Id. (“Moreover, even when a product is defective within the meaning of § 2, § 3, or § 4, an involuntary duty to recall should be imposed on the seller only by a governmental directive issued pursuant to statute or regulation.”); see also 15 U.S.C. § 2061(b)(1) (2006).
75 See supra note 18.
X. DEVELOPMENT OF POST-SALE DUTY LAW AFTER 1998

As our earlier discussion suggests, the rules that have evolved regarding a post-sale duty to warn fall into three general categories: (1) no duty if the product was reasonably safe at the time of sale; (2) a duty to warn only of risks that existed at the time of sale but were only later revealed; and (3) a duty to warn when a reasonable manufacturer would do so. This last rule is the broadest and is the one reflected in Section 10.

Under the Restatement’s rule, a manufacturer could have a duty to warn even of risks that did not exist at the time of the product’s sale. There may be a duty to warn under Section 10 if, for example, new safety technology becomes available that was not available at the time the product was originally sold, the new design eliminates a substantial risk arising from the product’s original design, and the manufacturer can readily identify and communicate an effective warning to the product’s current users.

Even under this rule, however, there will typically be no post-sale duty to inform of the availability of a product-safety improvement because the product users would be difficult to trace, the warning would not effectively reduce the risk inherent in the original design, or a reasonable manufacturer may find other reasons to decide against attempts to warn.77

An examination of the cases reveals that a few courts have specifically adopted as the law of their jurisdiction the Restatement (Third)’s negligence-based post-sale duty to warn and its section 10 factors for determining when that duty arises. Other courts that have essentially adopted the section 10 reasonable manufacturer rule did so before the adoption of the Restatement (Third). Since the Restatement (Third)’s adoption, other courts have recognized a post-sale duty to warn without actually mentioning the Restatement. Some jurisdictions have specifically rejected section 10 and others have refused to adopt a post-sale duty to warn without mentioning the Restatement (Third). A fair number of cases decided both before and after ALI’s adoption of the Restatement (Third) have imposed a post-sale duty to warn, limited to latent risks that existed at the time of sale. And finally, a few cases have specifically adopted section 13.

We have organized our brief discussion of the post-Restatement (Third) case law into the categories just described.

A. Cases Specifically Adopting Section 10

In Lewis v. Ariens Company, the Supreme Judicial Court of Massachusetts specifically adopted “the principles set forth in the

77 See id. § 10 (Reporter’s Note to cmt. a).
Restatement (Third) . . . regarding a manufacturer’s continuing duty to warn users of substantial product risks or dangers discovered postsale."**78

Lewis injured his hand in the impeller blades of a snow blower when he slipped and fell causing his hand to enter the machine’s discharge chute. The snow blower was manufactured and originally sold in 1966 by Ariens Company. Studies published in 1971 and 1975 identified the dangers of the snow blower as it was originally designed. Lewis had purchased the machine from the sister of a friend in 1982, sixteen years after it was sold by Ariens. The accident occurred in 1988.

In an earlier holding, the court had abandoned a strict liability approach in favor of negligence principles and revised Massachusetts’ law to say that a manufacturer is subject to a continuing duty to warn of risks discovered following the sale of a product.**79 Ariens Company argued, however, that any post-sale duty to warn did not extend to remote purchasers. In response, the court pointed out that section 10 does not limit the duty to warn to direct purchasers only.**80 But the court also observed that comment e to section 10 says that a seller’s inability to identify those for whom warnings may be useful may prevent a duty from arising, and that comment a to section 10 notes that the costs of identifying and communicating with product users years after sale are often daunting. On the facts of this case, the court found that Ariens had no duty to warn Lewis,

who purchased the product at least second hand, sixteen years after it was originally sold, and did not own the product until years after a duty to provide additional warnings arguably arose. In these circumstances, he is a “member of a universe too diffuse and too large for manufacturers or sellers of original equipment to identify.”**81

Nevertheless, the court concluded that “the principles set forth in [section] 10 represent a logical and balanced embodiment” of Massachusetts’ post-sale duty to warn rule.**82

Even earlier, the Supreme Court of Iowa had specifically adopted section 10 and its factors for determining whether a product seller has a post-sale duty to warn. In *Lovick v. Wil-Rich*,83 a farmer was injured when he attempted to lower the wings of a cultivator into position to begin cultivation. When Lovick removed a pin designed to hold the

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**78 751 N.E.2d 862, 864 (Mass. 2001).**

**79 Vassallo v. Baxter Healthcare Corp., 696 N.E.2d 909, 923 (Mass. 1998). Both Lewis and Vassallo involved the issue of whether the product manufacturer had breached the implied warranty of merchantability by failing to warn of the risk giving rise to the injury. But in Hoffman v. Houghton Chemical Corp., 751 N.E.2d 848, 859 (Mass. 2001), the Massachusetts court expressly recognized that negligent failure to warn and failure to warn under breach of warranty are to be judged by the same standard: the reasonableness of the defendant’s actions in the circumstances.**

**80 751 N.E.2d at 866.**

**81 Id. at 867.**

**82 Id.**

**83 588 N.W.2d 688 (Iowa 1999).**
wing in a vertical position in the event of a hydraulic or mechanical failure, the wing immediately fell on him because the linkage holding the hydraulic cylinder to the wing was broken. The cultivator that injured Lovick was manufactured and sold by Wil-Rich in 1981 and then sold by the original buyer to a second owner in the late 1980s. Lovick, an experienced farmer, was using the cultivator to cultivate a field belonging to the machine’s owner.\footnote{Id.}

The cultivator bore a warning sign which cautioned users to remove the pin prior to lowering the wings. The operator’s manual warned against going under the wings to remove the pins. In 1983, Wil-Rich learned that a wing of one of its cultivators had fallen and injured the operator. The company subsequently received several other such reports. In 1988, the company began to affix a warning label to its cultivators warning of the danger of going under the wing to remove the pin. In 1994, Wil-Rich began a campaign to notify owners of its cultivators of the danger of falling wings and also made a backup safety-latch kit available for installation on the wings. At trial, Lovick introduced evidence that a competitor of Wil-Rich instituted a safety program in 1983 for its similarly designed cultivator after learning of instances of the wing falling on the operator. The competitor’s safety program included efforts to locate the cultivator owners and equip the machines with a safety latch and an upgraded warning label.\footnote{Id.}

The Iowa legislature had enacted a products liability state-of-the-art defense statute in 1986 that provided, inter alia, that “[n]othing in this section shall diminish the duty . . . to warn concerning subsequently acquired knowledge of a defect or dangerous condition that would . . . diminish the liability for failure to warn.”\footnote{IOWA CODE § 688.12 (1987).} Although the post-sale duty to warn is rooted in general negligence principles, the \textit{Lovick} court said that “there are some distinctions which are important to recognize in considering the scope and nature of the post-sale duty [to warn]. Foremost, the burden of a manufacturer to warn product users can radically change after the sale has occurred and the manufacturer no longer has control over the product.”\footnote{Lovick, 588 N.W.2d at 694.} The “fighting question,” said the court, “is whether it is necessary to articulate the various factors to consider in analyzing the reasonableness of a manufacturer’s conduct once it acquires knowledge of a defect in the product following the sale.”\footnote{Id. at 695.} Concluding that the trial court’s general negligence instructions to the jury had failed to give adequate guidance as to how to assess the reasonableness of the manufacturer’s post-sale conduct, the court said that a jury must be instructed to consider those factors which make it
burdensome or impractical to provide a post-sale warning. Consequently, the court said “we adopt the Restatement (Third) of Torts: Products Liability section 10, including the need to articulate the relevant factors to consider in determining the reasonableness of providing a warning after the sale.”

The New York Court of Appeals, in Liriano v. Hobart Corp., also specifically cited section 10 for the proposition that a manufacturer may have a post-sale duty to warn in certain circumstances, including instances in which a product’s designed-in safety features have been circumvented or removed by product users and this fact is known to the manufacturer. Liriano, a grocery store employee, was injured in 1993 while using the store’s meat grinder without its safety guard. The meat grinder was manufactured and sold in 1961 with a safety guard affixed that prevented a user’s hands from coming into contact with the grinding “worm.” No warnings were placed on the meat grinder to indicate that it was dangerous to operate the machine without the safety guard in place. Hobart began to include such warnings in 1962. At the time of the accident, the safety guard had been removed and Hobart knew, before the accident, that removals of this sort were occurring. The court concluded that a post-sale modification of the product was not in and of itself a defense to a post-sale duty to warn claim. The court said that “[s]uch a duty will generally arise where a defect or danger is revealed by user operation and brought to the attention of the manufacturer; the existence and scope of such a duty are generally fact-specific.” But it did not decide whether, on the facts of the case, Hobart had a post-sale duty to warn.

In Robinson v. Brandtjen & Kluge, Inc., the U.S. Court of Appeals for the Eighth Circuit reaffirmed its earlier holding in another case that South Dakota law permits recovery for a negligent post-sale duty to warn. Referring specifically to section 10, the court concluded that the product manufacturer “did not breach a post-sale duty to warn in this case involving a printing press sold in the 1940s, more than 50 years before being acquired by the injured party’s employer. Though the court found there was no breach, it likely meant that there was simply

89 Id. at 695-96; see also Ahlberg v. Chrysler Corp., 481 F.3d 630, 633 (8th Cir. 2007) (“[I]n Iowa both a pre- and a post-sale duty to warn have been recognized as separate negligence theories of recovery.”).
90 700 N.E.2d 303, 307 n.3 (N.Y. 1998) (manufacturer’s post sale duty to warn depends on a number of factors including degree of danger product involves, number of reported incidents, burden of providing warning, and burden or ability to track product after sale).
91 Id. at 305.
92 Id. at 306.
93 Id. at 307.
94 500 F.3d 691 (8th Cir. 2007).
96 Brandtjen, 500 F.3d at 697.
97 Id.
no post-sale duty to warn in this case. It does say that, given the passage of time, it would be unreasonable to require the manufacturer to identify and warn all of the owners of its products.98 The difficulty of identifying those who need to be warned is an important factor under section 10 in determining whether a duty exists in the first place.

Section 10 is also cited by the Florida District Court of Appeals in Sta-Rite Industries, Inc. v. Levey as authority for the proposition that a swimming pool pump manufacturer had a duty to warn of the dangers of an unsecured protective grate covering the pool drain.99 However, Sta-Rite is not a post-sale duty case; the duty to warn in that case existed at the time the pump was first sold by the manufacturer.100

Finally, in Brown v. Crown Equipment Corp.,101 a federal district court ruling on a defense motion in limine concluded that Maine would recognize a negligence-based post-sale duty to warn where a manufacturer’s product is not defective at the time of sale but a hazard later develops because of a change in the user environment. It subsequently affirmed that view in ruling against the defendant’s motion for judgment as a matter of law after a jury had returned a verdict in the plaintiff’s favor, resting its conclusion specifically on the view taken by the Restatement in section 10.102 In Brown, the plaintiff was killed while operating a forklift in a warehouse. The forklift was manufactured in 1989. In 1995, the manufacturer learned that new shelf design in many warehouses exposed forklift operators to the risk of shelving entering the forklift operator’s area at an unshielded level and striking the operator. The manufacturer developed an upgrade kit for the forklift that extended the height of the operator’s backrest thus reducing the risk of intrusions into the operator’s area. However, the manufacturer did not convey this information to the forklift owner who was the plaintiff’s employer.103 On appeal, the U.S. Court of Appeals for the First Circuit said that, because other jurisdictions have disagreed on this question and the Maine Supreme Judicial Court had not spoken, the issue should be certified to the Maine court.104 In response, the Maine Supreme Judicial Court said that “in limited circumstances . . . there can be a post-sale duty to warn indirect purchasers, but we have not and do not now adopt . . . § 10.”105 The Maine court went on to rule, however, that under the ordinary

98 Id.
100 The court says that a jury question was presented as to whether the defendant had a duty to warn the “purchaser,” clearly implying that the duty existed at the time of sale. Sta-Rite, 909 So. 2d at 905.
102 Id. at 192-93.
104 Id. at 78.
common law principles of Maine negligence law, the manufacturer owed the plaintiff a post-sale duty to warn on the facts of this case.106

B. Cases Adopting a Reasonable Manufacturer Rule Decided Prior to the Adoption of the Restatement (Third)

Several other jurisdictions, in cases decided before the ALI’s final approval of section 10, have adopted a reasonable manufacturer standard for determining when a post-sale duty exists and utilized similar factors in deciding reasonableness.107

Robinson v. Brandtjen & Kluge, Inc. is a case in which the product’s design was state-of-the-art and was not defective at the time of manufacture but subsequent improvements in technology had made a safer design feasible at the time the injury occurred.108 Brown v. Crown Equipment is arguably a case in which there was no risk in the original product design but a risk arose when the operating environment for the product was subsequently changed. Both Lewis v. Ariens and Lovick v. Wil-Rich are examples of cases in which the product as originally designed carried a latent risk that did not become reasonably apparent until after the product had left the manufacturer’s control. However, nothing in either opinion suggests that the post-sale duty to warn is limited to cases involving latent risks, and the courts’ specific adoption of section 10’s principles indicate that there is no such limit on the duty.

C. Cases Recognizing Post-Sale Duty to Warn Decided After Adoption of Restatement (Third) but Not Mentioning Section 10

Since the Restatement (Third)’s adoption, other courts have recognized a post-sale duty to warn without mentioning section 10. The

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106 Id. at 1193.
107 See, e.g., Patton v. Hutchinson Wil-Rich Mfg. Co., 861 P.2d 1299, 1314-15 (Kan. 1993) (liability depends on reasonableness test, which looks at “(1) the nature of the harm that may result from use without notice, (2) the likelihood that harm will occur . . . (3) how many persons are affected, (4) the economic burden on the manufacturer of identifying and contacting current product users . . . (5) the nature of the industry, (6) the type of product involved, (7) the number of units manufactured or sold, and (8) steps taken other than giving of notice to correct the problem”); Cover v. Cohen, 461 N.E.2d 864, 872 (N.Y. 1984) (“The nature of the warning to be given and to whom it should be given likewise turn upon a number of factors, including the harm that may result from use of the product without notice, the reliability and any possible adverse interest of the person, if other than the user, to whom notice is given, the burden on the manufacturer or vendor involved in locating the persons to whom notice is required to be given, the attention which it can be expected a notice in the form given will receive from the recipient, the kind of product involved and the number manufactured or sold, and the steps taken, other than the giving of notice, to correct the problem.” (citations omitted)); Crowston v. Goodyear Tire & Rubber Co., 521 N.W.2d 401, 409 (N.D. 1994) (“The reasonableness of the post-sale warnings depend on the facts of each particular case” looking at “(1) the nature of the harm . . . (2) the likelihood that harm will occur . . . (3) how many persons are affected . . . (4) the economic burden on the manufacturer of identifying and contacting current product users . . . (5) the nature of the industry, (6) the type of product involved, (7) the number of units manufactured or sold, and (8) steps taken other than giving of notice to correct the problem.”).
108 See Brandtjen, 500 F.3d at 696.
Court of Appeals of Louisiana has observed that the Louisiana Products Liability Act has a provision that states:

A manufacturer of a product who, after the product has left his control, acquires knowledge of a characteristic of the product that may cause damage and the danger of such characteristic, or who would have acquired such knowledge had he acted as a reasonably prudent manufacturer, is liable for damage caused by his subsequent failure to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.\(^{109}\)

Connecticut imposes liability for a negligent breach of a manufacturer’s continuing, post-sale duty to warn of “known or knowable dangers associated with using its product.”\(^{110}\) Georgia law imposes on product manufacturers “a duty to exercise ordinary care to warn users of a known or reasonably foreseeable risk of injury or death after a product’s sale.”\(^{111}\) And under North Dakota law, “when a manufacturer learns about the dangers associated with the use of its product after it is manufactured and sold, the manufacturer has a post-sale duty to warn about these dangers.”\(^{112}\) All of these jurisdictions appear to reflect the Restatement’s negligence-based duty to warn post-sale but do not make clear whether section 10’s factors for determining reasonableness are the relevant factors for making the duty determination.

D. Cases Specifically Rejecting Section 10

A few courts have rejected section 10 and have done so for different reasons. In *Palmer v. Volkswagen of America, Inc.*, the Mississippi Court of Appeals concluded that there is no post-sale duty to warn under that state’s products liability act,\(^{113}\) the relevant portion of which provides:

The manufacturer or seller of the product shall not be liable if the claimant does not prove by the preponderance of the evidence that at the time the product left the control of the manufacturer or seller . . . [t]he product was defective because it failed to contain adequate warnings or instructions.\(^{114}\)

In *Modelski v. Navistar International Transportation Corp.*, the Appellate Court of Illinois phrased the question as “whether such a duty [to warn] includes an obligation to issue post-sale warnings of dangers

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\(^{110}\) Densberger v. United Techs. Corp., 297 F.3d 66, 69-70 n.3 (2d Cir. 2002).


\(^{113}\) 905 So.2d 564, 601 (Miss. Ct. App. 2003), rev’d in part on other grounds, 904 So.2d 1077 (Miss. 2005).

\(^{114}\) MISS. CODE ANN. § 11-1-63(a)(i)(2) (Rev. 2002) (emphasis added).
which were not known, nor should they have been known, at the time the product left the manufacturer’s control.”115 Modelski was killed when the seat on his Farmall tractor tilted backwards and he fell into the blades of a rotary mower that he was towing. The tractor seat was mounted atop the battery box cover that was hinged at the rear and secured at the front by two bolts. The tractor carried no warning of the consequences that might result if the bolts holding the front of the battery box cover failed or somehow became disengaged. The bolts did fail, allowing the battery box cover and seat to tilt to the rear. The tractor was manufactured in 1957.116 Modelski had bought the tractor in 1989, two years before his fatal 1991 accident, from someone who had acquired it in 1983 at a farm auction.117 The appellate court concluded that there was no post-sale duty to warn in negligence actions in Illinois, citing the Illinois Supreme Court’s 1980 opinion in Woodill v. Parke Davis & Co., holding that in a strict liability action for failure to warn the plaintiff must prove that the manufacturer knew or should have known of the injury-causing propensity of its product at the time the product left its control.118 The Modelski court concluded that there was “no reason to lessen that burden in a negligence action.”119 It is impossible to tell if the court was influenced by the fact that the tractor was first sold thirty-four years before the accident and had passed through the hands of several owners. That fact alone could support a conclusion that it was not possible to effectively communicate a warning of the risk to current tractor users and that thus there was no post-sale duty to warn in these circumstances. But the court did not limit its ruling to the facts of the case at hand, declaring instead that there is simply no post-sale duty to warn in either strict liability or negligence actions in Illinois.120

The Tennessee Court of Appeals declared, in a case where a fire was caused when a pillow came into contact with the unshielded bulb of a halogen lamp, that “Tennessee does not recognize a post-sale duty to warn. Although the Restatement (Third) of Torts adopts some post-sale duties, Tennessee [has] not adopted these provisions . . . .”121 And in Stanger v. Smith & Nephew, Inc., a federal district court concluded that even though “there is no strong indication that the Missouri Supreme Court would adopt the RESTATEMENT (THIRD) OF TORTS, which imposes

\[\text{References}\]

116 Id. at 241-42.
117 Id. at 241.
119 Modelski, 707 N.E.2d at 246; see also Birchler v. Gehl Co., 88 F.3d 518, 521 (7th Cir. 1996) (“The well established and generally accepted law in Illinois is that manufacturers do not have a continuing duty to warn.”).
120 Modelski, 707 N.E.2d at 247.
a continuous duty to warn” as the general rule,\textsuperscript{122} the defendants in the case \textit{sub judice} did owe a post-sale duty to warn. The product that caused the injury was a medical device for which, as with prescription drugs, there is an already established continuing duty to keep abreast of scientific developments affecting the manufacturer’s product and warn the medical community of any newly discovered risks.\textsuperscript{123}

E. \textit{Other Cases Refusing to Adopt a Post-Sale Duty to Warn}

Other jurisdictions have decided against creating a post-sale duty to warn without reference to the \textit{Restatement (Third)}. In \textit{Anderson v. Nissan Motor Co., Ltd.}, the U.S. Court of Appeals for the Eighth Circuit found that Nebraska would not impose a post-sale duty to warn.\textsuperscript{124} The primary reason for this conclusion was Nebraska case law emphasizing that Nebraska’s rules of evidence generally prohibit evidence of remedial measures taken subsequent to an injury causing event.\textsuperscript{125} No reference was made in the court’s opinion to section 10.

In Oklahoma, plaintiffs in products liability actions must prove, \textit{inter alia}, “that the defect existed in the product at the time it left the control of the defendant.”\textsuperscript{126} There may be liability for failure to warn at the time of sale but Oklahoma law “does not recognize a post-sale duty to warn or retrofit a product,”\textsuperscript{127} a rule established before adoption of section 10. And “[u]nder Texas products liability law, a manufacturer has no duty to warn about a product after it has been manufactured and sold.”\textsuperscript{128}

F. \textit{Cases Adopting a Post-Sale Duty to Warn but Only of Latent Risks}

In cases decided both before and after ALI’s adoption of the \textit{Restatement (Third)}, some courts have adopted a post-sale duty to warn but have limited the scope of that duty to warning of only those risks that existed at the time of the product’s sale but were not then reasonably

\textsuperscript{122} 401 F. Supp. 2d 974, 982 (E.D. Mo. 2005) (citations omitted).
\textsuperscript{123} Id. at 983.
\textsuperscript{124} 139 F.3d 599, 602 (8th Cir. 1998).
\textsuperscript{125} Id. at 601-02 (citing Rahmig v. Mosley Mach. Co., 412 N.W.2d 56, 82 (Neb. 1987)).
discoverable. When a manufacturer discovers or should have discovered such a latent risk, a duty to warn of the risk then arises.

The rule in Arizona is that there is a duty to warn post-sale but only “where a manufacturer or seller, believing that it has sold a non-defective product, subsequently learns that its product was, in fact, defective when placed in the stream of commerce.” Colorado, applying Restatement (Second)’s section 402A strict liability principles, limits the post-sale duty to warn to cases “where a danger concerning the product becomes known to the manufacturer subsequent to the sale and delivery of the product, even though it was not known at the time of the sale.” Under Maryland law, “[e]ven if there is no duty to warn at the time of the sale, facts may thereafter come to the attention of the manufacturer which make it imperative that a warning then be given.”

Michigan law, using negligence principles, says that a post-sale duty to warn may arise—but only if a latent defect existed in the product at the point of manufacture. In Ohio, “a manufacturer or vendor is negligent when he has knowledge of a latent defect rendering a product unsafe and fails to provide a warning of such defect.” The scope of the post-sale duty to warn in these states is more limited than the duty under section 10 which may impose a post-sale warning duty even if there was no undiscovered risk in the product at the time of sale.

A few states still embrace a strict liability standard for failure to warn cases. Pennsylvania has rejected the rule set forth in section 10 but does impose a post-sale duty to warn of defects existing at the time of sale. In Walton v. Avco Corp., the Pennsylvania Supreme Court ruled that a helicopter manufacturer had a post-sale duty to warn of a defective engine when the manufacturer learned after the sale of the helicopter, but before the injury, that the defect existed at the time the helicopter left the manufacturer’s hands. In Lynch v. McStome and Lincoln Plaza Associates, however, the Superior Court of Pennsylvania ruled that no post-sale duty to warn exists where no defect existed in the product at the time of sale. Lynch was injured when an escalator on which she was riding came to an abrupt stop. She appealed from a jury verdict in

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129 See infra notes 130-140.
131 Romero v. Int'l Harvester Co., 979 F.2d 1444, 1449 (10th Cir. 1992) (emphasis omitted) (applying Colorado law).
136 Lynch, 548 A.2d at 1281.
favor of the defendants, arguing that she should have been allowed to introduce evidence showing that the manufacturer had failed to notify the owner that a new escalator braking system, used by the manufacturer on its newer escalators, would have avoided the abrupt stop. But the court ruled that there was no post-sale duty to warn about changes in technology if the product was not defective at the time of sale.

G. Cases Specifically Adopting Section 13

Finally, a few cases have adopted section 13 of the Restatement (Third) as the governing rule. In Gamradt v. Federal Laboratories, Inc., the U.S. Court of Appeals for the Eighth Circuit said that under Minnesota law, a duty to warn will be imposed on a successor corporation only after considering the following, non-exhaustive list of relevant factors: (1) succession to a predecessor’s service contracts, (2) coverage of the particular machine under a service contract, (3) service of that machine by the purchaser corporation, and (4) a purchaser corporation’s knowledge of defects and of the location or owner of that machine. The court then cited to section 13, comment b: “The crux of the inquiry is whether the successor corporation has benefited economically from its relationship with the predecessor’s customers.” And in Tabor v. Metal Ware Corp., the Supreme Court of Utah said that “Utah imposes on a successor corporation an independent post-sale duty to warn of a predecessor corporation’s product defects under the conditions outlined in section 13 of the Restatement (Third) of Torts.”

H. Summary

In sum, those sections of the Restatement (Third) dealing with post-sale duties have received a mixed but generally favorable reception in the law since 1998. Where the post-sale duty issue was one of first impression, the Restatement position has been adopted more often than rejected. No need has apparently been felt to formally adopt section 10 in the several states whose law had already developed along the lines of that section’s principles but before the adoption of the Restatement. At least one state has rejected section 10 but does impose a post-sale duty to warn of risks that were inherent in the product at the time of sale. And a few states have explicitly rejected section 10 either because their statutes or rules of evidence limit liability to situations where there was a failure to warn at the time the product left the control of the manufacturer or seller.

139 Id. at 1278.
140 Id. at 1281.
141 380 F.3d 416 (8th Cir. 2004).
142 Id. at 421.
143 168 P.3d 814, 816 (Utah 2007).
or under “strict liability” principles, liability can only be imposed for
warning failures at the time of sale. A few states that had earlier decided
against adopting a post-sale duty to warn have not been influenced by
section 10 to change their minds.

XI. REGULATORY POST-SALE DUTIES

The above discussion pertains to the common law of post-sale
duties as it exists in the United States. While it is beyond the scope of
this Article, it is appropriate to briefly mention the ever-expanding
regulatory requirements in the United States and around the world.

Regulatory agencies in the United States have been in existence
for decades. Each agency that deals with post-sale duties has been
expanding and refining the responsibility of the manufacturer, product
seller, and product user to report safety issues to the government and
possibly to engage in some post-sale remedial program.

The main U.S. agencies are the Consumer Product Safety
Commission (“CPSC”), the National Highway Traffic Safety
Administration (“NHTSA”), and the Food and Drug Administration
(“FDA”). Most recently, Congress revised the CPSC’s laws and
regulations to expand reporting responsibilities and increase the fines for
not reporting.144

In addition, the European Union, Japan, Canada, Australia, and
other countries have enacted or enhanced reporting and recall
responsibilities for manufacturers and product sellers.145

These government reporting responsibilities are generally more
stringent than the common law post-sale duties and, therefore,
manufacturers of regulated products will first look to regulatory
requirements before even considering any common law duties.
Considering both regulatory and common law requirements is important,
however, since any products liability case will allege a violation of
common law post-sale duties and not a violation of some government
reporting responsibility.

Also, since compliance with the government’s recall
requirements will not normally be a defense in a products liability case,
the manufacturer and product seller will need to consider how far to go
in the recall to defend itself against a negligent recall claim.

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(section 20).
145 For more, see European Product Liability Review, LOVELLS NEWSLETTER (Lovells
Product+Liability+Review.
XII. CONCLUSION

Post-sale duties have been expanding in the United States by court decision and legislative action. The *Restatement (Third)* affirms this expansion and, in some respects, broadens the common law post-sale responsibilities of manufacturers. Manufacturers must act now to put into place an appropriate post-sale monitoring system and establish appropriate committees or trained personnel who can analyze the gathered information to determine whether post-sale actions might be appropriate.

A failure to take timely and adequate remedial actions can result in huge liability, including punitive damages, which could eventually result in large numbers of injured people and lead to the demise of the manufacturer.
Territorial Claims in the Domain of Accidental Harm

CONFLICTING CONCEPTIONS OF TORT PREEMPTION

Robert L. Rabin†

Territorial claims in the domain of accident law have a long and tortuous history. Criticism of tort as systematically failing to adequately compensate industrial injury victims led to a workers’ compensation movement in the Progressive era that literally swept the tort system aside, clearing the playing field for state-by-state no-fault compensation based on legislative/administrative benefits in place of tort adjudication.1 Some fifty years later, in the late 1960s, a similarly-grounded concern about inadequate compensation animated the auto no-fault movement that complemented, and in some states partially replaced tort with yet another system of legislatively-designated benefits for the victims of motor vehicle accidents.2

Then, in the mid-1970s, the tide turned. The focal point of institutional criticism of the tort system shifted dramatically from claims of under-compensation of injury victims to a perception that the system was overly generous (and unpredictably so).3 Nonetheless, for the better part of the next twenty years, one school of tort critics leveled their attacks at the internal dynamics of the tort system, pressing for legislative limitations on punitive damages, pain and suffering awards, and other remedial measures through caps and related stratagems.4 The reform efforts were incremental rather than territorial; that is, displacement of tort was not a priority agenda item.

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2 The movement was animated by the Keeton-O’Connell plan. See ROBERT E. KEETON & JEFFREY O’CONNELL, BASIC PROTECTION FOR THE TRAFFIC VICTIM (1965).

3 An early milestone enactment was the California Medical Injury Compensation Reform Act (“MICRA”) in 1975 addressing claims by the medical profession of excessive tort awards against physicians. CAL. CIV. CODE § 3333.2 (West 2009).

A more foundational critique emerged initially in the academic literature, in considerable part as a rejoinder to the expanding doctrinal reach of products liability law—with particular emphasis on the complex science and technology that was often critical to determining the outcome in defective design and warning cases. Critics posed the question of whether courts were up to the job with a negative rejoinder in mind. Juries, they asserted, could not weigh in a satisfying fashion the risk/benefit issues central to these cases, when compared to expert agencies.

Much of the early criticism came in the guise of proposals that courts recognize a regulatory compliance defense and defer to regulatory determinations in cases of conflicting territorial claims to decisionmaking authority. Thus, a prominent critic of the institutional competence of the tort system put his critique this way:

Judicial nondeference may make some sense when the administrative regulatory regime is casual or sporadic, as with consumer products. But it is wholly unpersuasive for comprehensively regulated industries. Vaccines, pesticides, aircraft, electric power plants and the like all entail potentially enormous mass-exposure hazards. Precisely because they can create public risks of this nature, these products and services are also subject to the most searching and complete state and federal safety regulation. Administrative agencies may find it politically convenient to disclaim final responsibility for the public risk choices that inhere in such licensing decisions. But the simple fact is that an agency cannot intelligently issue a license for such public-risk activities without comparing the licensee’s risks to those of the competition and determining that the new offering represents some measure of progress or, at worst, no measure of regression in the risk market in question.

Once that determination has been made by an expert licensing agency, the courts should respect it. Regulatory agencies are equipped to make the risk comparisons on which all progressive transformation of the risk environment must be based. The courts are simply not qualified to second-guess such decisions; when they choose to do so they routinely make regressive risk choices. Requiring—or at least strongly encouraging—the courts to respect the comparative risk choices made by competent, expert agencies would inject a first, small measure of rationality into a judicial regulatory system that currently runs quite wild.

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6 For a recent version of the critique, see Peter Schuck, FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot, 13 ROGER WILLIAMS U. L. REV. 73 (2008).


8 Huber, supra note 5, at 334-35.
For a variety of reasons, the regulatory compliance defense never gained a firm foothold in the state courts. Only one state, Michigan, affords it full recognition (by way of legislation); a handful of other states treat it as a bar to punitive damages. Both the Products Liability Restatement and the Restatement of the Law Third Torts: Liability for Physical and Emotional Harm, give it only non-determinative “some evidence” status, reflecting the view of most states courts.

Meanwhile, however, a far more formidable challenge to the territorial claims of tort has arisen. Beginning in 1992, with the landmark decision in Cipollone v. Liggett Group, Inc., the U.S. Supreme Court has decided a burgeoning number of preemption cases, squarely challenging the continuing vitality of tort in many domains of accident law. As I will indicate, Cipollone addressed the preemption question in an atypical context. The case did not involve competing claims to territorial authority between a regulatory regime and state tort law; rather, Cipollone involved a challenge to the continuing viability of tort in the face of statutory directives mandating explicit industry conduct.

11 Restatement (Third) of Torts: Prods. Liab. § 4 (1998) (“In connection with liability for defective design or inadequate instructions or warnings: . . . (b) a product’s compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.”); Restatement (Third) of Torts: Liab. for Physical & Emotional Harm § 13 cmt. b (Proposed Final Draft No. 1, 2005) (“[I]n products liability cases, despite the quasi-contractual relationship between the consumer and the manufacturer, the latter’s compliance with custom in designing its product is only some evidence of the adequacy of the product’s design.”).
As one moves beyond *Cipollone* to the far more common situations in which it is *agency* regulatory directives, rather than statutory warning language that arguably preempt tort law, it is critical to keep the institutional competence question in proper constitutional perspective. Preemption cases do *not* raise a question for free-standing judicial determination of whether agencies are better constituted to impose optimal standards of industry conduct than courts. That is a question of common law deference raised by the regulatory compliance defense; it is *not* the question posed by a claim of preemption. In preemption cases, whatever the frustration engendered by the difficulties in discerning legislative intent, the question under the Supremacy Clause is inescapably whether *Congress* intended to displace tort law.15

In Part I of this article, I will revisit *Cipollone* to reassess what it has to offer as a foundation for setting the boundaries of regulatory containment of the tort system. Then, in Part II, I will discuss three leading cases from the series of efforts by the Supreme Court to grapple with express preemption clauses in a variety of regulatory schemes.16 Against this backdrop, in Part III, I will discuss the circumstances under which it might be justified to imply preemption despite the absence of an express provision.17 A concluding note will tie the strands together.

I. *CIPOLLONE* REVISITED

Forty years of tobacco litigation came to a crossroads in *Cipollone*. The tobacco industry defendants, looking for a knockout punch to eliminate a continuing barrage of claims by smoking victims of failure to adequately warn, argued successfully for preemption of these tort suits based on language in the cigarette package warning label legislation.18 The amended version of that legislation contained a preemption provision, which read: “No *requirement* or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.”19

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15 U.S. CONST. art. VI, cl. 2 (The Supremacy Clause provides that the laws of the United States “shall be the supreme law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.”). For a recent reassertion of this point, see *Altria*, 129 S. Ct. at 543 (“Our inquiry into the scope of a statute’s pre-emptive effect is guided by the rule that ‘[t]he purpose of Congress is the ultimate touchstone’ in every pre-emption case.”).
16 The three leading cases I will discuss are *Lohr*, *Riegel*, and *Geier*, cited supra note 13. In particular, I will discuss the recently decided *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), addressing preemption in the context of prescription drug regulation.
17 The Court was sharply split: Justice Stevens wrote for a four-justice plurality, holding that the 1969 Act preempted failure to warn claims but not claims based on fraudulent concealment of material facts (or express warranties); Justice Blackmun wrote for three justices who rejected the displacement of common law tort claims; Justices Scalia and Thomas would have preempted categorically.
Cipollone has been taken to be the foundational case on express preemption and in particular on the preclusion of common law tort through the reading of tort duties as “requirements.” In fact, Cipollone provided a questionable foundation for any broad equation of tort duties with “requirements.” As recently as Riegel v. Medtronic, Inc., decided in the 2007-08 Term of the Court, Justice Ginsburg argued in dissent, in a case involving the preemption provision in the Medical Devices Amendments, that Congress could have meant “requirements” as precluding only state regulatory schemes imposing requirements beyond federal standards.

The key to this continuing skepticism is straightforward. Tort duties do not “require” anything other than the payment of damages. If tort liability does lead a defendant to a private assessment in favor of greater future precautionary measures, then tort, of course, has had a regulatory effect. But tort itself dictates no particular change in a losing defendant’s conduct. Indeed, under a strict liability regime, tort imposes liability with total indifference to whether a defendant might reasonably have decided against investing in additional safety. High priority is given to compensating injury victims and/or risk-spreading.

But the Cipollone plurality did not meet the challenge head-on. Rather, the plurality’s pivotal point was statutory construction of the cigarette labeling act: that the changed wording in the 1969 preemption provision—statutory language that prohibited conflicting “requirements”

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22 Id. at 1013-14 (Ginsburg, J., dissenting); see also Bates v. Dow Agrosciences LLC, 544 U.S. 431, 443 (2005) (“An occurrence that merely motivates an optional decision does not qualify as a requirement. The Court of Appeals was therefore quite wrong when it assumed that any event, such as a jury verdict, that might ‘induce’ a pesticide manufacturer to change its label should be viewed as a requirement.”); Sprietsma v. Mercury Marine, 537 U.S. 51, 63 (2002) (“The contrast between [the savings clause’s] general reference to ‘liability at common law’ and the more specific and detailed description of what is pre-empted by [the express preemption clause] indicates that [the preemption clause] was drafted to preempt performance standards and equipment requirements imposed by statute or regulation.”).
23 Tort as a regulatory regime has come to great prominence in the academic literature. For general discussion, see John C.P. Goldberg, Twentieth-Century Tort Theory, 91 GEO. L.J. 513, 513-17 (2003). For advocacy of viewing tort from a regulatory perspective in the context of preemption, see Richard A. Epstein, Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda, 1 J. TORT L. art. 5 (2006); Schuck, supra note 6.
24 Justice Blackmun, concurring in part and dissenting in part, made this point forcefully in Cipollone, 505 U.S. at 535-39. In fact, the same is often true of regulatory requirements: a violator who is willing to pay the penalty can ignore compliance. In general, however, the normative implications are quite different.
25 In this regard, see Justice Traynor’s landmark concurrence in Escola v. Coca Cola Bottling Co. of Fresno, 150 P.2d 436, 440-41 (Cal. 1944) (“Those who suffer injury from defective products are unprepared to meet its consequences. The cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business.”). For articulation of this position in the context of rejecting a regulatory compliance defense claim, see Ferebee v. Chevron Chemical Company, 736 F.2d 1529 (D.C. Cir. 1984).
rather than just “statements” (the 1965 statutory terminology)—suggested a more expansive intent than the earlier limitation to conflicting state regulatory measures.\textsuperscript{26} Even so, the \textit{Cipollone} plurality did not proscribe all tort litigation. Instead, it read the preemption provision narrowly to leave open the prospect of claims for fraud and misrepresentation against the tobacco companies.\textsuperscript{27} Indeed, in a nice bit of irony, tort claimants began to realize a measure of success for the first time immediately after \textit{Cipollone}, as plaintiffs relied on the nearly contemporaneous discovery of tobacco industry documents revealing a pattern of deceptive practices by the industry as a foundation for non-preempted tort claims.\textsuperscript{28}

What can be taken from \textit{Cipollone} that might be useful in providing broader guidance when regulatory agency directives are satisfied but injury victims nonetheless argue for liability in tort? It seems sensible to think that when Congress enacted, and then subsequently refined, specific cautionary language required on cigarette package labels, it did not mean to have that very process and outcome reopened in another forum through tort claims of failure to adequately warn. This is the core meaning of so-called “conflict” preemption, and it seems questionable—in the absence of an explicit savings clause—to read Congress as desiring, in effect, penalties on compliance, even in the guise of compensation.\textsuperscript{29}

\textsuperscript{26} The 1965 statute’s preemption clause stated: “(a) No \textit{statement} relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package; (b) No \textit{statement} relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.” Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, § 5 (1965) (current version at 15 U.S.C. § 1334 (2000)) (emphasis added).

\textsuperscript{27} This issue resurfaced before the Supreme Court in \textit{Altria Group, Inc. v. Good}, 129 S.Ct. 538 (2008), when the defendant tobacco company sought to interpose a preemption defense to plaintiff’s claim of economic harm from purchasing “light” cigarettes under the supposition that there would be less nicotine and tar intake. Defendant argued that this was a health and safety claim barred by the proscription of requirements exceeding the statutorily-prescribed warning label. A majority of the Court (5-4) disagreed, holding that the claim was one of fraud in violation of the state consumer protection law, rather than one based on health and safety. \textit{Altria} is discussed further in Part III.B.

\textsuperscript{28} See Robert L. Rabin, \textit{The Third Wave of Tobacco Tort Litigation, in REGULATING TOBACCO} ch. 7 (Robert L. Rabin & Stephen D. Sugarman eds., 2001).

\textsuperscript{29} This is a closer question than most proponents of preemption acknowledge, precisely because the well-established tradition of strict liability in tort poses a federalism challenge to conflict preemption—short of expressly-stated preclusion of tort. Thus, Professor Stephen Sugarman points out that compensation is a dominant concern reflected in state tort law and that there is no reason to think that federal regulatory legislation is indifferent to that concern—i.e., would be designed to extinguish it via preemption—unless there is explicit indication of that intent in the regulatory legislation. Moreover, the uniformity interest, offered as one justification for conflict preemption, does not override that concern because tort does not compromise uniformity; tort requires nothing beyond the payment of damages. E-mail from Stephen Sugarman to Robert Rabin (Sept. 29, 2008) (on file with author); E-mail from Stephen Sugarman to Robert Rabin (Sept. 30, 2008) (on file with author); E-mail from Stephen Sugarman to Robert Rabin (Jan. 8, 2009) (on file with author).

In response, Professor Peter Schuck argues

One simply cannot separate the compensation and regulatory issues without affecting drug manufacturer incentives in ways that are difficult to predict and that involve the
In the final analysis, there are competing considerations in resolving these preemption claims. On the one hand, it is beyond argument that Congress could limit preemption to conventional legislative and regulatory guidelines: Congress might recognize that tort plays a distinctive role in providing compensation to victims who suffer harm despite regulatory compliance. A regulatory regime like the Food and Drug Administration (“FDA”) provides no remedy to those who are injured despite compliance with regulatory directives. Correlatively, there is no inexorable principle that productivity gains from uniform national health and safety standards—a frequently invoked rationale for preemption—should be borne by injury victims in cases of residual harm. Moreover, once again, it is critical to underscore the dynamics of tort. Liability does not entail enforced departure from regulatory standards; it only compels payment of damage awards.30

The prospect of having to pay compensation under a strict liability rule, especially one not subject to a state-of-the-art defense, would surely increase the already large uncertainty that surrounds manufacturers’ large long-term investments that are necessary in order to develop socially valuable pharmaceutical products. It might also cause risk-averse manufacturers to include more in their labeling than would be optimal for consumers.

But this argument does not seem entirely responsive. For one thing, it is detached from reading preemption with congressional intent as the focal point. Congress knows how to create statutory immunity from tort law when it is concerned about the welfare of an industry. See e.g., Protection of Lawful Commerce in Arms Act, Pub. L. No. 109-92 (2005) (eliminating liability of gun manufacturers and sellers when guns are used in criminal or illegal activities to harm third persons). And for another, it rests entirely on empirical assumptions about consequential effects on industry investment decisions that are not well-documented. Indeed, Schuck rests his argument in this regard on a single citation to a newspaper article, Stephanie Saul, Bristol-Myers to Eliminate 4,800 Jobs, N.Y. TIMES Dec. 6, 2007, at C1, discussing the decline in approvals of new drug formulations between 2006-07. See Schuck, supra note 6 at 78 n.21. The Saul article makes no mention of tort liability as an explanation for job elimination. To the contrary, it references “[g]eneric competition, a dearth of new drugs and a more safety-conscious posture by the [FDA]” as factors explaining industry-wide layoffs. The article goes on to note that Bristol-Myers “is facing the same problem as many of the other drug-makers: the looming loss of patent protection for an important drug.” Saul, supra. For further skepticism about the empirical assumptions, see Michelle M. Mello & Troyen A. Brennan, Legal Concerns and the Influenza Vaccine Shortage, 294 JAMA 1817 (2005) (addressing the contraction of the vaccine suppliers’ market).

In the final analysis, one must discern congressional intent without clear guidance. But as I develop in the text, infra, the often-ignored compensation goal of tort, which has been prominent in the background when Congress has enacted regulatory legislation, provides a compelling basis for reading conflict preemption narrowly. See David A. Kessler & David C. Vladeck, A Critical Examination of the FDA’s Efforts to Preempt Failure-to-Warn Claims, 96 GEO. L.J. 461 (2008).

30 In addition, Kessler and Vladeck emphasize the distinctive, searching nature of the tort discovery process even when compared to the new drug approval protocol: “The information-gathering tools lawyers have in litigation are, by any measure, more extensive than the FDA’s. Indeed, the FDCA does not give the FDA the most important tool trial lawyers have—the right to subpoena relevant information from any source.” Kessler & Vladeck, supra note 29, at 491. But of course, there is a trade-off between the regulatory process that brings disciplined expertise to its review process, incorporating risk/risk analysis, and the determination by a lay jury in an adversarial process focused on the particulars of a plaintiff’s injury.

These strong, federalism-grounded arguments for taking a cautionary approach to displacing tort have, at times, led the Supreme Court to refer to a “presumption against preemption.” For the most recent example, see the majority opinion in Wyeth. 129 S. Ct. 1187, 1195 n.3 (2009). But as Professor Sharkey has argued, the Court has shown no consistency in invoking the
On the other hand, it is similarly clear that Congress can preclude recourse to tort if it chooses to do so. Immunity from liability for accidental harm is not an unknown proposition, and in addition to the benefits from nationally uniform health and safety standards, there is the institutional competence argument for making regulatory standards determinative: in the recent context of Riegel v. Medtronic, that the FDA has far greater expertise than juries in deciding optimal design and warning standards for medical devices.31

If Cipollone is a good starting point in highlighting these cross-cutting considerations, a more focused exploration of the parameters of preemption requires discussion of the Supreme Court’s subsequent efforts to forge a sensible pathway through the conflicting territorial claims of federal regulatory agencies and state tort law.

II. BEYOND CIPOLLONE: THREE LEADING CASES

Nearly two decades have passed since the Cipollone venture into the domain of tort. In the ensuing years, the Supreme Court has had numerous occasions to demarcate the boundaries of preemption with greater precision.32 Since every such effort has entailed a contextualized exercise in discerning Congressional intent, it is perhaps not surprising that commentators find little guidance in the Court’s performance.33 In my view, however, by focusing on a limited number of recent decisions, it is possible to point the way to a sensible working principle for resolving the tension between regulation and tort generated by preemption claims.

I begin with the Medical Devices Amendments to the Food, Drug and Cosmetic Act (MDA), which authorized FDA approval of new medical devices prior to marketing.34 In establishing the regulatory regime, Congress enacted an express preemption provision that has provided the Supreme Court with two opportunities—roughly a decade apart—to weigh in on the preclusive effect of the statute on tort claims.35

presumption. See Catherine M. Sharkey, Products Liability Preemption: An Institutional Approach, 76 GEO. WASH. L. REV. 449, 455-59 (2008). In my view, invoking the presumption (or ignoring it) is of no operational consequence.


See cases cited supra note 13.

See, e.g., Sharkey, supra note 30, at 459-71 (“The Supreme Court’s preemption jurisprudence reflects an incoherent, and at times internally inconsistent, conception of the tort-regulation pas-à-deux. . . . The Court has oscillated between competing conceptions of tort as either primarily regulatory or compensatory, with the regulatory view justifying preemptive results and the compensatory view compelling the opposite.”).


The Medical Devices Act preemption provision, reads as follows:

[No State . . . may establish or continue in effect with respect to a device intended for human use any requirement—
In *Medtronic, Inc. v. Lohr*, the Court interpreted the MDA in a fashion that left tort claims undisturbed. Ruling to the contrary in *Riegel v. Medtronic, Inc.*, the Court rejected a tort suit under the same preemption provision. Despite these contrasting holdings, the Lohr/Riegel tandem offers a useful perspective on what should be the critical factor in determining conflict preemption, as I see it: an analysis of whether the agency directive was grounded in the same evidence-based risk/benefit inquiry as the tort process would entail.

In *Lohr*, the plaintiff’s defective design claim was based on injury from the malfunctioning of a pacemaker inserted to correct a cardiac irregularity. The FDA had approved the device under the “substantial equivalence” provisions of the Amendments, a fast-track system under which new devices that appeared to be substantially similar to medical devices already on the market could be certified without independent testing of the product. There was, in other words, no evidence-based risk/benefit inquiry by the FDA, focused on the precise design of the defendant’s pacemaker; hence, there was no basis for a claim that the tort suit would be going over the same ground as the regulatory process. As a consequence, a comparative institutional competence claim for displacing a tort suit seemed unwarranted.

*Riegel* provides a counterpoint to *Lohr* that brings home the essential point. Plaintiff’s design defect claim in *Riegel* was based on the rupturing of a balloon catheter, manufactured by defendant, during an angioplasty procedure. The device had been cleared for marketing in the FDA’s product-specific pre-market approval process, not via the fast-track system. The Court characterized the claims as design defects, rather than manufacturing defects (that is, departures from the intended design).

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(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

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*Id.* at 360k(a).


37 *Id.* at 503.


39 *Id.* at 1006, 1011.

40 *Lohr*, 518 U.S. at 480-81. In both *Lohr* and *Riegel*, the Court characterizes the claims as design defects, rather than manufacturing defects (that is, departures from the intended design).

*Id.* at 483. See generally *Riegel*, 128 S. Ct. 999 (discussing design requirements to which medical devices are subjected in the approval process). See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB., §§ 2(a), 2(b) (1998). There is general agreement that tort claims based on injuries from manufacturing defects, which are departures from the approved product, are not preempted.


42 But might not the “substantial equivalence” determination be grounded in full-scale premarket approval of the earlier product? This remote possibility that the new product tracks the old in all material particulars, and that nothing substantial has occurred in the risk universe in the intervening time, is further put to rest in U.S. GOVERNMENT ACCOUNTABILITY OFFICE, GAO-09-190, MEDICAL DEVICES: FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS (2009), a highly critical review of the “substantial equivalence” process. See also Gardiner Harris, In F.D.A. Files, Claims of Rush to Approve Devices, N.Y. TIMES, Jan 13, 2009, at A14.

43 *Riegel*, 128 S. Ct. at 1005 (majority opinion).
track “substantial equivalence” process relied on in Lohr. Contra to Lohr, the Court preempted state tort claims, emphasizing that “premarket approval is specific to individual devices,” and referring to the substantial equivalence process in Lohr as an exemption rather than full-scale safety review.

A third leading case, Geier v. American Honda Motor Co., offered a refinement that contributed to identifying the pathway for future territorial limitations on the tort domain. Geier, which involved interposition of a preemption defense under the National Traffic and Motor Vehicle Safety Act, posed a not uncommon obstacle to conventional preemption analysis: the Act on its face appeared to equivocate on the displacement of state tort law (if not rejecting displacement entirely) by providing a “saving” clause—to the effect that “[c]ompliance with [a federal safety standard] does not exempt any person from any liability under common law.” At the same time, the Act contained an express preemption provision for regulatory safety standards.

Plaintiff sued in tort on a design defect theory, arguing that his injuries were enhanced by the absence of a driver’s side airbag; defendant responded by asserting a preemption defense based on a safety standard adopted by the DOT that allowed for the phasing in of air bags over time. At trial, defendant introduced testimony on technical feasibility, cost considerations, and consumer acceptance concerns that led the agency to opt for a graduated approach to the mandating of air bags.

But how was the Court to reconcile the seeming ambiguity created by both preemption and saving clauses appearing in the same

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44 Id. at 1006.
45 Id. at 1007. A caveat, however, will be relevant to my further discussion. Justice Scalia nowhere in the opinion mentions victim compensation as a complementary goal that Congress might also have in mind, along with risk-benefit considerations, in enacting regulatory legislation. Indeed, he refers to the possible reading of preemption as extending only to state regulatory activity, but not state tort law, as a “perverse distinction.” Id. at 1008. But the distinction is only perverse if one totally ignores the fact that state regulatory law offers nothing by way of compensation to accident victims, unlike tort law, which does double-duty in promoting both regulatory and compensation objectives. See also infra note 56.
48 Id. § 1397(k).
49 Id. § 1392(d) (“Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard.”). Note that in this preemption clause, it is not a “requirement” that is equated with tort liability, but a “safety standard.” Geier, 529 U.S. at 871.
51 See Geier, 529 U.S. at 877-78.
regulatory scheme? The Court’s resolution was to read congressional intent as limiting the saving clause to regulatory directives adopted by the agency that set a floor on safety, rather than those grounded in risk/benefit balancing. With reference to the air-bag regulation, the Court regarded no-air-bag tort claims as directly inconsistent with the optimality of a phased-in scheme of safety enhancement envisioned by the agency.

What is perhaps most interesting, however, about the Geier opinion is that the saving clause compelled the Court to take cognizance of a broader set of systemic congressional purposes than one finds in the advocacy of categorical preemption proponents, as well as in later cases like Riegel, which focus exclusively on tort as a competing regulatory regime. Contrary to this constrained reading of congressional intent, Justice Breyer remarked that:

[T]he saving clause reflects a congressional determination that occasional nonuniformity is a small price to pay for a system in which juries not only create, but also enforce, safety standards, while simultaneously providing necessary compensation to victims. That policy by itself disfavors pre-emption, at least some of the time. But we can find nothing in any natural reading of the two provisions that would favor one set of policies over the other where a jury-imposed safety standard actually conflicts with a federal safety standard.

In my view, there is no reason to think that simply because a saving clause is not present in a regulatory scheme, Congress has necessarily turned a blind eye to this concern for tort as a mechanism of injury compensation—again that is, apart from the situation of “actual conflict” referred to by Justice Breyer.

52 Id. at 868.
53 Id. at 874. The Court makes reference to “frustration-of-purpos[e]” as a rationale for invoking preemption, id. (alteration in original), and this factor is sometimes treated as an independent trigger for the defense. But as I see it, frustration of purpose—in Geier and more generally—is simply one variant in expressing the prospect of directly competing risk/benefit analysis that is the crux of the test for satisfying conflict preemption.
54 For advocacy of this categorical approach, see Epstein, supra note 23; Schuck, supra note 6.
55 Geier, 529 U.S. at 871 (emphasis added). Justice Breyer’s concession regarding congressional sensitivity to the compensation goal can plausibly raise the question of why a saving clause should not be taken as a legislative expression of intent to limit the preemption clause to conflicting state regulatory directives. It certainly can be argued that this is a more natural reconciliation of the preemption and saving clauses than that adopted by the Court, which resolved the facial conflict by relegating saved tort claims to regulatory directives meant to establish a floor on safety. Those latter directives would create no conflict with tort claims even without a saving clause.
56 In response to the Riegel decision, Senator Edward Kennedy (D-MA) remarked, “Congress never intended that F.D.A. approval would give blanket immunity to manufacturers from liability for injuries caused by faulty devices,” and Representative Henry Waxman (D-CA) added, “The Supreme Court’s decision strips consumers of the rights they’ve had for decades. . . . This isn’t what Congress intended, and we’ll pass legislation as quickly as possible to fix this nonsensical situation.” Linda Greenhouse, Justices Shield Medical Devices From Lawsuits, N.Y. TIMES, Feb. 21, 2008, at A1 (internal quotation marks omitted). These reactions are not conclusive, of course, on legislative intent, but surely Kennedy and Waxman, leaders in the enactment of the Medical Devices
If a saving clause coupled with a preemption provision poses one set of interpretive conundrums, what of a regulatory scheme that makes no explicit reference at all to tort through a preemption clause? Under some circumstances can a congressional intent to preempt be nonetheless implied? The following Part will address that question with special reference to the context of prescription drug regulation by the FDA.

III. IMPLIED PREEMPTION: PRESCRIPTION DRUG REGULATION AND BEYOND

The Supreme Court faced its latest challenge in the preemption arena in *Wyeth v. Levine*, involving the highly-contested question of preemption in the prescription drug area. Critical to the inquiry is that new prescription drugs are certified for marketing by the FDA under a different statutory scheme than the Court reviewed in the *Lohr/Riegel* tandem involving new medical devices—and it is a statutory scheme that has no express preemption provision. Thus, the case raised a question of implied preemption in an especially dynamic area of tort litigation.

In *Levine*, plaintiff’s arm had to be partially amputated after gangrene set in following a botched injection of the anti-nausea drug, Phenergan, by a so-called “IV push” procedure (direct injection into a vein) that mistakenly missed the mark and mixed the drug with arterial blood. Plaintiff argued inadequate warning of the risk of amputation— the risk that in fact came to fruition. In response, defendant Wyeth pointed to the explicit language

Amendments (“MDA”), are more privy to congressional deliberations on congressional aims than Justice Scalia, who concluded his armchair speculation with the comment that

it is implausible that the MDA was meant to “grant greater power (to set state standards ‘different from, or in addition to’ federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes.” That perverse distinction is not required or even suggested by the broad language Congress chose in the MDA, and we will not turn somersaults to create it.


That the MDA was intended to grant significant power to a jury is “implausible” only if one reads the desire to compensate victims, via tort liability, entirely out of the purview of Congress. While I support the Court’s conclusion in *Riegel*, where the tort suit would revisit the regulatory approval process with no claim of changed circumstances, it is quite another matter to adopt the broader implausibility rationale.


on the label that warned about the risk of amputation, and further noted that it had, in fact, sought to revise the warning to re-word the reference to the risk of amputation, and was instructed by the FDA to retain the existing warning.\(^{60}\)

The Supreme Court, by a 6-3 margin, upheld the Vermont state court’s damage award, premised on a rejection of the preemption defense. The majority opinion, however, does not treat the absence of an express preemption clause as determinative of the outcome. Instead, the majority places great emphasis on the FDA’s “changes being effected” (CBE) regulation, which provides that a manufacturer can take the initiative to strengthen a product risk warning without prior agency approval when “safe use of the drug product” would warrant such action.\(^{61}\) Despite evidence of “at least 20 incidents prior to [Levine’s] injury in which a Phenergan injection resulted in gangrene and an amputation,”\(^{62}\) Wyeth had not sought—nor had the FDA taken any action to preclude—a stronger warning.

Hence, in the majority’s view, there was no direct conflict between plaintiff’s tort claim and the agency’s earlier, now possibly outdated, approval. Indeed, the majority opinion suggests a sharply restrictive test for establishing conflict preemption: “absent clear evidence that the FDA would not have approved a change in Phenergan’s label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.”\(^{63}\) There is no hint here of the preemption determination resting on a distinction between express and implied congressional intent; instead, the dominant theme is consistent with the redundancy principle that, as I have expressed it, seems consonant with reconciling tort and regulatory functions.\(^{64}\)

\(^{60}\) The warning on the label read in part:

Due to the close proximity of arteries and veins in the areas most commonly used for intravenous injection, extreme care should be exercised to avoid perivascular extravasation or inadvertent intra-arterial injection. Reports compatible with inadvertent intra-arterial injection of Phenergan Injection, usually in conjunction with other drugs intended for intravenous use, suggest that pain, severe chemical irritation, severe spasm of distal vessels, and resultant gangrene requiring amputation are likely under such circumstances. Intravenous injection was intended in all the cases reported but perivascular extravasation or arterial placement of the needle is now suspect. There is no proven successful management of this condition after it occurs. . . .

\(^{61}\) Wyeth, 129 S. Ct. at 1192 n.1. Wyeth’s proposed revision was read by the Court as a formatting change rather than a heightened warning of risk. See id. at 1192 n.5.

\(^{62}\) See supra text accompanying notes 39-40. An alternative pathway for determining that the regulatory directive reflects meaningful consideration of the risk/benefit analysis that would be undertaken in the tort claim is spelled out in the “agency reference model” proposed by Professor Sharkey, supra note 30; for more detailed discussion, see her follow-up article, Sharkey, supra note 58. As a prelude to determining the agency directive/tort preemption issue, Sharkey would require that:
Moreover, the “implied” preemption characterization of new drug approvals is not quite as straightforward as commentators suggest. In fact, the FDCA has an express saving clause that provides: “Nothing in the amendments . . . shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provisions of State law.”

Whether one views this provision as a saving clause, or instead as a narrow preemption clause, depends on the spin that is put on “unless there is direct and positive conflict between such amendments and such provision of state law.” Whichever characterization is adopted, the key correlative question is whether the “provision of state law” language is read, like “requirements” in earlier-discussed cases, as including state tort awards. Since the Wyeth majority found no direct conflict between the agency action on Phenergan and a failure to warn claim, there was no occasion to address this issue.

This narrow reading of conflict preemption, in turn, puts to rest the broader position taken by the FDA (and defendant in Wyeth) that agency approval of a new prescription drug categorically displaces later tort relief for an injury victim. This is a salutary development. I see no courts should look to agencies to supply the empirical data necessary to determine whether a uniform federal regulatory policy should exist—as agencies are in the best position to gather and evaluate data—and to make informed choices regarding the welfare of the American public.

Sharkey, supra note 30, at 452-53.

There is appeal to this judicial “hard-look” position and it certainly would be beneficial if agencies would follow Sharkey’s lead on their own initiative. But I have three reservations about the courts imposing the requirement as a judicial initiative as Sharkey proposes. First, there is no plausible reason to read this stipulation into congressional intent as an intrinsic feature of the preemption inquiry. Second, the inquiry seems in part to miss the mark. While it would make a great deal of sense to have the agencies submit findings to support their risk/benefit analysis because that goes directly to the issue of comparative institutional competence, which is the central determinant (and rationale) for conflict preemption, I fail to see what expertise the agency has to supply in predicting the value of uniformity, which is not an element of the agency protocol for regulatory approval. Finally, I am concerned that imposing this requirement on the agencies would be an invitation to ex post rationalization (i.e., building a paper record after the fact).

Having expressed these reservations, I would emphasize that Sharkey’s proposal is in part meant to focus the preemption inquiry precisely in the right direction, as I see it. See Sharkey, supra note 58, at 423 ("[W]hen it comes to making an implied conflict preemption determination, it is critical to discern whether the FDA has weighed in on the precise risk the state action likewise seeks to regulate.").


Id.

During the Bush administration, the FDA, along with other regulatory agencies, took this position, venturing beyond contained conflict preemption in a series of regulatory preambles. See generally Catherine M. Sharkey, Preemption by Preamble: Federal Agencies and the Federalization of Tort Law, 56 DePaul L. Rev. 227 (2007). The FDA preamble declares that: “FDA believes that under existing preemption principles, FDA approval of labeling under the act . . . preempts conflicting or contrary State law.” Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, at 3922 (Jan. 24, 2006). For discussion, particularly focused on the FDA, see Sharkey, supra note 30, at 504-05, 511-13. See also Kessler & Vladeck, supra note 29.
reason to think that Congress, in enacting regulatory schemes like the provision for premarketing review of new prescription drugs, entirely lost sight of tort as the sole medium for providing victim compensation when injury occurs after an agency certifies a new product for marketing. As a consequence, I would read conflict preemption narrowly, confining it, as previously indicated, to cases in which plaintiff’s claim is based on agency action grounded in the same evidence-based risk/benefit inquiry as the tort process would entail.68

Under this narrowly-framed preemption defense, what are the principal types of tort claims that survive? Most importantly, claims should survive that are based on substantial new evidence of risk arising after a product design has been approved if the agency has failed to weigh in on the new findings in a determinate manner at the time of product use by the injury victim. I read the *Wyeth* majority opinion as consistent with this position: the majority appears to embrace the

The *Wyeth* majority gave short shrift to the FDA preamble, which had been inserted into an agency rule without public notice-and-comment, referring to it as “an agency’s mere assertion that state law is an obstacle to achieving its statutory objectives.” *Wyeth*, 129 S. Ct. at 1201.

68 Like Sugarman, supra note 29, Kessler and Vladeck argue that the compensation goal should in effect read preemption out of new drug approval cases:

> [T]he moment the FDA approves a new drug is the one moment the agency is in the best position to be the exclusive arbiter of a drug’s safety and effectiveness. On that day, the FDA has had access to and has devoted considerable resources to reviewing carefully all of the extant health and safety data relating to the drug. On that day, and that day only, we agree that the FDA’s determinations about labeling ought not be subject to re-examination by courts or juries in failure-to-warn cases.

Kessler & Vladeck, *supra* note 29, at 465. They attach great weight to the 2007 Amendments to the FDCA, Pub. L. No. 110-85, 121 Stat. 823 (2007). Kessler & Vladeck, *supra* note 29, at 467-69. Those provisions give the FDA greater authority to monitor post-approval risks associated with a drug, and to require labeling changes and safety studies by manufacturers. See *id.* at nn.23-25 (citing provisions of the FDCA). At the same time, however, Kessler and Vladeck assert that the Amendments codify “existing requirements that obligate drug manufacturers to provide up-to-date safety information to physicians and patients and authorize manufacturers to do so without first securing the FDA’s approval. The codification of this obligation undercuts the key pro-preemption argument the FDA and manufacturers make—namely, that the FDA alone decides the content of drug labels.” *id.* at 468-69, (discussing FDAAA tit. IX, § 901(a), 505(o)(4)(I), 121 Stat. 823, 925-26 (2007)).

Contrary to Kessler and Vladeck, Schuck reads the enhanced post-monitoring authority in the 2007 Amendments to support his case for categorical preemption of tort claims (apart from misrepresentations to the agency). See Schuck, *supra* note 6, at 83. It is a matter of whether one sees the glass as half-full or half-empty.

In contrast to both readings, I regard the Amendments as consistent with my position in the text. On the one hand, the manufacturer’s obligation to propose labeling revisions in light of access to new risk information seems germane to allowing a tort claim only so long as the FDA has failed to act on the information. On the other hand, the FDA’s bolstered authority to monitor and require labeling changes similarly generates a conflict situation only when the agency has taken post-approval action in view of the allegedly changed circumstances. Prior to the 2007 Amendments, post-approval monitoring by the agency was sharply criticized in Institute of Medicine of the National Academies, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (2007), *available at* http://books.nap.edu/openbook/0309103035/; U.S. Government Accountability Office, *Drug Safety: Improvement Needed in FDA’s Postmarket Decision-Making and Oversight Process* (2006), *available at* http://www.gao.gov/new.items/d06402.pdf.
proposition that new risk information, not addressed in determinative fashion by the agency, provides the foundation for a state tort claim.69

This category of surviving claims is a logical consequence of containing the comparative institutional competence argument for regulatory preemption within its own domain. If the tort claim rests on an assertion that substantial post-approval new evidence of risk has come to light, and has neither been incorporated into a revised warning, nor rejected by the agency as insubstantial, the foundational risk/benefit analysis on which agency certification was based is inapposite. Hence, the tort claim is not an effort to revisit and supersede the regulatory approval process.70

A second critical category of surviving claims should be those grounded in misrepresentations made to the agency in the certification or post-approval process. Once again, this limitation on the scope of preemption follows from a purposive analysis of congressional intent. The agency’s certification process is not duplicated by a tort claim based on risk/benefit information that should have been provided to the agency but was not.71 On this score, I subscribe to Peter Schuck’s proposal that the “disclosure deficit,” as he calls it, lifting the preemption bar, should not be limited to instances of fraud.72 Like fraudulent misrepresentations to the agency, instances of innocent or negligent misrepresentation (including knowing failure to provide material data) undermine the foundation for preempting tort based on narrowly-conceived conflict grounds.73

69 See Wyeth, 129 S. Ct. 1187 at 1197. In fact, as I read the dissenting opinion, there is no disagreement on this proposition. Rather, the dissent contests that there was new risk information that compromised the adequacy of the existing label. See Wyeth, 129 S. Ct. at 1122-25 (Alito, J., dissenting).

In Riegel, Justice Ginsburg had noted, “The Court’s holding does not reach an important issue outside the bounds of this case: the preemptive effect of § 360k(a) where evidence of a medical device’s defect comes to light only after the device receives premarket approval.” Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1013 n.1 (2008) (Ginsburg, J., dissenting).

Commentators who advocate broad, “categorical” preemption, as Schuck calls it, see Schuck, supra note 6, at 102, would make no allowance for new risk information emerging after regulatory approval. His view rejects victim compensation as a complementary consideration, characterizing tort exclusively as a contrasting regulatory regime, see id. at 78, 93, a characterization that in my view is indifferent to congressional intent as the foundation for preemption analysis. See also Epstein, supra note 23 (advocating blanket preemption for FDA drug approvals based on the comprehensive regulatory scheme established by Congress).

70 This, of course, says nothing about the merits of the tort claim. At trial, a court might find the studies methodologically flawed or unpersuasive for any of a variety of reasons. Or the plaintiff might fail to establish a cause-in-fact relationship between her injury and the product.

71 In this regard, it is critical to note that FDA certifications, like those of other health and safety regulatory agencies, are based on data supplied by the applicant. See Kessler & Vladeck, supra note 29, at 491.

72 Schuck, supra note 6, at 102-05.

73 I would also support a threshold requirement that the pleading be with particularity, as advocated by Schuck, supra note 6, at 105-07; see Fed. R. Civ. P. 9(b).
Let me trace, in somewhat more detail, the contours of these two important categories of tort cases that should survive preemption defense claims grounded in purportedly superseding agency directives.

A. New Evidence

Two experienced participant/observers, one the former commissioner of the FDA, put the case for limiting the preclusive effect of agency directives in perspective:

At the time of approval, the FDA’s knowledge-base may be close to perfect, but it is also highly limited because, at that point, the drug has been tested on a relatively small population of patients. Once the drug enters the marketplace, risks that are relatively rare, that manifest themselves only after an extended period of time, or that affect vulnerable subpopulations, begin to emerge. These are often not risks foreseen by the drug’s manufacturer or the FDA and, for that reason, are not addressed on the label.74

Two recent, highly publicized controversies are illustrative of the post-approval issues raised by new evidence of risk that need to be resolved in aligning the domains of regulation and tort. Initially, I will discuss the scenario in the mass tort litigation arising out of claims that antidepressant drugs have triggered suicidal reactions.75 Then, I will turn to the claims of cardiac disease stemming from ingestion of the anti-arthritis drug Vioxx.

Colacicco v. Apotex, Inc.,76 involved two consolidated wrongful death claims by survivors of adults who committed suicide, allegedly as a consequence of taking antidepressants. Collacicco committed suicide after beginning a prescribed regimen of ingesting the antidepressant Paxil; DeAngelis, the other decedent, had ingested Zoloft in the days before his suicide. Both drugs belong to the class of antidepressants known as selective serotonin reuptake inhibitors (SSRIs), which have triggered major scientific controversy in recent years over whether they promote suicidal tendencies.77

Paxil bore a warning label deflecting any causal association: “[t]he possibility of a suicide attempt is inherent in major depressive disorder and may persist until significant remission occurs.”78 Zoloft bore a similar warning label, deviating only in referring to “depression” rather than “major depressive disorder.”

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74 Kessler & Vladeck, supra note 29, at 466.
75 For detailed discussion, see Nagareda, supra note 58, at 25-36.
76 521 F.3d 253 (3d Cir. 2008), vacated and remanded, No. 08-437, 2009 WL 578682 (U.S. Mar. 9, 2009).
77 Related controversies involve causal effects in children and adolescents, although that was not an issue in Colacicco. For discussion of the scientific controversy, see Nagareda, supra note 58, at 26 n.106; Nicholas Bakalar, Suicide Findings Question Link to Antidepressants, N.Y. TIMES, July 10, 2007 at F7; U.S. Food and Drug Administration, Antidepressant Use in Children, Adolescents, and Adults, http://www.fda.gov/cder/drug/antidepressants/default.htm (last visited Feb. 13, 2009).
78 Colacicco, 521 F.3d at 256.
than “major depressive disorder.”\textsuperscript{79} The linch-pin for both the tort claims and the preemption defense was the fact that neither label indicated any causal relationship between ingestion of the drug and suicidal behavior.

In response to the plaintiffs’ claims of failure to adequately warn, the \textit{Colacicco} majority opinion supported granting summary judgment in favor of defendants by documenting that for more than a decade before the suicidal incidents occurred, the FDA had consistently monitored the controversy about the relationship between SSRIs and adult suicide: denying citizen petitions for labeling change, extending the existing warning to new disorders, and relying on advisory committee recommendations.\textsuperscript{80} The court concluded that there was an ongoing dialectic, in which the FDA had unwaveringly taken the position that the defendants’ warning labels were adequate.\textsuperscript{81}

Most critically, in my view, to assessing the significance of this holding is the court’s insistence that conflict preemption determinations are case-specific, and its concomitant careful delineation of what was not being decided:

\begin{quote}
[W]e need not decide whether preemption would be appropriate under different facts—such as where the FDA had not rejected the substance of the warning sought or where the FDA only stated its position after a lawsuit had been initiated—or under the broader theories of preemption argued by the parties. Thus, we do not decide whether the FDA’s mere approval of drug labeling is sufficient to preempt state law claims alleging that the labeling failed to warn of a given danger, [or] whether FDA approval of drug labeling constitutes minimum standards in the absence of the FDA’s express rejection of a specific warning . . . .\textsuperscript{82}
\end{quote}

It is these factual scenarios, put aside for another day by the court, that are critical to defining in further detail the limits of conflict preemption. In my view, the court has in fact articulated precisely where the boundaries should be drawn, with each of the prospective scenarios falling outside the scope of preemption. If the FDA had not rejected the substance of the proposed warning, had only stated its position after the onset of the litigation, or had relied on its mere approval of the label, preemption would be unwarranted, as I see it, because the tort claim would be raising evidentiary issues on which the FDA had not taken a determinative position.\textsuperscript{83}

\textsuperscript{79} \textit{Id.} at 257.
\textsuperscript{80} \textit{Id.} at 269-70.
\textsuperscript{81} \textit{Id.} at 271.
\textsuperscript{82} \textit{Id.}
\textsuperscript{83} The \textit{Colacicco} opinion, in fact, tips its hand on the “mere approval” question when it explicitly distinguishes “between the agency’s legal position in its amicus brief and its factual representations”.

The FDA’s summary of its scientific determinations must be distinguished from the agency’s construction of a statute, as the review of scientific information is strictly within its expertise. The FDA asserted facts [in this case] in support of its legal position, and we take notice of its statement of those facts, rather than its legal position.
By contrast, the Vioxx litigation is illuminating. In the early 1990s, Merck began to develop plans for marketing Vioxx, a non-steroidal anti-inflammatory drug (NSAID), as research indicated that it suppressed the pain and inflammation of arthritis sufferers, without causing the side-effects of gastrointestinal perforations and bleeding often associated with the competing over-the-counter products already on the market.

From the outset, Merck scientists expressed unease about possible adverse cardiac consequences of the product. But in September

Id. at 270 n.15.

This question has been widely discussed in the context of the FDA preamble on preemption, see Sharkey, supra note 58, at 421-24, with the focal point being whether the agency’s assertion of plenary power to preempt under the FDCA should be given Chevron deference or more limited Skidmore deference. See Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 468 U.S. 837 (1984); Skidmore v. Swift & Co., 323 U.S. 134 (1944). I see no reason why the agency’s views on congressional intent should be afforded any weight at all; the FDA has no comparative expertise advantage over the judiciary when it comes to statutory construction. The Wyeth majority reached a similar conclusion. See Wyeth v. Levine, 129 S. Ct. 1187, 1200-01 (2009).


85 A good description of the perceived health benefits of Vioxx is offered in In re Vioxx Products Liability Litigation, 401 F. Supp. 2d 565, 570-71 (E.D. La. 2005)):

Vioxx (known generically as rofecoxib) belongs to a general class of pain relievers known as non-steroidal anti-inflammatory drugs (“NSAIDs”). This class of drugs contains well-known medications sold either over the counter-such as Advil (ibuprofen) and Aleve (naproxen)-or by prescription-such as Daypro (oxaprozin) and Voltaren (diclofenac). NSAIDs work by inhibiting cyclooxygenase (COX), an enzyme that stimulates synthesis of prostaglandins, which are chemicals produced in the body that promote certain effects.

Traditional NSAIDs have been a longstanding treatment option for patients needing relief from chronic or acute inflammation and pain associated with osteoarthritis, [sic] rheumatoid arthritis, and other musculoskeletal conditions. This relief, however, comes with significant adverse side effects. Specifically, traditional NSAIDs greatly increase the risk of gastrointestinal perforations, ulcers, and bleeds (“PUBs”). This risk is increased when high doses are ingested, which is often necessary to remedy chronic or acute inflammation and pain. Scientists estimated that traditional NSAID-induced PUBs caused a significant number of deaths and hospitalizations each year in the United States.

In the early 1990s, scientists discovered that the COX enzyme had two forms-COX-1 and COX-2-each of which appeared to have several distinct functions. Scientists believed that COX-1 affected the synthesis or production of prostaglandins responsible for protection of the stomach lining, whereas COX-2 mediated the synthesis or production of prostaglandins responsible for pain and inflammation. This belief led scientists to hypothesize that “selective” NSAIDs designed to inhibit COX-2, but not COX-1, could offer the same pain relief as traditional NSAIDs with the reduced risk of fatal or debilitating PUBs. In addition, scientists believed that such drugs might be able to prove beneficial for the prevention or treatment of other conditions, such as Alzheimer’s disease and certain cancers, where evidence suggested that inflammation may play a causative role.

Id.
1999, when the FDA approved Vioxx for marketing, there was no conclusive evidence in that regard. Soon thereafter, however, unsettling data emerged. In March, 2000, a Merck study of 8,000 rheumatoid arthritis suffers, the Vigor study, compared the efficacy of Vioxx with that of a competing traditional NSAID product, Naproxen. Vioxx was found to be more efficacious than its competitor in reducing the gastrointestinal side-effects, but patients using it suffered five times as many heart attacks.

More studies followed and the concerns in the scientific community mounted, but Merck maintained that the data were inconclusive: with regard to the Vigor study, for example, Merck argued that it was the cardiac-protective characteristics of Naproxen rather than heightened risks of Vioxx that explained the disparity in cardiac events. In the end, however, Merck voluntarily pulled the product off the market when Approve, an ongoing 2004 trial of the efficacy of Vioxx in preventing colon polyps, indicated alarming rates of heart problems in Vioxx users.

During the four-year post-approval process, Merck reported its findings (and conclusions) to the FDA; independent scientists weighed in, often critically; and controversy raged within the agency itself. In particular, an in-house FDA scientist contended that his assessment of the Vioxx data, which indicated that Vioxx dramatically increased the risk of heart disease, was consistently suppressed by his superiors at the FDA. Most critically, however, throughout this period of agency monitoring, the FDA never arrived at a firm conclusion on cardiac risks associated with the product. The agency neither dismissed the growing evidence, nor on the other hand did it suggest that Merck change its label.86

As tort suits came to be filed in steadily growing numbers—expanding in volume after the product was removed from the market amidst great fanfare—the FDA remained agnostic in its stance on the cardiac risks posed by Vioxx.87 And concomitantly, the preemption defense played no substantial role in stemming the tide of lawsuits.88

Nor should it have, in my view. Whether the scientific data, in fact, supported liability in tort has been hotly contested.89 Legitimate questions exist as to whether there was substantial new evidence of risk post-approval, both on the threshold issue of generic risk, and in

86 See supra note 84.
87 As of November 2004, 1000 plaintiff groups had filed 375 personal injury lawsuits against Merck, but after Vioxx’s withdrawal from the market, attorneys expected a significant increase in filings. See Alex Berenson, et al., supra note 84.
89 Of the 18 cases tried to judgment prior to the national settlement, Merck won 13 and plaintiffs won 5, although some judgments for plaintiffs were later reversed on appeal. See Samuel Issacharoff, Private Claims, Aggregate Rights, 2008 SUP. CT. REV. (forthcoming), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1289505#.
individual tort suits brought by users with a spectrum of confounding cardiac risk factors, as well as a wide range of temporal dose-response circumstances. But these questions of risk analysis that might serve as barriers to reanalysis in tort were not issues on which the FDA had taken a stand. And consequently, the Vioxx litigation provides a nice counterpoint to the earlier-discussed SSRI tort suits, illuminating the boundaries of regulatory preemption by sharpening the definition of new evidence, and keeping the defense narrow in scope.90

B. Misrepresentations

In \textit{Altria Group, Inc. v. Good},91 the Supreme Court came full-circle back to its initial venture in marking the territorial restrictions on tort law, the preemption clause in the cigarette labeling act. Reaffirming its earlier plurality opinion in \textit{Cipollone}, the Court held that a claim of fraud—based in \textit{Altria} on advertising “light” cigarettes as delivering reduced tar and nicotine—was not preempted by the labeling act’s preclusion of “requirements” related to smoking and health beyond those expressly delineated in the statute.92

In a sharp dissent, Justice Thomas, writing for four members of the Court, twice noted the “theoretical [in]elegance” of carving out a divide between preempted claims of inadequate warning and non-preempted claims of fraud.93 But the asserted inelegance of the distinction is entirely beside the point. There is no theoretical elegance to statutes such as the federal auto safety act, discussed earlier,94 that requires tortured reconciliation of a preemption and saving clause, or the September 11th Victim Compensation Fund of 2001,95 a benefits scheme combining internally contradictory tort-centric and social welfare provisions.96 The interpretive task is to provide a defensible reading to congressional intent, not to evaluate theoretical elegance.97


92 Id. at 549.

93 Id. at 553, 560 (Thomas, J., dissenting).

94 See discussion of \textit{Geier}, supra Part II.


97 Justice Thomas asserts in that regard that “[t]he text of the statute must control.” \textit{Altria}, 129 S. Ct. at 558 (Thomas, J., dissenting). But that is an entirely illusory view; the foundational reading of “requirements” in \textit{Cipollone} to include tort suits cannot be found from textual reading of the preemption clause. It is based on an interpretive gloss—and a highly contested one at the time. \textit{See supra} text accompanying notes 20-22. Indeed, in my view, the generally accepted dichotomy between express and implied preemption is an oversimplification if it is taken to mean anything more than the difference between statutes that contain a preemption clause and those that do not. Defining the scope of an “express” preemption clause is always an interpretive matter (i.e., an exercise in implication).
In an important sense, the majority view in *Altria* provides a salient consideration in defining the scope of regulatory preemption provisions. The central thrust of *Altria* is to treat tort claims based on fraudulent misrepresentations as theoretically distinct from proscribed claims that would directly challenge the sufficiency of congressionally-determined upper limits on warning language. Fraud is inherently an exercise in paying lip-service respect to the legislative labeling directives. Rather than challenging the adequacy of the required warning, the misrepresentation claim in *Altria* is premised on defendant creating a false sense of security that the legislative directive has been satisfied.

Similarly, in the context of regulatory directives, there is no reason to conclude that Congress would anticipate sweeping exemption from tort liability where the claim of industry misconduct is based on a polluting of the agency process rather than a challenge to its substantive determinations. For this reason, I would read *Buckman* narrowly, containing its reach to stand-alone fraud on the agency claims, as in the case itself—where the Court concluded that a private right of action would be inconsistent with the FDA’s self-policing authority.

### IV. CONCLUDING THOUGHTS

In the preceding section, the focal point of my discussion was predominantly the intersection of FDA regulation and the tort system. It is a natural tack to pursue, both because it is highly topical (and much-discussed by the commentators) at this point in time and due to the FDA’s intrinsic importance as a singularly comprehensive regulatory

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98 *Altria*, 129 S. Ct. at 551 (majority opinion).

99 Fraud claims are to preempted inadequate warning claims somewhat as manufacturing defect claims are to design defect claims: they are deviations from the legislative or regulatory norm rather than challenges to its adequacy.

100 See *Buckman v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 344 (2001) (consultant to a manufacturer of orthopedic bone screws was alleged to have supplied false information to the FDA in the product approval process). For detailed discussion of the issue, see Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 NW. U. L. REV. 841 (2008). Sharkey would impose a primary jurisdiction-type requirement as a prelude to a private tort suit: “Once the FDA has made a finding of such fraud . . . private litigants should be able to wield such findings offensively to pursue damages against manufacturers in their state law tort litigation and, where necessary, to disarm regulatory immunity or preemption.” *Id.* at 844.

I would not impose any such restriction on state tort law. If the FDA has, in fact, exercised “primary jurisdiction” then I would, as a matter of course, concur that a tort suit can make use of the agency finding. But I would also allow a tort suit on grounds of fraud (or other material misrepresentation) where the agency has made no such finding. Where the agency approval is materially based on false information, a tort suit is not in conflict with the agency finding under my constrained definition of conflict; that is, the agency directive was not grounded in the same evidence-based risk/benefit inquiry as the tort claim because the evidence before the agency was polluted. It follows, of course, that if the FDA has investigated and rejected the fraud or misrepresentation allegations, then it would be appropriate to preempt the tort claim.
authority that nonetheless cannot possibly achieve perfection in preventing unanticipated injuries.

But my intent in this Article has been to be more all-encompassing. In the course of my discussion, I have alluded to a wide array of regulatory schemes that generate a broad spectrum of agency directives creating tensions with accident law—tensions that have crystallized into preemption claims with increasing frequency in recent years. Whatever the political leaning of the executive branch, there is no reason to think that sharply disparate views on the appropriate scope of preemption claims will disappear from the policy arena. In proposing a framework for addressing these tensions, based on focused examination of whether the agency directive is grounded in the same evidence-based risk/benefit inquiry as the tort process would entail, I join those commentators who seek to forge a path that recognizes the distinct benefits that both regulation and tort have to offer.
The Two Explosive Proof-of-Causation
Doctrines Central to Asbestos Claims

Jane Stapleton
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INTRODUCTION

For decades the volume of asbestos claims has been a unique and mesmerizing phenomenon. This historic wave of civil claims would never have been possible had U.S. common law courts not adopted two radical dispensations from orthodox rules for the proof of causation, tantamount to causal fictions, that enabled asbestos plaintiffs to establish against each defendant factual causation to the plaintiffs’ entire physical condition for which the defendant would, therefore, be jointly and severally liable. Yet these proof-of-causation doctrines have gone virtually unremarked by courts and the academy. We should not, therefore, be too surprised that, even though the Third Restatement (Torts): Products Liability (“Products Liability Restatement”) elsewhere acknowledged a doctrinal approach that courts had developed especially for the asbestos context,1 it was silent on the special causal proof rules on which asbestos cases proceed. Indeed, the Products Liability Restatement asserts that “[w]hether a product defect caused harm to persons or property is determined by the prevailing rules and principles governing causation in tort:”2 the Reporters had been led to believe that “traditional notions of causation retain their vitality in products liability.”3 What are these radical proof-of-causation doctrines? Why were they adopted? Why have they yet to face rigorous academic analysis? Why was the Products Liability Restatement silent about them? What might we learn from this apparently profound failure of the restatement process?

This Article is divided into six Parts. Part I describes how, in asbestosis cases, U.S. courts absolve plaintiffs from the requirement of proving the portion of the total injury for which each culpable exposer was responsible, and thereby, in effect, proceed on the fiction that asbestosis is an indivisible injury attracting joint and several liability. Part II investigates the origin of this indivisibility-of-injury doctrine in

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1 See infra note 84.
Borel v. Fibreboard Paper Products Corp, while Part III argues that this special proof-of-causation doctrine could apply to any cumulative condition that the court is prepared to hold is not “reasonably capable of being divided” on the available evidence.

Part IV describes a second, far more radical doctrine concerning proof of causation that U.S. courts developed in claims for asbestos-related cancer whereby a plaintiff is allowed to establish factual causation against a defendant merely by showing that the defendant’s tort exposed the plaintiff to a significant amount of asbestos and therefore to a significant risk of contracting an asbestos-related cancer. In effect, this allows the plaintiff to proceed on the basis that each significant exposure to the risks of asbestos was causally involved in the triggering of the cancer. Functionally, this doctrine is tantamount to the fiction that asbestos-related cancer is contracted by a threshold mechanism, which in turn explains why this doctrine is accompanied by a rule of joint and several liability. Part V argues that this exposure-to-risk doctrine, which allows proof of causation of a condition by merely proving exposure to the risk of that condition, could apply whenever a plaintiff sues for an indivisible condition (such as a cancer), the mechanism of which is unknown, and the defendant’s tort made a substantial contribution to the risk of that condition being contracted. Such a rule has a truly explosive potential in the field of toxic torts beyond asbestos. Part VI investigates why these two extraordinary proof-of-causation doctrines have been neglected by the parties to asbestos claims, the academy, and the American Law Institute itself.

I. THE “INDIVISIBILITY-OF-INJURY” DOCTRINE IN ASBESTOSIS CASES

Under orthodox common law rules concerning causation, a tortfeasor is liable for an indivisible injury that would not have happened absent that party’s breach. This is so even if there is another unrelated tortfeasor but for whom the injury would not have happened. For example, suppose a father, in breach of his duty of care, sends his eight-year-old son to a store to buy rat poison and the storekeeper, in breach of his duty of care, sells it to the boy. When the foreseeable happens and the boy, playing with the poison, ingests some and dies, the father is liable for the (entire) death and the shopkeeper is liable for the (entire) death: each is jointly and severally liable at common law.

In contrast, if the victim suffers “divisible” injuries, under orthodox common law rules concerning causation a tortfeasor is liable only for that portion of the disablement which would not have happened absent that party’s breach. For example, suppose a mother, in breach of her duty of care, breaks a finger on her daughter’s left hand. Later in a
completely unrelated incident a motorist, in breach of his duty, breaks the thumb on the girl’s right hand. The mother is only liable for the disability that would have flowed from the broken finger alone ("several liability"): she would not be liable for the injury to the thumb or the increased disablement the thumb injury caused.

Asbestosis is a cumulative and therefore, at least in theory, "divisible" disease: the more asbestos dust that is inhaled, the worse the disablement of the victim. Where a plaintiff has undergone a sequence of asbestos exposures and sues the party responsible for the first exposure, orthodox common law rules would only support the plaintiff recovering for the degree of disablement that would have resulted from that exposure alone: the plaintiff simply cannot prove that this defendant was a factual cause of the aggravation of his condition due to later exposures, just as the daughter cannot show her mother was a factual cause of the increased disablement due to her broken thumb.

But, since the first successful products liability claim in 1973 in the case Borel v. Fibreboard Paper Products Corp., U.S. courts have absolved asbestosis plaintiffs from the requirement of proving the portion of the total injury for which each culpable exposer was responsible and have thereby, in effect, proceeded on the fiction that asbestosis is an indivisible injury (just like the poisoning death of the boy). Any defendant responsible for a significant early exposure is held jointly and severally liable for the total disablement of the plaintiff, as it is known at the time of trial. Similarly, a defendant responsible only for a late period of exposure is held liable for the total disablement: the plaintiff does not have to establish the degree to which the tort of this defendant enhanced his disability. A good illustration of the Borel approach as applied to asbestosis is Norfolk & Western Ry. Co. v. Ayers, in which one asbestosis plaintiff had been exposed by the defendant for only three months and had worked with asbestos elsewhere as a pipe fitter for thirty-three years, yet the defendant was held liable for his total condition.

The Products Liability Restatement makes no mention of the indivisibility-of-injury doctrine, which assists plaintiffs to establish factual causation in relation to the cumulative disease of asbestosis. This neglect is particularly striking given that explicit black-letter treatment is given to other proof-of-causation doctrines in section 16, which, in part, reads:

§ 16. Increased Harm Due To Product Defect

(a) When a product is defective at the time of commercial sale or other distribution and the defect is a substantial factor in increasing the plaintiff’s
harm beyond that which would have resulted from other causes, the product seller is subject to liability for the increased harm.

(b) If proof supports a determination of the harm that would have resulted from other causes in the absence of the product defect, the product seller’s liability is limited to the increased harm attributable solely to the product defect.

(c) If proof does not support a determination under Subsection (b) of the harm that would have resulted in the absence of the product defect, the product seller is liable for all of the plaintiff’s harm attributable to the defect and other causes. . . .

The Products Liability Restatement gives the justification for subsection (c) as being that “[t]he defendant, a wrongdoer who in fact has caused harm to the plaintiff, should not escape liability because the nature of the harm makes such a determination impossible,” and makes comparison to the related, and even more radical (because it shifts the burden of proof), rule in Restatement (Second) of Torts:

§ 433B Burden Of Proof

. . .

(2) Where the tortious conduct of two or more actors has combined to bring about harm to the plaintiff, and one or more of the actors seeks to limit his liability on the ground that the harm is capable of apportionment among them, the burden of proof as to the apportionment is upon each such actor. . . .

The rationale for section 433B(2) is given in comment d, namely that:

[T]he injustice of allowing a proved wrongdoer who has in fact caused harm to the plaintiff to escape liability merely because the harm which he has inflicted has combined with similar harm inflicted by other wrongdoers, and the nature of the harm itself has made it necessary that evidence be produced before it can be apportioned. In such a case the defendant may justly be required to assume the burden of producing that evidence, or if he is not able to do so, of bearing the full responsibility.

Importantly, in the context of how asbestosis cases have come to be treated, comment e sounds a warning about drawing the boundary line around the exceptional rule in section 433B(2):

The cases thus far decided in which the rule stated in Subsection (2) has been applied all have involved a small number of tortfeasors, such as two or three. The possibility arises that there may be so large a number of actors, each of whom contributes a relatively small and insignificant part to the total harm, that the application of the rule may cause disproportionate hardship to defendants. Thus if a hundred factories each contribute a small, but still uncertain, amount of pollution to a stream, to hold each of them liable for the entire damage

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8 Id. § 16 cmt. d.
9 RESTATEMENT (SECOND) OF TORTS § 433B(2) (1965).
10 Id. § 433B cmt. d.
because he cannot show the amount of his contribution may perhaps be unjust. Such cases have not arisen, possibly because in such cases some evidence limiting the liability always has been in fact available.11

By the time the Products Liability Restatement was adopted in 1998, there had been twenty-five years of experience of asbestos cases. The resolution of virtually all asbestosis cases, tens of thousands of cases by the time the Products Liability Restatement was drafted, paralleled the unorthodox rule in section 16(c), yet there is no mention of asbestos anywhere in this section, its accompanying comments, or Reporters’ Note. The Products Liability Restatement’s silence on the point masks important questions concerning the operation of the U.S. tort system as it confronted its greatest threat, the asbestos disaster, such as why defendants in asbestosis cases had not tried to counter the devastating indivisibility-of-injury doctrine by bringing “proof [that] support[ed] a determination of the harm that would have resulted from other causes in the absence of the product defect” and thereby ensuring that the case was dealt with under the orthodox “several” liability rule of section 16(b).12 In vehicle crashworthiness cases, defendants routinely did bring expert testimony offering a “rational explanation derived from a causal analysis”13 to support the orthodox rule of “several liability”: indeed, these cases illustrated the orthodox rule of several liability set out in section 16(b) of the Products Liability Restatement.

Had this question been squarely addressed in the Restatement process, an important feature of U.S. law confronting toxic torts in the workplace would have been clearly exposed. It is well known among lawyers that for the vast majority of U.S. employees workers’ compensation is their sole common law remedy against their employer for personal injuries suffered from the conditions of work. Lawyers specializing in products liability are equally conscious of the fact that this denial of tort remedies against employers fuelled the explosion of products claims after the adoption of section 402A of the Restatement (Second) of Torts as employees sought tort damages for their personal injuries by pursuing those who had supplied to their employers products that had been instrumental in causing their injuries. Thus, if an employee was injured by an unguarded cutting machine on which he had been unreasonably required to work by his employer, the employee would resort to suing those forming the chain of manufacture and supply of the machine, even where the machine had come with a guard that the employer had removed; the claim against these product suppliers would allege that such a machine was defective unless it had a guard that could not be removed.

11 Id. § 433B cmt. e (emphasis added).
12 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 16(b) (1998).
13 Id. § 16 cmt. c.
Even within such a simple scenario, it is clear that a distortion of safety incentives results from the interaction between the sole remedy rule and the tort system: this is because a firm contender for being the cheapest cost avoider must be the employer who required the employee to work on an unguarded machine, yet the sole remedy rule prevents tort law from targeting this party with whatever deterrent effect its liability can generate. Even more profound are the distortions that are inevitably generated when the personal injury suffered by the employee is not by traumatic accident, such as having his arm severed by an unguarded blade, but by the exposure to toxic substances whose deleterious effect is latent. Here the typical number of implicated instrumentalities is significant: unlike our earlier plaintiff who knows the single instrumentality that was a cause of his traumatic injury, such as the unguarded machine, the victim of a toxic tort is likely to have been exposed to many versions of the agent implicated in his personal injury. Thus, even if an asbestosis victim had only one employer throughout his working life, it is likely that the asbestos to which he was exposed came from a variety of different manufacturers with each such chain of supply being composed of a number of mere suppliers between the manufacturer and the workplace.

In other major common law systems that do not impose a sole remedy rule on employees, this multiplicity of sources of the toxic agent does not greatly complicate the legal position of the asbestosis victim. This is because in relation to one period of exposure it is virtually always the case that such a victim sues only one defendant, his employer, no matter with how many sources of asbestos the employer required the employee to work. Tracing the sources of the different asbestos agents is not required for the employee to succeed against his employer and the sequential nature of employment provides a viable, if crude, benchmark, which is needed to apply the several liability that orthodoxy requires should attach to a cumulative disease such as asbestosis.

In an English case, for example, a Mr. Holtby worked from 1942 to 1981 as a marine fitter and in this work he was exposed to asbestos dust. For approximately half this period he was employed by Brigham & Cowan (Hull) Ltd.; for the remainder he was employed by other employers doing similar work in similar conditions; in some cases for quite long periods, such as five years, in other cases for periods measured in months. Holtby sued Brigham & Cowan (Hull) Ltd. for his asbestosis, arguing that this employer was liable in respect of the whole resulting disability, subject only to such rights as that defendant had against other tortfeasors. The argument was roundly rejected by the Court of Appeal

14 Occasionally, the employee sues the occupier of premises on which he was required to work. See, e.g., Fairchild v. Glenhaven Funeral Servs., Ltd., (2002) 1 A.C. 32 (H.L.) (appeal taken from England and Wales Court of Appeal (Civil Division) (U.K.)) (claim of Mr. Fairchild’s widow against Waddingtons plc).
for England and Wales where, in the lead judgment, Lord Justice Stuart-Smith said:

[T]he onus of proving causation is on the claimant; it does not shift to the defendant. He will be entitled to succeed if he can prove that the defendant’s tortious conduct made a material contribution to his disability. But strictly speaking the defendant is liable only to the extent of that contribution . . . . I do not think that these cases should be determined on onus of proof. The question should be whether at the end of the day, and on consideration of all the evidence, the claimant has proved that the defendant is responsible for the whole or a quantifiable part of his disability. The question of quantification may be difficult and the court only has to do the best it can using its common sense . . . . Cases of this sort, where the disease manifests itself many years after the exposure, present great problems, because much of the detail is inevitably lost . . . [but] the court must do the best it can to achieve justice, not only to the claimant but also to the defendant, and among defendants.15

In contrast, in U.S. sole-remedy jurisdictions for every period of asbestos exposure the special products tort stated in section 402A of the Restatement (Second) of Torts provides the asbestosis victim with, in place of the employer, a chain of defendants stretching back from each asbestos agent to which the victim was exposed during that period. The dramatic confluence of the sole remedy rule and the “chain” liability of the special products tort linked to the specific asbestos agent represented a perfect storm confronting modern U.S. tort doctrine. Its first impact was felt in Borel.

II. BOREL v. FIBREBOARD PAPER PRODUCTS CORPORATION

Until Borel in 1973, asbestos-related injuries were overwhelmingly seen as an issue confined to the employees of asbestos miners and manufacturers. Since such employees were barred from suing their employers by the sole remedy rule, successful asbestos claims had been confined to the unglamorous realm of workers’ compensation.16 In contrast, Clarence Borel was not employed by an asbestos manufacturer or miner: he worked for a company that installed insulation. He was exposed to asbestos from 1936 until January 1969, when he was diagnosed with asbestosis. In October 1969, Borel filed suit against eleven asbestos manufacturers with whose products he had been required to work. In February 1970, Borel underwent surgery whereupon it was discovered that he “had a form of lung cancer known as mesothelioma, which had been caused by asbestosis.”17 Borel died before the case

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17 Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076, 1081-82, 1086 (5th Cir. 1973). Mesothelioma is not a form of lung cancer; it affects tissue outside the lung. MOSBY’S MEDICAL & NURSING DICTIONARY 706 (Walter D. Glanze ed., 2d ed. 1986). It is also important to note that mesothelioma is not caused by asbestosis. See infra note 40 and accompanying text.
reached trial. At trial the jury found, inter alia, that all defendants were liable under the special products tort that is stated in section 402A of the Restatement (Second) of Torts, a finding the defendants appealed to the Fifth Circuit. In September 1973, the verdict in Borel’s favor was upheld by the Fifth Circuit, which, following the plaintiff, treated the claim as one for asbestosis.

The Fifth Circuit freely acknowledged that asbestosis was a cumulative disease and that, therefore, each inhalation was a factual cause of some part of the total injury:

It is undisputed . . . that Borel contracted asbestosis from inhaling asbestos dust and that he was exposed to the products of all the defendants on many occasions. It was also established that the effect of exposure to asbestos dust is cumulative, that is, each exposure may result in an additional and separate injury. We think, therefore, that on the basis of strong circumstantial evidence the jury could find that each defendant was the cause in fact of some injury to Borel.20

Moreover, the court also acknowledged the orthodox rule that “[i]n general, a defendant is liable only for that portion of the harm which he in fact caused.”21 But the court noted that:

A problem arises, however, where, as here, several causes combine to produce an injury that is not reasonably capable of being divided. In the instant case, the trial court resolved this issue by holding the defendants jointly and severally liable for the entire harm. Asserting error, the defendants argue that if the injury cannot be reasonably apportioned, the plaintiff must bear the entire loss unless it can be shown that the tortfeasors acted in concert or with unity of design.21

In rejecting the defendant’s appeal to the orthodox rule, the court described the sea change wrought by the Supreme Court of Texas in Landers v. East Texas Salt Water Disposal Co.22 In that case, the plaintiff owned a small lake that he had stocked with fish at considerable expense. Around April 1, 1949, the nearby pipe line of a salt water disposal company broke and a large quantity of salt water flowed over plaintiff’s land and into his lake. Around the same time another nearby but unrelated pipe line owned by an oil company broke, and large quantities of oil and salt water escaped, finding their way into the plaintiff’s lake. All the fish died from the resultant pollution, but orthodoxy required the plaintiff to prove “with reasonable certainty what portion of the total damage was attributable to each defendant.”23 This he was unable to do.

In Landers it was distasteful to the Supreme Court of Texas that orthodoxy:

18 *Borel*, 493 F.2d at 1081, 1086.
19 *Id.* at 1094.
20 *Id.*
21 *Id.*
22 248 S.W.2d 731, 731-32 (Tex. 1952).
23 *Borel*, 493 F.2d at 1095.
denies to a plaintiff the right to proceed to judgment and satisfaction against the wrongdoers separately because in such a suit he cannot discharge the burden of proving with sufficient certainty, under pertinent rules of damages, the portion of the injury attributable to each defendant. . . . [The Court rejected] the philosophy . . . that it is better that the injured party lose all of his damages than that any of several wrongdoers should pay more of the damages than he individually and separately caused. If such has been the law, from the standpoint of justice it should not have been; if it is the law now, it will not be hereafter. . . . Where the tortious acts of two or more wrongdoers join to produce an indivisible injury, that is, an injury which from its nature cannot be apportioned with reasonable certainty to the individual wrongdoers, all of the wrongdoers will be held jointly and severally liable for the entire damages . . . .

The Supreme Court of Texas noted that “the burden of proving the share contributed to the injury by each of the wrongdoers” could be, as it was on the Landers facts, just as onerous as in cases of simultaneous negligent collision, where there was neither concert of action nor unity of design and where courts have long sanctioned the imposition of joint and several liability.25 The Landers rule was set out in Restatement (Second) of Torts section 433B(2) while the Fifth Circuit in Borel, following the views of Prosser and Wigmore, reformulated it as:

Where several defendants are shown to have each caused some harm, the burden of proof (or burden of going forward) shifts to each defendant to show what portion of the harm he caused. If the defendants are unable to show any reasonable basis for division, they are jointly and severally liable for the total damages.

Of course, once we focus on the approach in Landers and Borel, we are led to ask whether all victims of cumulative toxic torts, even outside the areas of water pollution and asbestos, might claim the advantage of this indivisibility-of-injury doctrine when attempting to establish factual causation.

III. CAN ALL VICTIMS OF CUMULATIVE TOXIC TORTS ACCESS THE “INDIVISIBILITY-OF-INJURY” DOCTRINE?

It does not appear that the Borel defendants made any attempt to bring evidence to quantify their separate contributions to the total disability of Mr. Borel. The reasons for this defense omission are unclear: perhaps the defense lacked coordination; perhaps there was over-confidence among defendants that they would prevail on other aspects of the appeal; or perhaps the defendants believed that the Landers rule would not be extended to the context of workplace toxic

24 Landers, 248 S.W.2d at 734.
25 Id. at 735.
26 See supra note 9 and accompanying text.
27 Borel, 493 F.2d at 1095.
torts. Of course, once that extension was made, the defense omission proved fatal to their argument against joint and several liability.

An important consequence of the defense omission is that we do not know what quantification evidence could have been brought on the facts and by what criteria courts might have assessed whether it was sufficiently sound to support the orthodox rule of several liability for asbestosis defendants. What would the Fifth Circuit in *Borel* have required of the defendants to show that the asbestosis was “reasonably capable of being divided”? We do not know. Similarly, we do not know what the Supreme Court of Texas in *Landers* would have required of defendants to prove “with sufficient certainty . . . the portion of the injury attributable to each defendant” and thereby entitle the polluters to the orthodox rule of several liability. What is initially surprising is that later asbestosis defendants do not seem to have pursued these issues in an attempt to avoid the joint and several liability that had been imposed in *Borel*.

Certainly, once the *Borel* court had shown it was willing to use *Landers* to impose joint and several liability on an asbestosis defendant, future asbestosis plaintiffs had a further incentive to sue as many defendants as possible so as to undermine any defense argument that the asbestosis was “reasonably capable of being divided” among the responsible parties. Of course, the practice of asbestosis plaintiffs naming very large numbers of defendants raised the issue of whether extension of the exceptional rule in section 433B(2) to cases where there are a large number of defendants “may perhaps be unjust,” as foreshadowed by comment e to section 433B, but no asbestosis defendant seems to have tried to resist the rule on this or any other grounds.

Notice also that whereas the typical lack of fungibility of asbestos sources prevents most asbestos plaintiffs from securing the limited benefits of the market share doctrine, here that lack of

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28 Id. at 1094.
29 *Landers*, 248 S.W.2d at 734.
30 *Borel*, 493 F.2d at 1094.
31 See RESTATEMENT (SECOND) OF TORTS § 433B cmt. e (1965); supra text accompanying note 11.
32 This is in contrast to the use of the fairness-to-defendants argument in pollution cases such as *In re Methyl Tertiary Butyl Ether ("MTBE") Products Liability Litigation*, 447 F. Supp. 2d 289 (S.D.N.Y. 2006), and *In re Bell Petroleum Services, Inc.*, 3 F.3d 889 (5th Cir. 1993).
33 Under the market share doctrine the claimant need not establish that the defendant’s agent was the one that injured her. See, e.g., Sindell v. Abbott Labs., 607 P.2d 924, 937 (Cal. 1980). But in the interests of an equitable trade-off, liability under the market-share doctrine is proportionate. See *Brown v. Superior Court*, 751 P.2d 470, 485-87 (Cal. 1988). It is noteworthy that the California Supreme Court, which created the doctrine, has characterized it as one that assists a plaintiff to leap an evidentiary gap in proving causation to a defendant. See *Jolly v. Eli Lilly & Co.*, 751 P.2d 923, 930 (Cal. 1988) (“*Sindell* merely bridged the causal gap between DES manufacturers as a group and plaintiff’s injury.”). Contrast what must be a different characterization in New York, where a defendant cannot exculpate itself under this doctrine even if it can prove its product could not have been involved in the plaintiff’s injury. See *Hymowitz v. Eli Lilly*, Co., 539 N.E.2d 1069,
fungibility works strongly in the plaintiff’s favor because it increases the force of the plaintiff’s argument that quantification of separate contributions is not feasible as a practical matter and that, therefore, the defendant should be jointly and severally liable for the asbestosis on the basis given in Borel.

In short, since 1973 U.S. courts have applied what I will call “the Borel approach,” namely allowing asbestos plaintiffs to prove factual causation to any asbestos-related disease merely by showing a significant exposure to asbestos from the defendant’s tort. What this means for the asbestosis plaintiff is that he can establish that a defendant was a factual cause of (and jointly and severally liable for) his entire condition merely by showing that the defendant’s tort exposed the plaintiff to a significant amount of asbestos. This is tantamount to providing the asbestosis plaintiff with the benefit of an indivisibility-of-injury fiction: that, though we know asbestosis is in fact a cumulative disease, it will be treated in law as indivisible.

Next: In the context of other cumulative conditions, how generally available is this indivisibility-of-injury doctrine? There is no indication, or conceivable reason of principle why, this proof-of-causation doctrine is limited to asbestosis, to workplace injuries, or to injuries caused through the instrumentality of a product. So, is it the case that U.S. tort law recognizes the following radical proof doctrine for cumulative toxic torts?

The indivisibility-of-injury doctrine for proof of factual causation in cumulative toxic torts: That whenever a plaintiff sues a defendant for a cumulative condition and the court is satisfied that it is not “reasonably capable of being divided” on the available evidence, a rule of joint and several liability, tantamount to a fiction of the injury being indivisible, will be imposed on the defendant?

Or are there further limits to the rule? First, suppose, for example, that a plaintiff suffers from accumulated hearing loss. For an illustration of how the orthodox rule of several liability is applied to this cumulative condition, see Thompson v. Smiths Shiprepairers (North Shields) Ltd., [1984] 1 Q.B. 405 (U.K.). In Thompson, plaintiffs had been engaged in the ship repair industry, where they had been exposed to excessive noise over extended periods of their employment, which resulted in deafness. All excessive noise had contributed to their disabilities, but the defendant employers were not found guilty of negligence until 1963. By that time, considerable damage had been done, though it was not recognizable. Id. at 405-06. Mustill, J., stated:

The defendants as well as the plaintiffs are entitled to a just result. If we know—and we do know, for by the end of the case it was no longer seriously in dispute—that a
Suppose further that it is established that some of that loss, a small but not reasonably quantifiable part, was due to the tort of the defendant while other contributions to the loss came from innocent sources such as an accidental exposure to a lightning strike. Can the plaintiff invoke the *indivisibility-of-injury* doctrine to render the defendant liable for the plaintiff’s entire hearing loss? Or does the *indivisibility-of-injury* doctrine rule only come into effect when all contributions to the cumulative condition were tortious?35

Secondly, in *Borel* the Court did not explicitly require that the plaintiff join those responsible for all sources of asbestos to which Mr. Borel was exposed,36 and later courts certainly did not regard this as a pre-requisite before asbestosis plaintiffs could claim the benefit of the *indivisibility-of-injury* doctrine and its powerful corollary of joint and several liability.37 But if this is the case, it generates a peculiar anomaly that can be illustrated with an example of lead poisoning (which is a cumulative condition: the more lead ingested, the worse the disablement). Let us assume for the sake of simplicity that when it is discovered that a child is suffering from lead poisoning it can be established that all possible sources of the lead ingested by the child were tortious, though because of their number and complexity it is not possible to prove “with sufficient certainty . . . the portion of the”38 child’s total condition attributable to each lead source.

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Id. at 443-44. Note that in Britain, exercises in quantification in relation to cumulative conditions “have now become commonplace, following the decision of Mustill J in *Thompson v Smiths Shiprepairers Ltd* [1984] QB 405, whether as between successive employers or as between tortious and non-tortious exposure by the same employer.” Barker v. Corus UK Ltd., [2006] 2 A.C. 572, ¶ 123 (H.L.) (Baroness Hale of Richmond, concurring). 35 Compare *RESTATEMENT (SECOND) OF TORTS* § 433B(2) (1965), with *id*. § 433B cmt. d (suggesting that this rule is limited to cases where all contributions were tortious).

What prevents such a child from using the *indivisibility-of-injury* doctrine to impose joint and several liability on the party responsible for just one such exposure, say the manufacturer of the lead-based paint that lined the rental property where the child spent a year when he was growing up, and which he ingested from accessible painted surfaces, paint chips, and paint flakes and dust?\(^{39}\) And if the *indivisibility-of-injury* doctrine is available to our lead-poisoned child, why has this exceptionally powerful and valuable proof-of-causation doctrine not been exploited by plaintiffs’ lawyers and analyzed in detail in the law reviews?

As striking as this *indivisibility-of-injury* doctrine is, a profoundly more radical doctrine was deployed to assist victims of asbestos-related cancers. We now turn to this judicial creation and its explosive potential for toxic tort liability.

IV. **THE “EXPOSURE TO RISK” DOCTRINE IN MESOTHELIOMA AND OTHER ASBESTOS-CAUSED CANCERS CASES**

Mesothelioma (a cancer of the of the mesothelial cells that line the internal chest wall and surround the organs of the chest cavity) and lung cancer (bronchogenic carcinoma) are cancers caused by asbestos, but they are not thought to be a complication of asbestosis.\(^{40}\) Though a person with asbestosis may develop one of these asbestos-related cancers, his asbestosis and his asbestos-related cancer are merely epiphenomena of the inhalation of asbestos: both are caused by the inhalation but the former phenomenon (asbestosis) does not cause the latter (asbestos-related cancer). Moreover, asbestos-related cancer is not a cumulative disease in which each inhalation of asbestos generates a certain amount of disability: while it is true that the more a person is exposed to asbestos the more likely it is that an asbestos-related cancer will be contracted, once contracted the severity of the disablement is

\(^{39}\) Compare the imposition of a form of market share liability in *Thomas ex rel. Gramling v. Mallett*, 701 N.W.2d 523, 527 (Wis. 2005). Note that attempts by plaintiffs in lead poisoning cases to invoke the burden-shifting rule of alternative liability under RESTATEMENT (SECOND) OF TORTS § 433B(3) (1965) failed in several cases. See, e.g., *Philadelphia v. Lead Indus. Ass’n*, Inc., 994 F. 2d 112, 125 (3d Cir. 1993); *Swartzbauer v. Lead Indus. Ass’n*, Inc., 794 F. Supp. 142, 147 (E.D. Pa. 1992); *Jackson v. Glidden Co.*, No. 87779, 2007 WL 184662, at *4 (Ohio App. Jan. 25, 2007); *Skipworth ex rel. Williams v. Lead Indus. Ass’n*, Inc., 690 A.2d 169, 172 (Pa. 1997). But see *Canada ex rel. Landy v. McCarthy*, 567 N.W.2d 496, 499, 503 (Minn. 1997). In a case involving successive lead-paint poisonings suffered by the minor plaintiff at separate rental properties, the trial court determined that plaintiff’s injuries were divisible, a ruling not challenged on appeal, and went on to instruct the jury to apportion among multiple tortfeasors damages between pre-July 1992 lead poisoning and damages occurring after that time. *Id.* at 508.

\(^{40}\) See Employers’ Liability Policy “Trigger” Litigation, [2008] EWHC 2692, ¶ 25 (QB) (U.K.) (Burton, J.) (“Notwithstanding that for some time . . . mesothelioma was, it seems, thought to be a development, or aspect, of asbestosis even by those dealing with insurance claims in relation to it, it is a quite separate disease.”). This judgment contains a sophisticated account of the current state of knowledge concerning mesothelioma aetiology.
independent of the amount of asbestos to which the victim had been exposed. An asbestos-related cancer is an “indivisible” condition.

The crucial point to note about asbestos-related cancer is that we do not know the basic mechanism by which the cancer is triggered. On the one hand, the mechanism could be that the cancer is triggered by a single fiber. If we knew this to be the mechanism, courts might allow asbestos-related cancer plaintiffs to jump the evidentiary gap they face in proving that it was the fiber of an individual defendant that triggered the cancer by crafting an extension\(^\text{41}\) of the well-known alternative liability rule in Summers v. Tice,\(^\text{42}\) restated in the Restatement (Second) of Torts section 433B(3) as:

> Where the conduct of two or more actors is tortious, and it is proved that harm has been caused to the plaintiff by only one of them, but there is uncertainty as to which one has caused it, the burden is upon each such actor to prove that he has not caused the harm.\(^\text{43}\)

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\(^{41}\) It would need to be an extension, because it would need to be free of two features of the Summers v. Tice case, discussed infra note 42, which have been taken to be pre-requisites of the alternative liability rule. These pre-requisites require that (1) all tortfeasors are named as defendants and (2) that their tortious conduct had been at the same time. Importantly, comment \(h\) to section 433B reads:

> The cases thus far decided in which the rule stated in Subsection (3) has been applied all have been cases in which all of the actors involved have been joined as defendants. All of these cases have involved conduct simultaneous in time, or substantially so, and all of them have involved conduct of substantially the same character, creating substantially the same risk of harm, on the part of each actor. It is possible that cases may arise in which some modification of the rule stated may be necessary because of complications arising from the fact that one of the actors involved is not or cannot be joined as a defendant, or because of the effect of lapse of time, or because of substantial differences in the character of the conduct of the actors or the risks which they have created. Since such cases have not arisen, and the situations which might arise are difficult to forecast, no attempt is made to deal with such problems in this Section. The rule stated in Subsection (3) is not intended to preclude possible modification if such situations call for it.

Restatement (Second) of Torts § 433B cmt. \(h\) (1965).

Mesothelioma plaintiffs have been refused the assistance of the alternative liability rule in section 433B(3) in many cases. See, e.g., Marshall v. Celotex Corp., 651 F. Supp. 389, 392 (E.D. Mich. 1987) (plaintiff’s failure to name as defendants all those who possibly could have caused the injury precluded the application of alternative liability); Vigilto v. Johns-Manville Corp., 643 F. Supp. 1454, 1457 (W.D. Pa. 1986) (alternative liability would not lie because it was not certain that all parties who possibly could have caused the injury were joined as defendants), aff’d 826 F.2d 1058 (3d Cir. 1987); Rutherford v. Owens-Illinois, Inc., 941 P.2d 1203, 1216-21 (Cal. 1997); Black v. Abex Corp., 603 N.W.2d 182, 192 (N.D. 1999) (alternative liability theory was not applicable where all possible defendants were not named); Goldman v. Johns-Manville Sales Corp., 514 N.E.2d 691, 696-99 (Ohio 1987); Gaulding v. Celotex Corp., 772 S.W.2d 66, 69 (Tex. 1989) (rejecting an alternative liability theory where plaintiff did not join all possible defendants).

\(^{42}\) The radical proof-shifting rule in Summers v. Tice, 199 P.2d 1, 4-5 (Cal. 1948) (en banc), is accompanied by joint and several liability. Strictly, application of the Summers rule is confined to cases where the injury could only have been caused by one party. It could therefore only apply where there had only been one asbestos source and it is not known who supplied that source, as in the mesothelioma case of Gaulding v. Celotex Corp., 772 S.W.2d 66 (Tex. 1989).

\(^{43}\) Restatement (Second) of Torts § 433B(3) (1965). The Summers rule is also restated in Restatement (Third) of Torts: Liability for Physical Harm (Basic Principles) § 28 (b) (Proposed Final Draft No. 1, 2005)
But we do not know that the mechanism that triggers asbestos-related cancer is the single-fiber, let alone, if it is, whether the most likely fiber was one during early exposure or one during a later exposure.

On the other hand, the mechanism might be one in which the cancer is only triggered when a threshold burden of many fibers accumulates in the lungs. If we knew this to be the mechanism, courts could confidently assume every exposure up until this triggering moment was causally involved in the cancer occurring and could confidently apply joint and several liability. But this approach is also not available in asbestos-related cancer cases under orthodox rules because it cannot be established that the mechanism of such a cancer is triggered by a threshold burden of fibers triggering the disease.

The most that can be said about the mechanism of an asbestos-related cancer is that, while it can be shown that each exposure to asbestos materially increased the risk of the disease, scientifically it cannot be shown that any specific one of a series of exposures materially contributed to the plaintiff’s asbestos-related cancer. This is in stark contrast to the cumulative disease of asbestosis. So, whereas in the context of asbestosis it is accurate for the Proposed Final Draft of the Third Restatement to state that “all of the asbestos products to which the plaintiff was exposed contributed to the harm,” this statement is simply wrong when applied to the context of asbestos-related cancers.

Under orthodox rules requiring the plaintiff to prove the defendant was the factual cause of his asbestos-related cancer, this lack of scientific understanding should prove fatal to virtually all asbestos-related cancer claims. So, for example, if an asbestos-related cancer victim had been exposed in sequence to asbestos from defendant A, then to asbestos from defendant B, and then to asbestos from defendant C, he will be unable to prove factual cause against any of the defendants under orthodox rules of proving causation.

But, as we have seen, since 1973 U.S. courts have applied “the Borel approach,” namely allowing asbestos plaintiffs to prove factual causation to any asbestos-related disease merely by showing a significant exposure to asbestos from the defendant’s tort. What this means for the victim of an asbestos-related cancer is that he can establish that a defendant was a factual cause of (and jointly and severally liable for) his cancer merely by showing that the defendant’s tort exposed the plaintiff to a significant amount of asbestos and therefore to a significant risk of contracting an asbestos-related cancer. In effect, the case proceeds on the basis that each and every significant exposure to the risks of asbestos was causally involved in the triggering of the cancer, a basis that is tantamount to the fiction that asbestos-related cancer is contracted by a

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threshold mechanism. As with the *indivisibility-of-injury* doctrine for the cumulative disease of asbestosis, the *Products Liability Restatement* makes no mention of this *exposure-to-risk* doctrine by which plaintiffs can establish factual causation in relation to indivisible asbestos-related cancers.

**V. CAN VICTIMS OF TOXIC TORTS SUFFERING INDIVISIBLE INJURIES ACCESS THE “EXPOSURE TO RISK” DOCTRINE?**

In *Borel*, the Fifth Circuit virtually ignored the mesothelioma aspect of Mr. Borel’s condition. As noted earlier, the case was treated as a claim for his asbestosis and the Court simply assumed, wrongly, that the mesothelioma had been caused by the asbestosis.\(^{45}\) It is understandable why neither the defendants nor the plaintiff gave the mesothelioma any independent attention: since the asbestosis from which Mr. Borel was suffering was very advanced by the time the mesothelioma was discovered,\(^{46}\) the latter did not affect the value of the claim in any significant way.

Later when plaintiffs made “pure” mesothelioma and asbestos-related lung cancer claims (that is claims that did not also claim accompanying asbestosis), courts imposed no more than the minimal requirements that the *Borel* court had laid down for the proof of asbestosis: thus, once the plaintiff could show that the tort of the defendant had resulted in him being exposed to significant quantities of asbestos, that defendant could be held jointly and severally liable for any asbestos-related condition, including asbestos-related cancer. As we have seen, in the context of asbestos cancers this *Borel* approach was tantamount to assuming that asbestos-related cancer is contracted by a threshold mechanism and that, therefore, every exposure to asbestos is taken to have been causally involved in that disease occurring.

In some early asbestos-related cancer cases the medical testimony supported that assumption. For example, in *Eagle-Picher Industries, Inc. et al. v. Balbos*,\(^{47}\) the Court of Appeals of Maryland noted that:

\[\text{[A] medical expert for the plaintiffs testified that “all of [the] exposures to asbestos were a significant contributing causal factor to the mesothelioma,” because the causation is “cumulative.” The defendants’ medical expert also}\]

\(^{45}\) See *supra* note 17.

\(^{46}\) Mesothelioma can take forty years or more to manifest itself. Thus, by that time many, if not all, of the employees who worked in asbestos industries in the early part of the twentieth century, and were at risk of mesothelioma, would have contracted asbestosis and died of that or other diseases before any mesothelioma developed or was revealed. See, e.g., Employers' Liability Policy “Trigger” Litigation, [2008] EWHC 2692, ¶ 25 (QB) (U.K.).

\(^{47}\) 604 A.2d 445 (Md. 1992).
believed that a person must reach an undefined “threshold” of asbestos exposure before exposure will cause mesothelioma.\footnote{48 Id. at 459 (alteration in original).}

But soon astute judges began to acknowledge the lack of medical understanding of the aetiology of asbestos-related cancers and therefore the real challenge that asbestos-related cancer claims presented to orthodox legal analysis. For example, in \textit{Lineaweaver v. Plant Insulation Co.},\footnote{49 37 Cal. Rptr. 2d 902 (Ct. App. 1995).} Associate Justice Newsom noted in concurrence that:

\begin{quote}
[T]he majority assumes that plaintiffs may be able to prove that asbestos disease is “cumulative in nature.” The evidence regarding asbestosis in the present case indeed supports this assumption; the disease was described as resulting from a progressive scarring of the lungs. But cases involving mesothelioma—the fatal cancer which is the other principal asbestos-related disease—will involve quite different testimony. I do not think we can easily assume that this disease reflects the cumulative impact of exposure to asbestos fibers over time, though the odds of contracting it may go up with increased exposure. In any event, the courts should not invoke scientific assumptions of this kind in justifying a rule of general application.\footnote{50 Id. at 910 (Newsom, J., concurring).}
\end{quote}

A very important case in which the court acknowledged the scientific uncertainty regarding the mechanism by which inhalation of asbestos leads to asbestos-related cancer was \textit{Rutherford v. Owens-Illinois, Inc.},\footnote{51 941 P.2d 1203, 1207 (Cal. 1997).} where the victim had died of lung cancer (not mesothelioma cancer). In \textit{Rutherford}, the Californian Supreme Court exposed the way in which the application of the Borel approach (namely, allowing plaintiffs to proceed on the basis that every exposure to asbestos was causally involved in the contraction of their asbestos disease) to indivisible asbestos-related cancer cases rested on the fiction that asbestos-related cancer is contracted by a threshold mechanism. The Court observed that:

\begin{quote}
[If each episode of scarring contributes cumulatively to the formation of a tumor or the conditions allowing such formation, each significant exposure by the plaintiff to asbestos fibers would be deemed a cause of the plaintiff’s cancer.\footnote{52 Id. at 1218.}
\end{quote}

In other words, if we knew that the mechanism was that the cancer is only triggered when a threshold burden of many fibers accumulates in the lungs, every exposure that deposited one of these fibers\footnote{53 In the case of “negligible” exposures, it could not be concluded that even one fiber would have been ingested. As a result, factual cause could not be established. Hence, plaintiffs must establish against each defendant at least a \textit{non-negligible} exposure.} would uncontroversially be a factual cause of the triggering. Each fiber would
be an actual contributing cause, and joint and several liability would follow.

The Court also observed that if we knew that the cancer is triggered by a single fiber, the case would be "analogous"\textsuperscript{54} to the facts of \textit{Summers v. Tice} in that the mechanism of the injury would have been known; there would have been no actual "contributing or concurrent causation" because only one exposer would in fact have furnished the relevant single fiber; and yet the plaintiff would be "without the evidentiary means whatsoever to prove from which [exposure] the injurious single pellet" had originated.\textsuperscript{55} But the Court refused to allow asbestos-related cancer plaintiffs to access the burden-shifting rule of alternative liability from \textit{Summers} on the grounds that, inter alia,\textsuperscript{56} the mechanism of the asbestos-related cancer was not known to be that of a single fiber. As we shall see, the Court also justified its view that the doctrine of alternative liability was unavailable by boldly asserting that the asbestos-related cancer plaintiffs \textit{did} have the means of proving factual cause against a defendant.

The Court and the parties all appreciated that the most that could be said about the etiology of asbestos-related cancers was that exposure to asbestos increased the \textit{risk} of the cancer occurring: indeed, the parties argued their case in terms of exposure to risk:

Medical testimony was also presented to establish that the plaintiffs’ asbestos-related disease was “dose-related”—i.e., that the \textit{risk} of developing asbestos-related cancer increased as the total occupational dose of inhaled asbestos fibers increased. Dr. Allan Smith . . . testified that asbestos-related lung cancers are dose-related diseases, and that all occupational exposures through the latency period can contribute to the \textit{risk} of contracting the diseases. Owens-Illinois's own medical expert . . . testified that asbestos-related cancers are dose responsive, and that if a worker had occupational exposure to many different asbestos-containing products, each such exposure would contribute to the degree of \textit{risk} of contracting asbestos-related lung cancer . . . .\textsuperscript{57}

So, in a bold sleight of hand the Court merely asserted that “asbestos plaintiffs can meet their burden of proving legal causation under traditional tort principles, without the need for an ‘alternative liability’ burden-shifting instruction.”\textsuperscript{58} The court reasoned that:

\begin{itemize}
  \item \textsuperscript{54} \textit{Rutherford}, 941 P.2d at 1218.
  \item \textit{Id.} at 1215, 1218.
  \item \textit{Id.} at 1217 (noting other reasons such as the fact that not all tortfeasors were named as defendants and “that different toxicities and brands of asbestos products and their differing effects on different asbestos-related diseases make it inappropriate to apply a Summers alternative liability/burden-shifting rule to asbestos cases”); see also supra note 42.
  \item \textit{Rutherford}, 941 P.2d at 1209 (emphasis added).
  \item \textit{Id.} at 1213; see also Tragarz v. Keene Corp., 980 F.2d 411, 421 (7th Cir. 1992) ("[T]he frequency, regularity, and proximity test becomes even less rigid for purposes of proving substantial factor when dealing with cases in which exposure to asbestos causes mesothelioma. . . . [Because] mesothelioma can result from minor exposures to asbestos products . . . there is ample medical testimony and other evidence indicating that even a minimal exposure to asbestos \textit{can} induce or \textit{contribute} to the development of mesothelioma. . . . The record . . . contains ample . . . . . .
\end{itemize}
[In asbestos-related cancer cases, a particular asbestos-containing product is deemed to be a substantial factor in bringing about the injury if its contribution to the plaintiff or decedent’s risk or probability of developing cancer was substantial.59

While it is true that the exposure to asbestos due to one tortfeasor contributes to the total cancer risk faced by a plaintiff, to treat this contribution to total risk as equivalent in law to a contribution to the indivisible cancer the plaintiff contracts is hardly allowing plaintiffs to prove factual cause against that defendant simply “under traditional tort principles.”60 Nevertheless, despite the Court’s lack of candor, its approach confirms that the application of the Borel approach to asbestos-related cancer cases rests on a radical fiction and illustrates how it is that plaintiffs with such claims are allowed to establish factual cause when the mechanism of their disease is not established.

If it is appropriate, as the California Supreme Court tells us it is, to treat every non-negligible exposure to risk as a factual cause, this must mean that we are proceeding on the idea (a fiction) that every asbestos fiber was involved in the cancer mechanism: and this would only be the case in an indivisible disease such as cancer if that were a threshold mechanism. In other words, the risk contribution explanation of why an asbestos-related cancer plaintiff is permitted to establish factual cause against an individual exposer confirms our characterization that this permission rests on the fiction of a threshold mechanism for asbestos cancer.

How do we know that the California Supreme Court intended its risk contribution explanation to relate merely to the issue of proof of factual cause rather than to recognize, in an even more radical61 move, that risk creation is itself actionable?62 It is because the Court made no attempt to deny the plaintiff’s claim that the defendant was jointly and severally liable for the entire cancer (absent legislative abrogation). It approved the jury verdict that Owens-Illinois was liable for 100% of the plaintiff’s economic losses even though the jury had concluded that the Owens-Illinois contribution to the total risk was only 1.2%.63

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59 Rutherford, 941 P.2d at 1219. The plaintiffs still had the burden of proof that the individual defendant was responsible for a non-negligible amount of exposure. Indeed, this was the central issue of dispute in the case. See id. at 1220; see generally Joseph Sanders et al., The Insubstantiality of the “Substantial Factor” Test for Causation, 73 Mo. L. Rev. 399 (2008) (discussing proof of causation and the substantial factor test).

60 Rutherford, 941 P.2d at 1213.

61 Apart from market share liability (which, as we have seen, has been regarded as inapplicable to asbestos cases), there is no orthodox principle to justify a defendant being liable to a plaintiff only for a proportion of the latter’s indivisible injury.


63 Rutherford, 941 P.2d at 1225. Proposition 51, adopted in 1986, provides that in a tort action governed by principles of comparative fault, a defendant shall not be jointly liable for the
Of course, it is to be regretted that the California Supreme Court did not squarely admit the radical nature of the exposure-to-risk doctrine (i.e., contribution to risk is deemed contribution to indivisible cancer) and the fiction of a threshold mechanism on which it rests. One consequence is that it evaded the explosive issue of whether this special doctrine, which applies to proof of factual causation in asbestos cancer cases, should be accompanied by joint and several liability. Similarly, had the *Rutherford* court been more candid about this radical doctrine, it would have triggered a long-overdue debate about what the limits of that doctrine are.

So, at least now we might ask: how general is, or should be, this special proof of causation doctrine resting on exposure-to-risk? There is no indication, or conceivable reason of principle why, the rule is limited: to asbestos-related cancer cases; to workplace injuries; or to injuries caused through the instrumentality of a product. On the basis that “[p]laintiffs cannot be expected to prove the scientifically unknown details of carcinogenesis,” is it the case that U.S. tort law recognizes the following radical doctrine for indivisible conditions?

The exposure-to-risk doctrine for proof of factual causation for indivisible conditions: That whenever a plaintiff sues a defendant for an indivisible condition (such as a cancer) the mechanism of which is unknown and the defendant’s tort made a substantial contribution to the risk of that condition being contracted, that tort is deemed to have contributed to the contraction of that condition. (In other words the plaintiff is allowed to rely on a fiction that the condition is contracted by a threshold mechanism for which joint and several liability attaches.)

Or, are there further limits to the rule? For example, does the exposure-to-risk doctrine only become available to plaintiffs who can show that all contributions to the risk were tortious? Is it only available when the risk of the condition can be generated by one type of agent alone? Such issues arose in recent mesothelioma litigation in Britain. Here, the House of Lords adopted a special rule of proof for factual cause using a contribution to risk is deemed contribution to injury approach comparable to that in *Rutherford*. Interestingly, however, while allowing the doctrine in cases where some sources of risk were innocent, the Lords affixed several liability to the doctrine. The Lords also limited it to single-agent conditions, thereby preventing its use by smokers (such as Mr. Rutherford), who are exposed to asbestos and contract lung cancer

plaintiff’s non-economic damages, but shall only be severally liable for such damages “in direct proportion to that defendant’s percentage of fault.” CAL. CIV. CODE § 1431.2(a) (West 2009). The *Rutherford* plaintiffs elected not to challenge the applicability of Proposition 51 to their wrongful death claim, hence liability for non-economic losses was treated as several. *Rutherford*, 941 P.2d at 1210 n.4.

64 *Rutherford*, 941 P.2d at 1219.

65 See generally Barker v. Corus UK Ltd., [2006] 2 A.C. 572 (H.L.) (U.K.). By squarely acknowledging the radical new rule and eschewing any fiction, the Lords were able to face the normative question about whether it should be twinned with a several liability co-rule. *Id.*
because of the diverse agents in play (asbestos and tobacco both being sources of the risk of lung cancer).66

VI. WHY WERE THESE TWO PROOF-OF-CAUSATION DOCTRINES NEGLECTED?

The Products Liability Restatement made no reference to the two proof-of-causation doctrines central to asbestos cases: the indivisibility-of-injury doctrine (from asbestosis cases) for proof of factual causation in cumulative toxic torts and the exposure-to-risk doctrine (from asbestos-caused cancers cases) for proof of factual causation in claims for indivisible conditions. Why this neglect? Here are some suggested explanations for the neglect of: the parties to asbestos claims themselves; the academy; and the American Law Institute.

A. Parties to Asbestos Claims

In the early 1980s, entrepreneurial plaintiffs’ lawyers succeeded in consolidating masses of cases in sympathetic venues and securing a phased litigation process in which an adverse verdict in the first general liability phase would have had a drastic multiplier effect for defendants: as one prominent plaintiffs’ lawyer noted with considerable understatement, these pressures on defendants “created an atmosphere to settle the cases.”67 In other words, early on in modern asbestos litigation, plaintiffs’ lawyers seem to have convinced many defendants that it was “better business” to settle asbestos claims than to dispute matters such as the proof-of-causation doctrines used by courts to assist plaintiffs. These early front line defendants were major asbestos manufacturers, a relatively small group whose culpability was being easily established.68

Moreover, it was the case that early claims were overwhelmingly concerned with the cumulative disease of asbestosis, to which every significant exposure from a defendant’s product would have actually contributed some degree of the total injury. The only issue was that the theoretical possibility of apportionment of the cumulative disease offered by section 433B(2) was in practice defeated by the confluence of the sole

66 Id. ¶ 24 (Lord Hoffmann) (“I do not think that the exception applies when the claimant suffers lung cancer which may have been caused by exposure to asbestos or some other carcinogenic matter but may also have been caused by smoking and it cannot be proved which is more likely to have been the causative agent.”). Of course, the single agent requirement raises the question of whether mesothelioma is itself a “single agent” condition. See Michele Carbone et al., The Pathogenesis of Mesothelioma, 29 SEMINARS IN ONCOLOGY 2, 3-4 (2002) (speculating that approximately twenty percent of mesothelioma cases may not be caused by asbestos fibers).


68 In contrast, “defendants of today . . . are likely to be far less culpable than the major asbestos manufacturers who have all been through bankruptcy.” Sanders et al., supra note 59, at 428 (2008).
remedy rule (diverting claims away from employers) and the multiple tortfeasors created by the liability rule in section 402A. Given the American costs rule (under which defendants pay their own costs even if they prevail), these defendants would have viewed settling with asbestosis plaintiffs as the most efficient strategy to deal with the avalanche of claims being filed by seriously sick plaintiffs.

The Borel approach that allowed plaintiffs to recover for any asbestos-related “disease” from all defendants to whose asbestos products the plaintiff was exposed was accepted by defendants in so many thousands of asbestosis cases that it had become well entrenched as a matter of substantive doctrine by the mid to late 1980s when significant numbers of claims started to be made for asbestos-related cancers (in relation to which a plaintiff could not establish, under orthodox rules, any actual contribution from a defendant, unlike the asbestosis plaintiff). Defendants in these cancer claims simply did not dispute the Borel approach, an acquiescence often supported by sanguine acceptance of crude (and incorrect) scientific testimony that such cancers were “cumulative” diseases. That the latter misinformation was admitted as testimony at a time when elsewhere in the tort system controversy raged about how to ensure the quality of expert evidence, confirms that by this stage asbestos litigation was regarded as sui generis: such an “elephantine mass of asbestos cases . . . [that it] defies customary judicial administration . . .”

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69 While the total number of claims for mesothelioma filed before 1980 was 238, there were 2411 filed in 1989 alone. Indeed, mesothelioma filings continued to surge, doubling during the period from 1994 to 2002. CARROLL ET AL., supra note 67, at 71, 74.

70 See, e.g., Eagle-Picher Indus. Inc. v. Balbos, 604 A.2d 445, 459 (Md. 1992) (“Eagle does not dispute . . . that the principle of proximate causation by which the evidence concerning causation in fact is to be determined is the substantial-factor rule, and not the “but-for” rule. . . . In products liability involving asbestos, where the plaintiff has sufficiently demonstrated both lung disease resulting from exposure to asbestos and that the exposure was to the asbestos products of many different, but identified, suppliers, no supplier enjoys a causation defense solely on the ground that the plaintiff would probably have suffered the same disease from inhaling fibers originating from the products of other suppliers.”). Moreover, even when a defendant merely queried whether joint and several liability was an appropriate corollary of the exposure-to-risk doctrine in mesothelioma cases, the court concluded that this was now an argument “better addressed to the Legislature than to the courts.” Mavroudis v. Pittsburgh-Corning Corp., 935 P.2d 684, 689 (Wash. Ct. App. 1997).

71 For example, in Eagle-Picher Industries, the Court of Appeals of Maryland noted that:

[A] medical expert for the plaintiffs testified that “all of [the] exposures to asbestos were a significant contributing causal factor to the mesothelioma,” because the causation is “cumulative.” The defendants’ medical expert also believed that a person must reach an undefined “threshold” of asbestos exposure before exposure will cause mesothelioma.

Eagle-Picher Indus., 604 A.2d at 459. But cf. Reserve Mining Co. v. Environmental Protection Agency, 514 F.2d 492, 508 n.25 (8th Cir. 1975), order modified by Reserve Mining Co. v. Lord, 529 F.2d 181 (8th Cir. 1976). In a significantly more sophisticated judgment concerning air and water pollution, the United States Court of Appeals for the Eighth Circuit noted that “[i]t is significant that the witnesses generally agreed that no known safe level of exposure exists for mesothelioma.” Id.; see also supra note 40.


In short, by the time asbestos-related cancers came before the courts, the mammoth volume of asbestos claims had produced a great deal of common interest between plaintiffs’ lawyers, defendants, and trial courts: a unique interest in managing and processing claims as cheaply as possible. Taking fine doctrinal points about how factual causation could be established and divided does not easily fit within this agenda.

Also and finally, in the context of other well-settled, broad-brush, plaintiff-friendly proof-of-causation rules such as that in *Summers v. Tice*, the market share approach, and the heeding presumption in the area of products liability, the two proof-of-causation doctrines in asbestos cases may not even seem all that remarkable to U.S. practitioners.

B. The Academy

One possible explanation why the attention of academics was not attracted to the special causation rules in asbestos cases in the early years of asbestos litigation was because, until *Borel*, asbestos claims were located in the field of workers’ compensation. This is a field that most academics regard as deeply unfashionable and unheroic.

It is tempting to speculate that a reason for continuing academic neglect may be that the two proof-of-causation doctrines in asbestos cases were created by courts themselves rather than being prompted by some academic initiative as had been the case, for example, with the market-share doctrine, whose real-world impact, it should be emphasized, is trivial in comparison to that of these two asbestos rules. Certainly it is true that even today academics are far more entranced by the intricacies of market share and other academic creations than they are...

74 For example, the two proof-of-causation doctrines in asbestos cases were not noted in *W. Page Keeton et al., Prosser and Keeton on Torts* (W. Page Keeton ed., 5th ed. 1984) and to date exceptionally few American legal scholars have shown any interest at all in the radical treatment of factual causation in asbestosis and asbestos-related cancers. For exceptions where some interest was shown in these matters, see Mark A. Behrens & William L. Anderson, *The "Any Exposure" Theory: an unsound basis for asbestos causation and expert testimony*, 37 Sw. U. L. Rev. 479 (2008); Mark A. Geistfeld, *supra* note 62, at 496-97 (2006); Donald G. Gifford, *The Challenge to the Individual Causation Requirement in Mass Product Torts*, 62 Wash. & Lee L. Rev. 873, 908-09 (2005); Donald G. Gifford, *The Death of Causation: Mass Products Torts’ Incomplete Incorporation of Social Welfare Principles*, 41 Wake Forest L. Rev. 943, 947 990-91 (2006); Sanders et al., *supra* note 59, at 409-10.

75 In *Sindell v. Abbott Laboratories*, “the wellspring of the majority’s new theory” of market share liability was a law review piece, 607 P.2d 924, 943 (Cal. 1980) (citing Naomi Sheiner, *Comment, DES and a Proposed Theory of Enterprise Liability*, 46 Fordham L. Rev. 963, 1007 (1978)).
inspired by the formidable theoretical and forensic potential of these two proof-of-causation doctrines that govern tens of thousands of tort claims.

Of course, the academic neglect of the asbestos proof-of-causation doctrines is also consistent with the general “flight from doctrine” to theory that characterized the closing decades of the twentieth century in U.S. legal academia. The reasons for this are complex. However, to the extent this trend was fuelled by the national academic market and the desire of scholars for their work to transcend the doctrinal fragmentation across the multiplicity of tort-law jurisdictions in the United States, it does not directly explain our phenomenon of neglect because the asbestos causation rules have “swept the nation” even more comprehensively than section 402A of the Restatement (Second) of Torts, to which intense academic attention has been paid.

Nevertheless, the increased academic interest in theory has at a broad level deflected attention away from doctrinal analysis, leading prominent judges to dismiss modern law reviews as irrelevant to the actual cases and doctrinal dilemmas that confront them. In general, the multiplicity of jurisdictions and vastly increased access to the information generated in them does not help. Even in the era of Internet blogs this situation continues to inhibit academics selecting from the stream of case law a “canon” of core cases that raise fundamental doctrinal questions and around which a national debate could revolve. Given this complex doctrinal landscape, perhaps it was simply by accident that scholars failed to recognize the phenomenon of the asbestos proof-of-causation rules and expound their profound implications in major law review articles.

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76 Comment to the author by Geoffrey Hazard, Thomas E. Miller Distinguished Professor of Law at the University of California, Hastings School of Law, at the Council Meeting of the American Law Institute in N.Y., N.Y. (Oct. 2006). See generally Jane Stapleton, Benefits of Comparative Tort Reasoning: Lost in Translation, 1 J. TORT L. 6, at 3 (2007).

77 Of course, outstanding doctrinal work still emerges. Two extraordinary achievements, invaluable throughout the common law world for their brilliant account and analysis of American tort law doctrine, are Dan B. Dobbs, The Law of Torts (2000) and David G. Owen, Products Liability Law (2d ed. 2008).


79 Supported by six of his colleagues, the Chief Judge of the United States Court of Appeals for the Second Circuit recently admitted, “I haven’t opened up a law review in years. . . . No one speaks of them. No one relies on them.” Adam Liptak, When Rendering Decisions, Judges are Finding Law Reviews Irrelevant, N.Y. TIMES, Mar. 19, 2007, at A1 (quoting Chief Judge Dennis G. Jacobs) (internal quotation marks omitted); see also Judge Alex Kozinski, Who Gives a Hoot About Legal Scholarship?, 37 Hous. L. Rev. 295, 295 (2000).

80 This “core canon” phenomenon thrives in unified common law systems such as England, Canada, and Australia, See Stapleton, supra note 76, at 2-3.
C. The Institute

More worrisome is the fact that the *Products Liability Restatement* was silent about both the asbestosis *indivisibility-of-injury* doctrine (even though it was the most flamboyant application of the principle restated in section 16(c) of that *Restatement*) and the *exposure-to-risk* doctrine in asbestos-caused cancers cases (even though it is one of the most intellectually radical developments in U.S. tort law in the past 50 years).

It is true that at the time the *Products Liability Restatement* was being drafted there were no cases that dwelt on the propriety of these special proof-of-causation doctrines: the *Products Liability Restatement* was adopted in May 1997, many months before *Rutherford* was handed down. Nevertheless, the reality was that at the time the Restatement was being drafted these doctrines were well-entrenched, critical to masses of claims clogging the courts, and virtually uniformly adopted across the states. Why the silence from the Institute?

One possibility is that the ALI membership did not have the necessary experience with asbestos litigation. To say that all ALI members are elite judges, practitioners, or academics does not establish the breadth of their experience: one wonders how many members today are closely acquainted with workers’ compensation practice. On the other hand, it seems realistic to assume that at the time the *Products Liability Restatement* was being drafted a number of members would have known about the special proof-of-causation doctrines that had facilitated and continued to facilitate the resolution of asbestos claims, claims which threatened to overwhelm the tort system. So let us assume, for the sake of argument, that these doctrines did come to light during the restatement process but that a decision was made not to include them. On what grounds might such a decision have been made?

Might the two doctrines have been omitted because they are in practice mostly confined to the special field of asbestos? This seems a poor reason for exclusion. The *Products Liability Restatement* restates the rule of market share liability, yet that doctrine has scarcely been applied outside the product-specific area of DES litigation. Indeed, the *Products Liability Restatement* explicitly discusses the hostility of courts to applying market share to asbestos cases, while at the same time

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81 See also *Mavroudis v. Pittsburgh-Corning Corp.*, 935 P.2d 684, 687 (Wash. Ct. App. 1997) (a mesothelioma case) (“Although we are aware that substantial factor causation instructions are commonly given in asbestos-injury cases tried in Washington, no published Washington case cited by the parties or found by this court through independent research directly addresses the propriety of substantial factor instructions in asbestos-injury cases.”).


83 *Restatement (Third) of Torts: Prods. Liab.* § 15 Reporters’ Note, cmt. c (1998); see also note 33 and accompanying text.
remaining silent on courts’ adoption in asbestos cases of proof-of-causation doctrines that are far more radical than market share because they support joint and several liability. In any case, elsewhere the Products Liability Restatement does include a special approach that courts take to asbestos, namely the indulgent treatment of pure economic loss claims for abatement.84

Moreover, how do we know these special proof-of-causation doctrines are only acceptable for use in asbestos cases? Since the explosive potential of these doctrines has been left unanalyzed by courts or scholars it remains an open question whether they could be applied more generally, in the way, for example, that the rule of “alternative liability” in Summers v. Tice has become widely available outside shooting cases. Why could not the plaintiff with lead poisoning use the indivisibility-of-injury doctrine to establish that, in law, a defendant was a factual cause of the plaintiff’s total condition (and was jointly and severally liable for it) even though it is clear that this defendant was, in fact, a very minor contributor to the plaintiff’s cumulative condition? Similarly, when a plaintiff suffers from an indivisible condition the mechanism of which is unknown, can he rely on the exposure-to-risk doctrine to establish that, in law, a defendant was a factual cause of that condition (and was jointly and severally liable for it) even though, in fact, the most that can be shown is that this defendant had made a contribution to the risk of that condition being contracted?

Perhaps the Products Liability Restatement was silent about the asbestos proof-of-causation doctrines for a more prosaic reason: that while Prosser personally promoted the adoption of the rule in section 402A (on a very thin bed of case law),85 there happened to be no eloquent “sponsor” of these two proof-of-causation doctrines within the ALI to argue for their inclusion (despite their immense importance in tens of thousands of claims). If so, this casts a cautionary light on the restatement processes of the ALI generally.

CONCLUSION

It is important to emphasize that the Borel approach, in allowing asbestos plaintiffs to prove factual causation to any asbestos-related disease merely by showing a significant exposure to asbestos from the defendant’s tort, represents two distinct doctrines.

84 See Restatement (Third) of Torts: Prods. Liab. § 21 cmt. c (1998) (“In the case of asbestos contamination in buildings, most courts have taken the position that the contamination constitutes harm to the building as other property.”); id. (explaining that pure economic loss claims related to the costs of asbestos abatement are generally treated as tort claims and have been accepted without the extreme judicial caution generally shown to pure economic loss claims in tort).

When applied to an asbestosis claim, the approach can be seen as an application of the general approach underlying section 433B(2) where we know the defendant has actually contributed some harm to the plaintiff. In effect, the Borel approach applied in asbestosis claims is tantamount to the adoption of an indivisibility-of-injury fiction for cumulative disease. It invites us to think about other non-asbestos toxic tort contexts where, though the plaintiff clearly suffers from a cumulative condition such as lead poisoning, she might be granted access to this indivisibility-of-injury doctrine and thereby subject a defendant to joint and several liability for her entire condition even though it is clear that the defendant was not responsible for the full severity of her condition.

We should acknowledge that this indivisibility-of-injury doctrine for cumulative diseases might be seen as merely a moderate extension of the generally sympathetic doctrinal attitude towards plaintiffs on the issue of factual cause. As Judge Posner has noted, “[t]he general tendency of courts in tort cases, once negligence is established, is to resolve doubts about causation, within reason, in the plaintiff’s favor.”\footnote{Kwasny v. United States, 823 F.2d 194, 196 (7th Cir. 1987).}

In contrast, when the Borel approach is applied to an asbestos-related cancer claim, it subjects all those who tortiously exposed the plaintiff to asbestos, and therefore to a significant risk of contracting an asbestos-related cancer, to joint and several liability for the plaintiff’s entire injury. This is so even though it is virtually certain that, whatever the mechanism of contraction of the cancer, not every exposure to asbestos played a part in it. This exposure-to-risk doctrine, which is tantamount to the adoption of the fiction of a threshold mechanism for indivisible injuries, is far more radical and explosive in its potential than the impact of applying the Borel approach in the context of cumulative diseases such as asbestosis.

Though the importance of the distinction between these two proof-of-causation doctrines is very great, the current draft of the Restatement (Third) of Torts: Liability for Physical and Emotional Harm, does not clearly distinguish them.\footnote{The Draft also does not adequately explain why it discusses most asbestos causal issues under section 27 (a section that explains that a non-necessary factor may yet be a factual cause as in, say the merged fires case) rather than under section 28 (burden of proof). RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM §§ 27-28 (Proposed Final Draft No. 1, 2005). This is presumably because the Reporters have chosen to characterize the courts’ approach to asbestos cases as setting up fictions of what actually happened (and therefore belonging in section 27, which concerns how things had actually happened) rather than as special rules dispensing the plaintiff from the orthodox burden of proof (the issue dealt with in section 28). See id.} In a Note, the Reporters merely report that:

>Courts have assumed, without much discussion, that the model for disease causation, even for progressive disease like asbestosis, is the one contained in this Comment [i.e., the threshold mechanism]. Since the first asbestos case in
which a plaintiff was successful, courts have allowed plaintiffs to recover from all defendants to whose asbestos products the plaintiff was exposed.88

This suggests that, whatever were the flaws in the process leading to the *Products Liability Restatement*, the restatement process is still failing to record doctrines of central relevance to much of tort practice and to the future development of the law.

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88 *Id.* § 27 Reporters’ Note cmt. g; see also *id.* (“[B]ecause of the absence of scientific knowledge about the marginal increments of harm, courts have treated even dose-dependent diseases [such as asbestosis] the same as other diseases, whose severity is assumed not to be dose dependent.” This is despite the fact that it is known “that asbestosis is a dose-dependent disease.”).
Strict Liability for Defective Product Design

THE QUEST FOR A WELL-ORDERED REGIME

Larry S. Stewart†

I. INTRODUCTION

Restatement (Third) Torts: Products Liability (hereafter “Restatement (Third)”) was an ambitious effort to codify and update thirty years of products liability development and evolution. It sought to describe a “well-ordered” set of rules to guide courts and practitioners, but given the highly politicized nature of the subject, doing so was not without controversy, and success has been elusive. Whether the new Restatement will ultimately be judged a success depends in large part on how success is defined, and, while that outcome may still await future developments, some conclusions can already be drawn.

For one, the new Restatement has resulted in focusing attention on many issues and setting an agenda for debate and discussion. For another, it has already served to clarify and improve some aspects of products liability law. For example, while the core provisions of section 2(b) were and remain highly controversial, within that section are rules that bring welcomed improvements such as the comment d provision, which states that “open and obvious” dangers do not necessarily preclude liability1 and other rules that are already finding judicial approval such as the comment l provision that a warning is not a substitute for a safer design, and when a safer design can reasonably be implemented, it is the seller’s duty to do so rather than merely warning of the risk.2 In addition, section 11, post-sale failure to recall, forges new but needed ground, and section 18, dealing with disclaimers and other contractual exculpations, states an obvious rule in a concise, direct way.3

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1 Restatement (Third) of Torts: Prods. Liab. § 2 cmts. g, l (1998).
2 Kampen v. Am. Isuzu Motors, Inc., 157 F.3d 306 (5th Cir. 1998); Rogers v. Ingersoll-Rand Co., 144 F.3d 841 (D.C. Cir. 1998); Uniroyal Goodrich Tire Co. v. Martinez, 977 S.W.2d 328 (Tex. 1998).
3 Restatement Third also leaves open the question of whether direct-to-consumer mass marketing of prescription drugs and medical devices should obviate the learned intermediary rule. Restatement (Third) of Torts: Prods. Liab. § 6 cmt. e (1998). For recent developments in that
It is, however, a much different picture for what is arguably the most important part of the project: the core provisions for design defect claims.4 Those provisions, contained in section 2(b), proposed sweeping new changes that would (1) restrict design defect claims to a negligence based, risk/benefit regime in which proof of an alternative design would be mandated,5 (2) abolish 402A strict liability and relegate its consumer expectation test to only a factor for consideration in the risk/benefit regime, and (3) prevent alternative pleading of any other theory of liability. In effect, Restatement (Third) would create a new “reasonable alternative design” test for the vast majority of defective design claims.

Born in controversy and at odds with the original rationales for and concepts of strict liability, many viewed those core provisions as anti-consumer. And, as critics predicted, in the ensuing decade, those provisions have been largely rejected by the courts, with findings that they go “beyond the law,” set the bar for recovery too high, and would amount to regression in the law.

This Article will explore the development of the Restatement (Third), how the design defect proposals veered off course, why the core provisions for design defect claims have been rejected, and what should be the guiding principles and normative rules in a well-ordered strict liability design defect regime with appropriate conceptual foundations.

II. PRODUCTS LIABILITY FOR DESIGN DEFECTS

Modern products liability law sprang from widespread dissatisfaction with the glacial progress and often unsuccessful results of negligence claims for product defects. While privity limitations had been largely eliminated by the 1960s,6 liability remained elusive because of “contract” limitations and defenses, and often insurmountable proof requirements concerning what went wrong and how manufacturers failed to act reasonably. As a result, critics argued that new rules were needed, which would recognize that products sellers7 bore special responsibility regard, see Perez v. Wyeth Laboratories, 734 A.2d 1245 (N.J. 1999) and State ex rel. Johnson & Johnson Corporation v. Karl, 647 S.E.2d 899 (W. Va. 2007).

By the early 1980s, claims of unsafe design came to predominate products liability litigation. Aside from the sheer number of such claims, each commands special attention because a single case can implicate an entire product line.

Under Restatement (Third), there are some situations in which proof of an alternative design is not required. They are manifestly unreasonable design cases under section 2(b) comment e; circumstantial evidence cases under section 3; statutory violations under section 4; food product cases under section 7; and failure-to-recall cases under section 11. For most cases, however, proof of an alternative design would be a requisite element.


Products liability laws apply to all in the chain of distribution, including designers, manufacturers, wholesalers, distributors, and retailers, even if they do not have physical possession of the product. RESTSTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1, cmt. c (1998); e.g., Rivera v.
to consumers because they implicitly represented that their products are safe; the public has a right to expect that reputable setters will stand behind their products; and the burden of injuries should be placed upon those who market the products, rather than the users of those products.8

Beginning with Greenman v. Yuba Power Products, Inc.9 and the adoption shortly thereafter of Restatement (Second) Torts section 402A, “strict liability” for product defects came to replace negligence as the primary basis for products liability. Section 402A avoided the inherent proof problems of negligence by providing for liability even though the seller “has exercised all possible care in the preparation and sale of his product.”10 Under strict liability, sellers are liable for harms caused by products that are “in a defective condition unreasonably dangerous,” that is “dangerous to an extent beyond that which would be contemplated by the ordinary consumer . . . .”11 In the lexicon of products liability law, this came to be known as the “consumer expectations” test. As such, it mirrored implied warranty of sales law stripped of its contractual limitations and defenses. Thus, after 402A, if a product malfunctioned, sellers were liable for both the loss of the product as well as any injuries resulting from the malfunction.

The cost of rendering the product reasonably safe was not a factor in the liability equation. The manufacturer could either design out the defect or it had to bear the burden of resulting injuries. Liability did not exist, however, for all product defects. Section 402A recognized that there are some products that science and art cannot make completely safe but which still have utility. For those “unavoidably unsafe” products, comment k provided a defense to a seller who markets “an apparently useful and desirable product, [even though it is] attended with a known but apparently reasonable risk” as long as the seller provides “proper directions and warning.”12

Under 402A there was no distinction between manufacturing and design defects. Greenman itself involved a design defect,13 and the language of 402A clearly covers both types of defect. Indeed, the inclusion of comment k underscores that design defects were included since otherwise there would be no purpose for an “unavoidably unsafe” product defense.

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11 Id. § 402A (2)(a) cmt. i; see also id. § 402A (2)(a) cmt. g (“Defective condition. The rule . . . applies only where the product is . . . in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him.”).
12 Id. § 420(a) cmt. k.
13 Greenman, 377 P.2d at 899-90.
While 402A swept the land, the idea that product defectiveness could be determined on the basis of what an ordinary consumer would expect did not meet with universal acceptance. Some believed that defectiveness should be anchored in traditional negligence concepts, a proposition championed by Dean John Wade in his article “On the Nature of Strict Tort Liability for Products.” Dean Wade argued for nullification of strict liability for all product defects, both manufacturing and design. He proposed instead that liability for defective products be based only on the reasonableness of the marketing decision under a reasonably prudent seller standard. Because his conceptual analysis utilized a number of risk/benefit factors, this approach came to be known as the “risk/benefit” test. That is, however, somewhat of a misnomer since Dean Wade did not advocate using the risk/benefit factors as a test of design defect. His proposal was only that the jury issue in such cases should be simply whether the defendant acted as a reasonably prudent marketer.

By the 1980s, what began as an academic debate became partisan as manufacturing interests began advocating that design defects should only be decided under a risk/benefit test. Their argument was that while the consumer expectation test was appropriate for manufacturing defect claims where consumers would expect that products were built according to design, it was meaningless for design defects since consumers could not know all the considerations involved in arriving at a particular product design. According to manufacturers, the only appropriate way to evaluate design defect claims was by a cost-benefit analysis that weighs the risks and benefits of the design. This was, however, different from the simple negligence standard that had been proposed by Dean Wade. What the manufacturing industry sought was an express risk/benefit test whereby juries would have to make a cost-benefit analysis to determine liability.

This approach stood strict liability on its head by taking what was an affirmative defense under 402A for “unavoidably unsafe”

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14 John W. Wade, On the Nature of Strict Tort Liability for Products, 44 Miss. L.J. 825 (1973). There were earlier iterations of Dean Wade’s article but this is the one commonly cited as the origin of the risk/benefit test.

15 Id. at 839-40.

16 Industry interests were coordinated by the Products Liability Advisory Council (PLAC). According to its web site, PLAC was formed in the early 1980s and consists of over 130 corporate members representing a broad cross-section of product manufacturers and several hundred products liability defense attorneys that advocate for changes in products liability laws to favor manufacturers, principally through coordinating efforts across jurisdictions and filing amicus briefs. For an overview of cases tracing PLAC’s role, see Larry S. Stewart, Courts Overrule ALI “Consensus” On Products, TRIAL MAG., Nov. 2003, at 18.

17 This position is somewhat paradoxical since Defendants, such as Ford Motor (the Pinto car), the former A. H. Robbins (the Dalkon Shield), the asbestos industry, and McDonald’s (hot coffee), who knowingly make similar assessments and used them as a basis for not investing in product safety, have been subject to distain by juries in the form of significant punitive damage awards.
products and making it the basis of a liability regime in which products would be presumptively safe unless plaintiffs carried the burden of proving that the risks inherent in the product outweighed its benefits. Conceptually, the risk/benefit approach rejected corrective justice for a law and economics theory by which product sellers would be liable only when the risks of the product, on balance, outweighed the benefits of having the product on the market.

Much confusion resulted in the ensuing arguments over the proper rule for design defect claims. Many courts did not seem to appreciate or chose to ignore the conceptual difference between strict liability and a negligence-based, risk/benefit theory. Resulting decisions were a hodge-podge of rules, ranging from the “consumer expectation” test to the “risk/benefit” test, with various hybrid combinations that conflated aspects of the two doctrines. The hybrid systems, however, lack the conceptual basis for applying rules, which are necessarily invoked in products liability cases. That lack of conceptual foundation led to confusing, inconsistent, and conflicting results.

Nowhere is this more evident than in the recent decision of the Illinois Supreme Court in Mikolajczyk v. Ford Motor Co. There, in attempting to reconcile the consumer expectation and risk/benefit tests in a strict liability context, the court nonsensically concluded that “[t]hese two tests . . . are not theories of liability; they are methods of proof by which a plaintiff “may demonstrate” that the element of unreasonable dangerousness is met.” As the Mikolajczyk decision painfully demonstrates, conflating the two tests ultimately leads to doctrinal collapse. Unfortunately, in the development of Restatement (Third) the conceptual differences between strict liability and risk/benefit were ignored. Indeed, under Restatement (Third) strict liability for design defect ceased to exist, becoming just a label for what is a negligence based, risk/benefit concept.

III. THE NEW RESTATEMENT

In 1991 the American Law Institute undertook to draft a comprehensive new restatement of products liability law. That project proposed that products liability claims be divided into manufacturing defects, design defects, and failure to warn cases, a concept that closely paralleled the Products Liability Advisory Council (“PLAC”) agenda. For manufacturing defects, the proposed new Restatement acknowledged the basic rationales for modern products liability law and urged

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20 Id. at *20.
21 See supra notes 17-18 and accompanying text; see infra note 43 and accompanying text.
continuance of a strict liability regime but with the twist that injured consumers could only bring a single claim, thus foreclosing the possibility of an alternative or independent claim for negligence.

For design defects, the new Restatement also followed the PLAC agenda. According to the new Restatement, the policy rationales for strict liability were not applicable to design defect cases and a different concept of responsibility was needed. As related in the new Restatement, consumer expectations of safe design were allegedly too difficult to discern because consumers cannot know all the considerations involved in product design and the focus of liability instead should be on the “trade-offs” in product design and requiring consumers to bear responsibility for proper product use.22 This change would be accomplished by restricting design defect cases to a single negligence based, “risk-utility balancing” claim that required proof of an alternative design.23 Injured consumers would no longer have the option to bring alternative claims for both strict liability and negligence, could no longer bring design defect claims under 402A strict liability and its consumer expectation test, and, in most cases, experts would be required to present an alternative design for the product.

While evidence of alternative design potentials was a common element of many products liability cases, especially when the defendant’s own records or conduct supplied the proof, there was little jurisprudential support for mandating it as a requisite element of a claim. And, the mere fact that plaintiffs presented such evidence does not justify making it a mandatory requirement. Indeed, even Dean Wade only considered it one of many other considerations in his analytical discussion.24 But, by elevating proof of an alternative design to a mandatory element, the new Restatement created a new “reasonable alternative design” test for most design defect cases that would undermine strict liability rationales.

The policy rationale for the new design defect liability was suspect, but that was lost in a highly controversial claim that the design defect proposals of the new Restatement, including proof of an alternative design, constituted the majority rule in the United States.25 “Majority rules” are powerful because they relieve the necessity for policy analysis by invoking stare decisis. But the products liability

23 Id. § 2(b).
24 Wade, supra note 14, at 837 (referring to the “manufacturers ability to eliminate the unsafe character of the product without impairing its usefulness”). Making alternative design proof mandatory, however, opens the door to foreclosing claims under the guise of Daubert “gate keeping.” The results in just the first six years following Daubert are striking. Challenges to expert testimony increased by 50%, summary judgments based on the exclusion of expert testimony increased by over 100%, and 90% of those summary judgments were against the plaintiffs. Of those cases, 24% were products liability claims. L. DIXON & B. GILL, RAND INST. FOR CIVIL JUSTICE, CHANGES IN THE STANDARDS FOR ADMITTING EXPERT EVIDENCE IN FEDERAL CIVIL CASES SINCE THE DAUBERT DECISION (RAND 2001).
decisions were a conglomeration of results that defied any majority rule,26 and there was no support for a contention that courts had rejected the basic rationales of modern products liability law in design defect claims. Many commentators saw these design defect proposals as nothing more than a thinly disguised “tort reform” agenda.27

As far as a new focus on manufacturer expectations is concerned, allowing design “trade-offs” to trump product safety undermines the basic purpose of modern products liability law. Rather than making products presumptively safe, as they would be in an unqualified risk/benefit regime, the focus of products liability law should remain on encouraging the design, production, and marketing of safe products. And, shifting the cost of injuries to consumers to incentivize them to take precautions would saddle them with the burden of discovering product risks, which are or should be known to but are often not disclosed by product sellers. This approach is contrary to established precedent, which provides that consumers are not negligent in failing to discover product defects or guard against the possibility of their existence.28

The deliberations over these proposals and their rationales were some of the most contentious in ALI history. Although the proposals were ultimately adopted by the ALI, many believed that the core provisions of section 2(b) were fundamentally flawed, a conclusion that was in significant part based on the rejection of the strict liability policy rationales for design defect claims.

IV. POLICY RATIONALES

Public policy rationales are the foundations upon which the legal rules rest. In the case of products liability, the original policy rationales that led to the adoption of strict liability were the ameliorative societal

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26 The “counting” of Florida illustrates the flaws in the majority rule claim. In the Reporters’ Notes for Restatement (Third) it is claimed that Radiation Technology, Inc. v. Ware Const. Co., 445 So. 2d 329 (Fla. 1983), is “the leading case in Florida” and, in it, Florida adopted the risk/benefit test for design defect cases and implicitly required proof of an alternative design. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) Reporters’ Note, cmt. d (1998). There are, however, no such holdings in Radiation Technology, and it is far from being the leading Florida decision.

27 See, e.g., Douglas E. Schmidt et al., A Critical Analysis of the Proposed Restatement (Third) of Torts: Products Liability, 21 WM. MITCHELL L. REV. 411, 412-13, 419-20 (1995) (collecting numerous articles stating that section 2(b) is “a vehicle for social reform” rather than a restatement of the existing law); Marshall S. Shapo, A New Legislation: Remarks on the Draft Restatement of Products Liability, 30 U. MICH. J. L. REV. 215, 218 (1997) (Section 2(b) is not a description of existing law, but the invention of drafters who acted as “a sounding board for essentially political discussion.”); Frank J. Vandall, Constructing a Roof Before the Foundation is Prepared: The Restatement (Third) of Torts: Products Liability Section 2(b) Design Defect, 30 U. MICH. J.L. REFORM 261, 261-65 (1997) (Section 2(b) is “a wish list from manufacturing America” in which “[m]essy and awkward concepts such as precedent, policy, and case accuracy have been brushed aside for the purpose of tort reform.”).

28 RESTATEMENT (SECOND) OF TORTS § 402A cmt. n (1963); e.g., West v. Caterpillar Tractor Co., Inc., 336 So. 2d 80, 89 (Fla. 1976).
effects of risk spreading, litigation efficiencies resulting from simpler liability rules, deterrence of unsafe practices, and consumer expectations about the fitness and safety of products. But Restatement (Third) took a different tact for design defects. It found those rationales unsatisfactory and opted instead for a rationale based on “manufacture expectations” that a reasonably designed product will still carry some risk that cannot be designed out of the product at reasonable cost, and that product users should bear some of the risk of product design.²⁹

Dismissal of the strict liability rationales for design defects does not, however, survive analysis. Spreading the risk of product injuries through seller liability continues to best serve societal goals, a point Restatement (Third) acknowledges in the case of manufacturing defects but dismisses for design defects. But the applicability of this rationale does not vary with the cause of the product defect. If risk-spreading is a valid liability rationale, there is no principled reason why it does not also support strict liability for design defects. Indeed, risk spreading would probably be more efficient in a strict liability regime for design defects since, most likely, there would be greater liability for product injuries.

Deterrence of unsafe practices, whether in a manufacturing or design context, is even more important now in an era of rapidly changing technology, deregulation, and underfunding of regulatory agencies than it was in the 1960s. The Restatement (Third) recognizes that fact for manufacturing defects by continuing strict liability rather than shifting to a fault-based regime under which sellers might escape liability. But, when it came to design defects, Restatement (Third) glossed over deterrence by arguing that too much deterrence would result in “excessively sacrificing product features,” and its different liability regime was “fair” because it would result in incentives to cause “consumers to engage in safe use and consumption of products.”³⁰ Those arguments, however, simultaneously overstate and understate the case for dismissal of a deterrence rationale. They overstate the case because the former argument applies with equal force to manufacturing defects. Excessive quality control can affect product features just as excessive design. They understate the case because the latter argument would also apply to manufacturing defects and is, in any event, already addressed by product misuse and comparative negligence defenses. Indeed, legal “incentives” for consumer safety would probably add nothing since product users already have substantial personal incentives to avoid injury.

The reality is that shifting to a negligence-based, risk/benefit regime for design defect claims would seriously undermine deterrence. Gone would be incentives to produce products that are safe for foreseeable uses, since sellers would only have to design to a standard

³⁰ Id.
whereby benefits outweighed risks, and, when sued for a defective design, they could take refuge in the opinions of compliant experts and the inherent difficulties of proving an alternative design. If injury deterrence is a valid liability rationale, it applies with equal justification to both manufacturing and design defects.

Litigation efficiencies would also be seriously undermined by a “reasonable alternative design” test regime. Strict liability was conceived to avoid the perils of negligence-based liability. Restatement (Third) would not only revive those risks but would make them more onerous since injured consumers would have to prove a previously unknown form of negligence: that the sellers’ conduct was negligent and that the seller could have adopted an alternative design. Litigation in such a regime would be more expensive, more extensive, and would result in far fewer consumer awards.

The reasons for dismissal of the consumer expectations rationale for design defects are equally unavailing, a point foreshadowed by the contradictions and obvious unease in Restatement (Third)’s dismissal of consumer expectations. In the same comment, Restatement (Third) states that “consumer expectations do not play a determinative role in determining defectiveness” but a few lines later concedes that consumer expectations “may substantially influence or even be ultimately determinative on risk-utility balancing.” And, its criticism of consumer expectations as unworkable is undermined by the implicit invocation of consumer expectations as the foundation for comment e “manifestly unreasonable” designs and section 3 inferences of product defect. Moreover, the criticism of consumer expectations is further weakened by its express retention as the defect test for food and used products in sections 7 and 8. Indeed, when it is to their tactical advantage, defendants have no conceptual compunction about advocating a consumer expectations test.

Restatement (Third)’s principal criticism, that discerning consumer expectations about product design is too difficult, is unpersuasive when compared to the use of other legal tests, such as negligence concepts, which are routinely applied in myriad complex cases like those arising from professional malpractice. Nor are products too complex for consumers to understand. It is not necessary for a

31 Green v. Smith & Nephew AHP, Inc., 629 N.W.2d 727, 751-52 (Wis. 2001). ("[Section] 2(b) increases the burden for injured consumers not only by requiring proof of the manufacturer’s negligence, but also by adding an additional—and considerable—element of proof to the negligence standard.").
32 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. g (1998).
33 Tobacco defendants have consistently argued for a “consumer expectations” test so they can defend on the historical record of tobacco dangers. E.g., Wright v. Brooke Group Ltd., 652 N.W.2d 159 (Iowa 2002). And, it is not uncommon for defendants to claim that a risk/benefit test should not apply to design defect claims involving “simple” products to pave the way for an argument that the claim should fail because the danger was open and obvious. E.g., Mikolajczyk v. Ford Motor Co., No. 104983, 2008 WL 4603565 (Ill. Oct. 17, 2008).
consumer to appreciate all the details or intricacies of a product to have an expectation of safety. With modern marketing and advertising, there are virtually no products for which consumers cannot have an expectation of safety. If consumer expectations are sufficiently discernable that they can be “ultimately determinative” in one context, then there is no principled reason why they are not also sufficiently discernable to guide strict liability for design defects. Beyond this argument, there is a salutary benefit from a degree of unpredictability in the consumer expectations test that encourages sellers to err on the side of safer designs.

In the end, dismissal of this and the other policy rationales as support for a strict liability design defect regime just does not add up. Shifting to a “manufacturer expectations” rationale and a more easily defended risk/benefit regime would enviably lead to less liability. Lost would be the fundamental purpose of strict liability—to relieve injured consumers of having to prove negligence, the societal purposes of deterrence of unsafe practices, and of having the cost of injuries borne by the manufacturers rather than consumers, who are ordinarily powerless to protect themselves.

V. JUDICIAL HISTORY

The dismissal of modern products liability rationales for design defect cases was a harbinger for what followed in the courts. The case was not made that courts had rejected those rationales or were even open to their modification. Nor was any case made that design defect liability needed to be restricted. With no compelling rationales for section 2(b) and serious questions about its support from case law, it was not surprising that before the ink was dry, the design defect provisions of Restatement (Third) were in trouble and have now been largely rejected.

While still only in draft form, the Georgia Supreme Court refused to mandate proof of an alternative design and the Supreme

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34 Green, 629 N.W.2d at 742-43 (“These standards are straightforward and may be applied even in “complex” cases. . . . As we have explained, juries are always called upon to make decisions based on complex facts in many kinds of litigation. . . . The problems presented in products liability jury trials would appear no more insurmountable that similar problems in other areas of the law. For these reasons, we reject the notion that the consumer-contemplation test cannot be applied in cases involving technical or mechanical matters.”) (citations and quotations omitted).

35 Implicit in the argument that consumer expectations are too difficult to discern is a distrust of the jury process—that even if appropriately instructed, juries are unable to handle such a task. A moment’s thought, however, exposes the biased elitism of such paternalistic thinking. Jurors are routinely entrusted with decisions involving myriad complex factual situations, huge financial implications, and life or death consequences, and they perform their duty with admirable dedication.

36 Products liability claims already represent only an infinitesimally small percentage of tort litigation. R. LAFOUNTAIN ET AL., EXAMINING THE WORK OF STATE COURTS, 2007: A NATIONAL PERSPECTIVE FROM THE COURT STATISTICS PROJECT 6 (2008) (reporting that according to the most recent data, products liability cases amount to only 4% of new tort cases).

37 Banks v. ICI Americas, Inc., 450 S.E.2d 671 (Ga. 1994).
Courts of California and Connecticut\textsuperscript{38} rejected section 2(b). The decision of the Connecticut Court in \textit{Potter v. Chicago Pneumatic} was stunning, coming just days after final passage of \textit{Restatement (Third)}. The \textit{Potter} court boldly questioned the scholarship underlining section 2(b), concluding it was wrong. The court independently reviewed the law and found “that the majority of jurisdictions do not impose upon plaintiffs an absolute requirement to prove a feasible alternative design” and that such a requirement “imposes an undue burden on plaintiffs that might preclude otherwise valid claims from jury consideration.”\textsuperscript{39} \textit{Potter} also rejected the core principle that the consumer expectation test should not apply in design defect cases but ultimately adopted a “modified” consumer expectation test under which the test to be applied would depend on whether a product is “complex.”\textsuperscript{40}

After \textit{Potter}, the Supreme Courts of Missouri, Kansas, Oregon, Wisconsin, New Hampshire, and the Maryland Court of Appeals all refused to adopt section 2(b).\textsuperscript{41} Against this parade of decisions, only Iowa has expressly adopted section 2(b), and it did so in a tobacco claim in which the plaintiff urged its adoption to prevent the defendant from relying on consumer expectations.\textsuperscript{42}

One should note, however, the recent, bizarre, convoluted decision of the Illinois Supreme Court in \textit{Mikolajczyk v. Ford Motor Co.}\textsuperscript{43} While expressly refusing to adopt section 2(b)\textsuperscript{44} or to require proof of an alternative design,\textsuperscript{45} the court reversed a plaintiff’s verdict for failure to give a jury instruction that relegated consumer expectations to an element in a risk/benefit test that appeared to require proof of an alternative design.\textsuperscript{46} While the \textit{Mikolajczyk} court acknowledged that both the consumer expectations and risk/benefit tests were established Illinois

\textsuperscript{38} Carlin v. Superior Court, 920 P.2d 1347 (Cal. 1996); Potter v. Chicago Pneumatic Tool Co., 694 A.2d 1319 (Conn. 1997).
\textsuperscript{39} \textit{Potter}, 694 A.2d at 1331-32.
\textsuperscript{40} \textit{Potter} failed to provide guidance for how to determine when a product was “complex,” which only creates new uncertainties and litigation issues. As noted in \textit{Green}, the so-called “complex design” is a false paradigm that does nothing to further a well-ordered regime. 629 N.W.2d 727, 742 (Wis. 2001).
\textsuperscript{42} Wright v. Brooke Group Ltd., 652 N.W.2d 159, 162, 169 (Iowa 2002). Texas and Tennessee courts have also affirmatively used section 2(b) but those courts were constrained to do so because they were interpreting tort reform legislation which already contained a risk/benefit test and, in the case of the Texas, a proof of alternative design requirement. Ray v. Bic Corp., 925 S.W.2d 527, 533 (Tenn. 1996); Hernandez v. Tokai Corp., 2 S.W.3d 251, 256-57 (Tex. 1999).
\textsuperscript{43} No. 104983, 2008 WL 4603565 (Ill. Oct. 17, 2008).
\textsuperscript{44} \textit{Id.} at *16.
\textsuperscript{45} \textit{Id.}
\textsuperscript{46} \textit{Id.} at *30.
law, it used misguided conclusions that the two tests are not theories of liability and that parties are entitled to have juries instructed on their theory of the case to hold that a section 2(b) type instruction must be given whenever the defendant elects to offer risk/benefit proof. In other words, under Mikolajczyk the defendant is allowed to dictate the type of claim that a plaintiff can submit to the jury. This muddled, unprincipled reasoning amounts to doctrinal collapse from which any conclusion could follow.

The other decisions rejecting section 2(b) are remarkable because they bluntly state that the Restatement (Third) “goes beyond the law” and sets the bar too high. They recognize that Restatement (Third) would unduly restrict remedies, elevate defendant protectionism over consumer interests, and return to a pre-Restatement (Second) era where meritorious claims frequently went without redress. And appending a mandatory requirement of proof of an alternative design, as Restatement (Third) seeks to do, would only compound that effect. On a more basic level, these cases reflect a failure of acceptable rationale for the core provisions of section 2(b) and unwillingness on the part of courts to abandon the original products liability rationales. In addition, these cases make it clear that whatever one made of the pre-Restatement (Third) “weight of authority” and to whatever extent it is relevant to a well-ordered design defect liability regime, it is no longer debatable that the core provisions of section 2(b) are not the majority rule today.

VI. GUIDING PRINCIPLES AND NORMATIVE RULES FOR DESIGN DEFECT CLAIMS

In many jurisdictions, common law rules for products liability claims have been constrained by waves of “tort reform” enactments.

47 Id. at *22.
48 It is without question that strict liability and negligence are theories of liability, not different types of evidence. Moreover, the idea that a defendant can dictate the theory of liability under which the case is to be decided is without foundation in American jurisprudence. Hopefully, this embarrassing opinion will soon be corrected.
51 Even under Restatement (Second), products liability claims were extremely difficult with favorable state court outcomes in the country’s most populous counties of just 40.5% and in federal courts of just 26.8%. Deborah Jones Merritt & Kathryn Ann Barry, Is the Tort System in Crisis? New Empirical Evidence, 60 OHIO ST. L.J. 315, 386-87 (1999).
52 While Restatement (Third) would not require production of a prototype to establish an alternative design, that provision does not ameliorate the burden of this new requirement. Nor does it lessen that burden to provide that expert testimony would not be necessary in “obvious” cases and that, in any event, a plaintiff “is not required to establish with particularity the costs and benefits associated with adoption of the suggested design,” RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. f (1998), since most cases are not “obvious” and dispensing with an economic analysis still leaves the base requirement of alternative design intact.
53 Carlin v. Superior Court, 920 P.2d 1347, 1349 (Cal. 1996); Potter, 694 A.2d at 1340; Green, 629 N.W.2d at 749, 752.
Where courts still play significant roles in the development of products liability law, normative rules for design defect claims have been elusive but that need not be the case. There are clear choices available, grounded in the different regimes of strict liability and negligence. Each choice is conceptually different and focuses on different aspects of product commerce. Strict liability addresses the product itself, how safe it is, and how it is used, while negligence concerns the marketing decisions that lead to the product being offered for sale or use. Each informs important aspects of products liability and both should be available to injured consumers who seek redress for harm from product injuries. In addition, each informs other aspects of products liability law in ways that can affect the choice between a strict liability or negligence regime.

A. Strict Liability

Strict liability should hold sellers liable for product designs that are unreasonably dangerous, regardless of whether the product seller exercised all possible care in the preparation and sale of the product. This liability standard is consistent with the rationales for modern products liability law, especially consumer expectations of product safety and fitness that exist in the absence of disclosure or warnings of danger, which often do not occur or are carefully camouflaged for marketing considerations. Indeed, as Restatement (Third) acknowledges, safety and performance expectations can be readily created by the ways in which products are portrayed in modern advertising campaigns. In much the same fashion, safety and fitness expectations can also be created by the absence of information about product dangers. Holding product sellers to such a standard is conceptually consistent with the obligation of sellers to test product designs since consumers can reasonably expect that product testing will be done, and its results will be accounted for in the product that is offered for sale and use. Indeed, it is a basic tenet of products liability law that consumers have the right to assume that products are safe and do not have to guard against product defects or the possibility of their existence.

Strict products liability is also consistent with parallel, implied warranty liability for harm to the product itself. There is no principled reason why the results should be different simply because the harm was

54 Under 402A, injured consumers had the option of bringing either a strict liability or negligence claim, or both claims in a single action. RESTATEMENT (SECOND) OF TORTS § 402A cmt. a (1963) ("The rule stated here is not exclusive, and does not preclude liability based upon the alternative ground of negligence of the seller, where such negligence can be proved."); see, e.g., Ford Motor Co. v. Hill, 404 So. 2d 1049, 1052 (Fla. 1981) ("If so choosing . . . a plaintiff may also proceed in negligence."). While in most cases strict liability will be the theory of choice, in some instances as with, for example, products with sordid safety histories, cases with clear, compelling evidence, and products with publicly known risk histories, negligent marketing may be the best choice for an injured user.

to a person rather than the product. In either case, because the manufacturer stands to economically benefit from the distribution and sale of the product, it should be obligated to produce a reasonably safe product, and, in the case of malfunction, should provide redress for all harm, whether to the product or to a user.56

Restatement (Third), however, decrees that product design (when it causes personal injury) can only be approached through the lens of a cost-benefit analysis.57 But that denigrates product safety to a subsidiary role in which product sellers could escape liability for unsafe products if consumers were unable to marshal proof of alternative designs or prove sufficiently overweighing risks. Such a rule puts consumers at risk of becoming guinea pigs for field-testing new products with no effective remedy when the tests go array.

The Restatement (Third)’s “alternative design test” is not the only way that designs can be evaluated. As 402A recognized, the foundation of liability rules can be found in foreseeable product uses, including foreseeable misuses. For those uses, consumers should have a right to expect there will be a zone of safety within which users and bystanders will be reasonably free from product harm. Thus, the proper degree of safety for a product should be set by its foreseeable use, and sellers, who produce products that cause injury when being used in a foreseeable way, should be liable for the resulting harm.

In section 3, Restatement (Third) comes close to this standard for design defects. Nominally based on res ipsa loquitur, that section recognizes an inference of product defect when the “product fails to perform its manifestly intended function . . . .” a proposition that is, according to Restatement (Third), as “well-formed” as the consumer expectations that apply in food and used products.58 Although not specifically mentioned, section 3 is necessarily based on consumer expectations since manifestly intended product functions are grounded in what consumers expect about the features, functions, and safety of the product. However, in its single-minded but confusing effort to abolish consumer expectations for design defect claims, Restatement (Third) glosses over that fact.59 Ultimately, section 3 falls short because, as noted, the res ipsa inference is normally used only when the product is lost or destroyed, and the plaintiff is required to prove that the harm was not caused by other factors, including the conduct of others, proof that

56 As noted in Restatement Third, implied warranty and strict liability are substantively identical. Id. § 2 cmts. n, r.
57 Id. § 2 cmt. d.
58 Id. § 3 cmt. b. By its terms, section 3 is applicable to both manufacturing and design defects. As noted in Restatement Third, both res ipsa loquitur and strict liability perform similar functions by “allowing deserving plaintiffs to succeed notwithstanding what would otherwise be difficult or insuperable problems of proof.” Id. § 2 cmt. a.
59 As noted herein, while claiming that consumer expectations cannot be the “test” for product design, Restatement Third recognizes that consumer safety expectations can be the determinative factor in design evaluation. See supra note 32 and accompanying text.
would not be necessary under 402A. Nevertheless, section 3 signals the way in which design defect liability should be described.

Foreseeable uses need to be distinguished from foreseeable risks. Negligence liability is contained by foreseeable risks so that actors are only required to take precautions against risks that are foreseeable. Product strict liability, which holds sellers liable even though exercising all possible care, is not limited to foreseeable risks and encompasses all risks arising from unreasonably dangerous products.60 Restatement (Third), however, rejects holding manufacturers liable for unforeseen risks because, it argues, any increased investment in safety that would be fostered is a matter of “guesswork.”61 But if it is “guesswork,” than it equally cannot be said that an increased scope of liability would not produce a higher level of safety vigilance. In any event, this argument ignores the historical record of the ameliorative impact of strict liability litigation on product safety. Using foreseeable risks to limit defect design liability will necessarily undermine that effect. The ultimate result would be defendant protectionism at the expense of product safety.

As a basis for design evaluation, or for any other purpose, foreseeable product uses may be established in many ways. Some will be obvious from the nature of the product, others may be created by the way a seller portrays the product, still others may be discerned from industry experience, and others may be informed by the testing process. But regardless of the source, if a product design permits injury when the product is being used in a foreseeable way, liability for the resulting harm should follow. Thus, it does not necessarily follow that the only way a product design can be evaluated is by comparison with an alternative design or under a risk/benefit test. Consumer expectations about safety for foreseeable uses, as informed by product portrayal, can form a rational, reasonable basis for liability determinations.

Adopting this test for design defects would eliminate any need to specify whether a claim was based on a manufacturing or design defect since in either case the test would be the same.62 As noted in Restatement (Third), at times the cause of a defect is not clear63 and, in those instances, a plaintiff is at risk of making the wrong choice or of having to make alternative claims, which might appear to a jury as implausible or indecisive. That is the very type of result that Restatement (Second) sought to eliminate by the adoption of 402A liability.

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60 Green v. Smith & Nephew AHP, Inc., 629 N.W.2d 727, 745-46 (Wis. 2001). The obligation of product sellers is to discover and design risks out of their products or, if unable to do so, provide appropriate warning of them.
B. Negligence

Negligence, on the other hand, should hold sellers liable for marketing a product when a reasonably prudent seller would decline to do so. Unlike strict liability, negligence does not depend on a finding of product defectiveness or inherent danger. It is sufficient that negligent conduct creates an unreasonable risk of harm to users of the product and foreseeable bystanders. From a conceptual standpoint, the analysis is one of reasonableness based on the risks of injury from the product versus the benefits afforded by the product, but the ultimate liability issue is one of prudent conduct. The inquiry is whether in marketing the product the seller created an unreasonable risk of injury due to the condition of the product.

C. Related Issues in Alternate Liability Regimes

Products liability cases do not always arise in factual scenarios that neatly fit either a strict liability or negligence claim. And, because of the way these different theories impact other aspects of products liability law, it is sometimes important to be able to bring a case based on one or the other theory, or even under alternative theories. Therefore, both liability theories should be available to injured product users and foreseeable bystanders as alternate liability theories, and courts should avoid hybrid regimes that conflate strict liability and negligence. One way to do so is to be cognizant of how these theories impact related product liability issues.

1. Obligation to Test Product Designs

Product sellers cannot feign ignorance of risks. As correctly noted in Restatement (Third), manufacturers have an obligation to test product designs, are charged with the knowledge such testing would impart, and, where feasible, must adopt safer designs over warning of risk.

In properly ordered regimes, whether a product was adequately tested or the manufacturer responded in a proper manner to the testing results should not be an issue in strict liability claims since liability exists for unreasonably dangerous designs regardless of the manufacturer’s care. Even if a manufacturer appropriately tested its product, it matters not in strict liability if the product still was unreasonably dangerous for foreseeable uses. On the other hand, a manufacturer’s marketing decision

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64 Early decisions used the “inherently dangerous” nature of some products to justify liability. Under modern concepts that is no longer necessary and characterizing products as “inherently dangerous” adds nothing to the analysis. E.g., MacPherson v. Buick Motor Co., 111 N.E. 1050 (N.Y. 1916); Radiation Tech. Inc. v. Ware Const. Co., 445 So. 2d 329, 331 (Fla. 1983).

65 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmts. f, g (1998).
should be informed by the results of proper testing, whether it was done, and, what it revealed, which could be most relevant to a negligence claim. Thus, product testing issues have significantly different roles and conflating liability regimes can lead to confusion and serious conceptual problems in hybrid liability regimes.

2. Product Warnings and Disclaimers

Warnings should alert users to inherent risks or dangers of products. Disclaimers seek to avoid liability by “contractual” limitations. The latter are unavailing in modern products liability law. On the other hand, product warnings are a common feature of product marketing, reflecting the fact that in many instances it may not be commercially feasible to design a completely safe product and the common acceptance that when there is a residual risk of danger, the seller is obligated to warn of that risk. But how that obligation translates into products liability law has been a somewhat muddled picture.

*Restatement (Third)* treats failure to warn or the inadequacy of warnings as a product defect. Under that approach, plaintiffs generally must prove that a warning was required and that either the seller failed to provide one or the warning that was provided was inadequate. But, in describing the rules that should apply in design defect contexts, *Restatement (Third)* presents contradictory positions. On the one hand, it states that warnings are not a substitute for safe design and, where “a safer design can reasonably be implemented, . . . adoption of the safer design is required over a warning that [would lead to] a significant residuum of such risks.” On the other hand, it recognizes warnings as a factor that can be considered in liability determinations.

In part, *Restatement (Third)* has it correct. Products liability law’s goal of elimination of product defects would be achieved in part by limiting the role of warnings so that they cannot be used as a substitute for safe design, an all too common impulse on the part of some manufacturers. *Restatement (Third)* has it wrong, however, when it unqualifiedly allows warnings to be taken into account in evaluating design liability. Under those circumstances, warnings would become substitutes for safe design since they could offset product risks or even dictate a reasonable design finding. *Restatement (Second)* was closer to the mark when it recognized that liability should only be constrained if a product was “useful and desirable” and the seller provided “proper

66 Id. § 18.
67 Id. § 2(b) cmt. i.
68 The rules for warning claims are set forth in *Restatement (Third)* section 2(c). They are not, however, the focus of this Article and are referenced herein only insofar as they relate to design defect claims.
70 Id. § 2 cmt. f.
directions and warning.” Neither Restatement, however, goes far enough because they do not explain how warnings should work in a well-ordered design defect regime.

Since it is the obligation of manufacturers in the first instance to produce safe products, warnings should only relieve liability for product design when the manufacturer demonstrates that product dangers could not have been reasonably designed out of the product and that the product was “useful and desirable.” This two-pronged test requires examination of the rigor and validity of the design process and a demonstration that the product served a useful purpose. The burden should be on the manufacturer to justify the use of warnings by making this showing since it controls the design process, has better information than injured consumers, and presumably has better technical knowledge.

This obligation becomes more muddled when it comes to so-called open and obvious risks. Restatement (Third) accepts the traditional view that warning of obvious risks is unnecessary because the existence of such risks constitutes “notice” of their presence and a further warning would serve no useful purpose. This rule, however, has it backwards. It is focused on individual users (and when they might successfully bring a failure to warn claim), rather than when a warning must be given to fulfill the obligation that is owed to the entire user population. In terms of providing warnings, it matters not whether a particular member of the user population required a warning; the warning must be provided if any segment of the user population needs it.

The rule is also wrong to the extent that it implies that “obviousness” can be determined simply from the nature of the product. That concept is wrongheaded because “obviousness” of risk is not a static quality but one that will vary with the capabilities of the user population. What might be obvious to a narrow, experienced user population might become less obvious or unobvious when the population expands to include less capable members. Since the seller’s obligation to warn runs to all foreseeable users, the obligation to warn must be measured by the least capable in that population. In addition, some product users may not have real alternatives to using dangerous products, and in those circumstances, a warning may make the difference. It may also be foreseeable that users will ignore, be inattentive of, or be distracted from a risk, in which case warnings should be required. “Obviousness” is therefore a nuanced concept and not all cases of patent danger should automatically foreclose an obligation to warn of danger. In the final analysis, rather than a blanket rule that looks only to the nature of the defect, if after all reasonable efforts to provide a safe design a

72 See Part VI.E for discussion of the “open and obvious” defense.
73 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) cmt. j (1998).
product still contains inherent risk, the product seller should be required to warn against those risks if there is a reasonable chance that a warning can contribute to risk avoidance for any foreseeable user group, for any foreseeable use. The inquiry would then focus on the real point of strict liability—that is, whether, had a warning been given or been given in a more adequate manner, it would have contributed to avoiding or lessening the plaintiff’s injuries.

Once a defendant establishes prima facie that warnings were warranted and given, the consumer could then contest the adequacy and reasonableness of the warnings. Contesting the warnings would not, however, be appropriate if it was demonstrated that the product user would have used the product even if warned in a proper and appropriate manner.

In properly ordered regimes, warnings should thus play significantly different roles in strict liability and negligence claims. For strict liability, warnings should be an affirmative defense with the burden on the manufacturer to establish that warnings were an appropriate way to address product safety and that the warning it provided accomplished that purpose. For negligent actions, the burden would be on the plaintiff to establish that the product seller failed to provide a warning sufficient to reduce or avoid foreseeable risks of harm from the product. This is another instance of where serious conceptual problems exist about how these concepts apply in hybrid liability regimes.

3. Open and Obvious Defects

Restatement (Third) has it right on the so-called “open and obvious” defect defense. As explained, the fact that a design-related risk is open and obvious bears on the issue of defectiveness and negligence but does not necessarily preclude liability. It is, after all, product sellers who are best placed to know and understand how a product can be made safe, and no blanket rule should absolve them of that obligation. To hold otherwise could encourage marketing of products with open and obvious defects, rather than utilizing a rigorous design protocol to develop a safe product. It would therefore be counterproductive and imprudent to preclude liability merely because the risk was open and obvious. Pursuant to modern concepts of risk allocation, the obviousness of a product risk should only be a factor to be considered in assessing responsibility.

In either case, comparative negligence is also a defense to products liability claims if based on grounds other than the failure of the user to discover the defect or guard against the possibility of its existence. E.g., West v. Caterpillar Tractor Co., 336 So. 2d 80, 89-90 (Fla. 1976).

RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. g (1998).

Id. § 2 cmt. d.
4. Alternative Designs; Industry Practice; State of the Art

Evidence of alternative product designs should be relevant to both strict liability and negligence claims. For the former it can inform the issue of whether inherent risks could have been designed out of the product; for the latter it can inform the issue of whether it was prudent to market the product as designed. In neither case, however, should such evidence be required since there are many other ways to establish the unreasonable danger of a design or carelessness in marketing a product.

Alternative designs may represent industry practice, which is sometimes confused with “state of the art.” It is generally accepted that industry practice is simply the range of practices found within an industry on any given subject and may represent a measure of what a prudent seller would or would not do. As such, it has no bearing on strict liability since such liability is independent of the care exercised and allowing industry practice to denominate product design would be tantamount to allowing an industry to set its own liability parameters. On the other hand, compliance with or failure to follow industry practices can bear on the reasonableness of marketing a product under a negligence claim. This is another instance where serious questions of application can arise in a hybrid liability regime.

“State of the art” differs from industry practice (although it could be, but rarely is, coextensive with industry practice). State of the art generally is the most advanced state of technology at any given point in time. Sellers generally contend that they cannot be held to product designs that do not reflect the “state of the art” at the time the product was designed and manufactured. While it is a truism that sellers cannot be required to use technology that did not exist, the fact that a particular design had not yet been adopted by any manufacturer should be immaterial as long as it was technologically feasible at the time the product was designed and built. On the other hand, sellers should be held to the expert standard of knowledge that was available to the relevant industry at the time the product was designed and produced, and failure to apply that knowledge can be relevant in negligent design cases.

5. Inferences of Defect and Negligence

It is commonly accepted that when products fail in normal usage, an inference arises that the failure was due to product defect or seller negligence.\textsuperscript{78} The rule does not require identification of a specific defect or determination of whether it was a manufacturing or design defect.\textsuperscript{79} Often the inference arises when the product has been lost or destroyed, but the rule is not restricted to those circumstances. The rule is also often

\textsuperscript{78} \textit{Id.} § 3.
\textsuperscript{79} \textit{E.g.}, Cassisi v. Maytag Co., 396 So. 2d 1140, 1153 (Fla. Dist. Ct. App. 1981).
explained as a substitute for (missing) proof of a specific defect but, to give full effect, it should not be so limited and should apply even where there is proof of a specific defect. Otherwise, a deserving plaintiff could be prejudiced by trying to develop proof of a specific defect, which a defendant could then use to negate an inference of liability.

This rule should not, however, be a simple inference to merely establish a prima facie case. Were that its sole function, it would “disappear” once dispositive motions were denied and plaintiffs would be left with no evidence for the jury to consider. To achieve its intended purpose, this inference must remain in the case for jury consideration, a point alluded to but not specifically delineated in Restatement (Third).\(^{80}\)

VII. CONCLUSION

Restatement (Third) missed the mark for normative rules in a well-ordered design defect regime. Intended or not, it has been seen as rolling back decades of progress and returning to an era of defendant protectionism. To establish normative rules, renewed efforts that build upon the modern rationales of strict liability are necessary. When approached in this manner, it is possible to define a just set of rules that encourage the design and sale of reasonably safe products and, at the same time, properly limit liability.

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\(^{80}\) RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 3 cmt. b (1998) (“Section 3 allows the trier of fact to draw the inference . . . .”); e.g., Escola v. Coca Cola Bottling Co., 150 P.2d 436, 439-40 (Cal. 1944); see also FED. R. EVID. 301.
Manufacturers’ Liability for Defective Product Designs:
The Triumph of Risk-Utility

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I. INTRODUCTION

This Article marks a notable anniversary for its authors. Ten years ago, in 1998, we celebrated the publication of the Restatement (Third) of Torts: Products Liability, on which we served as co-Reporters,¹ and we coauthored and published an article claiming that American courts had reached a consensus regarding the standard by which to judge whether a product design is defective.² This Article reviews what has happened in the decade since then and concludes that


we got it right the first time. Beyond simply sharing our current research with the reader, we want to shed some new light on how the Restatement came to be the way it is and to explain how and why the consensus we described earlier remains rock solid. The Restatement project and the consensus article are linked because the standard that virtually all American courts use in judging product designs is the one we included in section 2(b) of the Restatement—whether the defendant manufacturer could have adopted a safer alternative design and whether failure to do so “renders the product not reasonably safe.” As this Article explains, trial courts vary somewhat (though less now than ten years ago) in what they say to juries; and appellate courts vary somewhat (less now) in the rhetoric they use to write their opinions; but in the overwhelming majority of American jurisdictions, claims of defective design reach triers of fact only when the plaintiff offers plausible proof that her injuries would have been reduced or avoided by the adoption of a reasonable alternative design.

II. THE TREATMENT OF DESIGN DEFECT IN THE RESTATEMENT (THIRD)

When we started work as co-Reporters in 1992, we understood that the products liability project would address a number of issues that would, in varying degrees, be controversial. How should component parts suppliers be treated? Commercial used-product sellers? How should crashworthiness claims be sorted out? Should a robust post-sale duty to warn be implemented? We knew that each of these issues would generate vigorous debate and controversy. But we also knew that none would surpass in intensity the controversy surrounding the proper standard for defective product design. The reason for this had more to do with rhetoric than substance. For thirty years, American courts across the country had been applying a fault-based risk-utility standard in reviewing the defectiveness of product designs. But over the same period, most of these courts had been explicitly referring to section 402A of the Restatement (Second) of Torts, which trumpeted strict liability as the

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3 See Restatement (Third) of Torts: Products Liability § 2(b) (1998).
4 See infra Part IV.
6 See id. § 8.
7 See id. § 16.
8 See id. § 10.
operative rule. So long as the inherent contradiction between applying a fault standard to determine liability and using strict liability rhetoric to explain the outcome continued unchallenged, all had gone smoothly enough. But to come along in a new Restatement and point out the obvious inconsistency would seem, to those who truly believed in the myth of strict liability, nothing short of heresy.

Another aspect of developing an acceptable standard for defective design would have to be addressed. Even if we could count on reasonable minds to see that the operative standard for defective design was rooted in risk-utility balancing, it was not so clear that reasonable minds would agree that only a marginal, rather than an aggregative, approach would be acceptable. Marginal risk-utility analysis asks whether the manufacturer could have adopted a safer, cost-effective version within the broader category of design into which the defendant’s product falls; aggregative risk-utility asks whether the risks of the broader category outweigh, in the aggregate, the category’s social utility. Under category liability, even inherently, unavoidably unsafe product designs that cannot be redesigned to be significantly safer may be deemed defective if their aggregate risks are found to outweigh their aggregate utilities. We knew that American courts have never imposed category liability for very good reasons, but we were concerned that an unintended consequence of convincing ALI members that risk-utility, not strict liability, not strict liability, was the operative standard for defective design would be to give category liability new-found (and undeserved) respectability.

A. Recognizing a Fault-Based Standard for Defective Design

The first task we undertook as Reporters was to divide the concept of product defect into three subcategories that American courts had come to recognize: (1) manufacturing defects, (2) design defects, and (3) failures to warn (marketing defects). The drafters and promoters of section 402A in the early 1960s had relied almost entirely on manufacturing defects which, because they could be defined mechanically without reference to notions of unreasonable risk, could serve as the basis for strict liability. Because the drafters of section 402A had in mind only manufacturing defects, they saw no reason to distinguish among the other types of defects to which their strict liability

10 See, e.g., Thibault v. Sears, Roebuck & Co., 395 A.2d 843, 846 (N.H. 1978) (applying an “unreasonably dangerous” risk-utility test for defective design, the court insists it is imposing “strict liability” under section 402A).


13 See OWEN, PRODUCTS LIABILITY LAW, supra note 9, § 7.2.
rule might apply.\textsuperscript{14} To be sure, the drafters of section 402A appear also to have relied on a special subset of design defects involving products that malfunction, thereby failing to perform their manifestly intended function in a self-defeating manner.\textsuperscript{15} In those special design cases the defects are functionally equivalent to manufacturing defects, so strict liability works as well for them. Indeed, manufacturing and design malfunction defects may be said to disappoint consumer expectations and thus may be deemed defective on that basis. By contrast, courts generally dealt with failures to warn under the negligence rubric, often outside the bounds of section 402A.\textsuperscript{16} After all, the defendant’s “failure” to provide adequate warnings carried with it a built-in negligent quality not involving any shortcoming inherent in the product itself. So far, so good. The critical analytical error that many courts and commentators made in the post-section 402A developmental period was to assume that product designs that were unreasonably dangerous, but neither self-defeating nor prone to malfunction, could be dealt with under the same section 402A strict liability rubric as could manufacturing defects and malfunctioning, self-defeating designs. Because virtually no such mainstream design cases reached juries in the 1960s and early 1970s,\textsuperscript{17} the incoherence of purporting to hold manufacturers strictly liable for their negligent design choices did not surface.\textsuperscript{18} Observers of the developing American products liability system simply assumed that the strict liability rule in section 402A applied not only to manufacturing defects but to all manners of design defects, as well.

As mainstream design cases\textsuperscript{19} began to reach juries in greater numbers in the 1970s and 1980s, many courts came to understand that a fault-based, reasonableness standard was necessary with which to determine design defects. But the “strict liability under section 402A” rhetoric persisted, notwithstanding the underlying reality that fault of the manufacturer was the determinative consideration. Thus, the two significant implications of dividing the defect concept into its three separate constituents were (1) the requirement that we squarely face the question of what the basis of liability should be for mainstream, “classic”


\textsuperscript{15} See Michael D. Green, \textit{The Unappreciated Congruity of the Second and Third Torts Restatements on Design Defects}, 74 \textit{Brook. L. Rev.} 807 (2009).


\textsuperscript{18} See Prentis v. Yale Mfg. Co., 365 N.W.2d 176, 184 (Mich. 1984); Birnbaum, supra note 9, at 600-01.

\textsuperscript{19} We have referred to design cases not involving product malfunction as “classic” design cases. See Henderson & Twerski, \textit{Achieving Consensus}, supra note 2, at 876-77.
design defects; and (2) the necessity that we bring failure to warn cases, clearly resting on risk-utility balancing, within the umbrella concept of product defect. The first of these implications is of primary interest here. We have dealt with the second elsewhere.20 At the outset, we were tempted to recognize that classic design defects reflected negligence on the part of the manufacturer in parallel fashion to failure to warn. But we knew that many courts were deeply committed to section 402A’s “strict liability” rhetoric, and might reject the new Restatement out-of-hand for that reason, without giving it a fair hearing.21 So we decided to capture in plain words the essence of Learned Hand’s classic formulation for negligence,22 in which the plaintiff must show that a precaution (an alternative design) could have been adopted at acceptable costs (failure to adopt renders the defendant’s product not reasonably safe), and that failure to adopt the precaution caused the plaintiff’s injuries. The black letter of the new Restatement makes no mention of “negligence” or “fault;” it leaves such language to the comments.23 Thus, under the new Restatement, a court is free to adopt or reaffirm the substantive, risk-utility standard that American courts had been applying for decades prior to our work and at the same time continue to insist that manufacturers are strictly liable for harm caused by design defects.24 Of course, nothing prevents courts from embracing the risk-utility standard openly; by now, a majority of courts have done exactly that. But nothing in the Restatement forces courts to do so.

Observe that the distinction here drawn between risk-utility balancing and strict liability is not bridged merely by holding the manufacturer responsible for time-of-trial knowledge of risk and risk-avoidance technology that may not have been available at the time of original sale. Although doing so could be characterized as imposing “strict liability” in the sense that the manufacturer might not have been negligent in failing to discover risk and risk-avoidance information that was unknowable at time of sale, the standard for judging the design nevertheless involves risk-utility balancing at time of trial. Although most American courts do not hold product sellers responsible for information not available at time of sale,25 even the small minority that do are committed to judging product designs based on risk-utility balancing.

A true non-risk-utility approach to holding manufacturers liable for the generic risks presented by their products would be to hold them liable for all the harm their products cause—to let actual causation

20 See Henderson & Twerski, Doctrinal Collapse, supra note 16.
21 We did not want to be remembered, fairly or not, as “the guys who tried to kill strict products liability.”
22 See United States v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947).
24 See id. § 2 cmt. n.
25 See HENDERSON & TWERSKI, supra note 9, at 197-99, 341-52.
determine liability. Elsewhere we have referred to such an approach as “enterprise liability” and have argued that it would be unworkable. Not only is actual causation an inadequate basis for sorting out claims in court—without a requirement of defect, everything ends up being a cause in fact of everything else—but also no one could insure against the relevant losses because of high levels of moral hazard—product users would have inadequate incentives to use products carefully. Not surprisingly, our courts have never adopted such an approach, or even considered it seriously. But what a number of courts have considered is basing design-based liability on the disappointment of consumer expectations. Historically, such an approach traces its pedigree to comment i to section 402A, in which the drafters justified their new rule of strict liability by pointing to the disappointment of consumer expectations that defect-caused product failures cause. Earlier in this analysis we explained how manufacturing defects and self-defeating designs trigger product malfunctions that disappoint expectations of safe product performance. That is clearly what the drafters had in mind when they authored comment i. But if the courts were to extend the consumer expectations concept to include situations in which products perform exactly as intended but nonetheless cause injury, a form of strict, enterprise liability would be achieved. Even if the accident could not have been avoided cost-effectively by redesigning the product, liability could be imposed because the mere fact that the product caused injury could be found to have disappointed consumer expectations of safe product usage.

Of course, this new expectations-based rule of quasi-enterprise liability would not require the imposition of liability upon a showing that the defendant’s product caused harm. Under a true enterprise liability approach, causation, alone, would require the imposition of liability, but not here. To impose liability under the approach being considered here, in addition to a finding of causation, the trier of fact would also be required to find that the happening of the accident disappointed consumer expectations. Presumably, if the product-related risks were fairly obvious, a jury could conclude that a product did not disappoint expectations even if it helped to cause a terrible accident. Bearing in mind that jurors, in determining whether expectations were disappointed, draw on their own life experiences rather than rely on proof adduced by

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26 See James A. Henderson, Jr., Why Negligence Dominates Tort, 50 UCLA L. REV. 377 passim (2002); see also Henderson & Twerski, Closing the Frontier, supra note 11, at 1276-97.
27 See Henderson, supra note 26, at 390-400.
28 Henderson, Judicial Review of Manufacturers’ Conscious Design Choices, supra note 17, at 1554; see also Henderson & Twerski, Closing the Frontier, supra note 11, at 1292, 1296-97.
29 See HENDERSON & TWERSKI, supra note 9, at 254-69.
30 See id. at 269-78.
the parties,\textsuperscript{31} it would not be unfair to characterize such a quasi-enterprise liability approach as one based on the jury’s whim.\textsuperscript{32}

This foray into the possibility that courts might pursue a quasi-enterprise-liability, “jury’s whim” approach to design defects based on the disappointment of consumer expectations would seem puzzlingly unnecessary save for one critical fact—that is exactly the path that critics of the Restatement project have pursued in opposing the adoption of a risk-utility, reasonable-alternative-design approach to defective design. Besides knowing full well when we began work as Reporters that the operative design defect standard in most states was fault-based risk-utility balancing, we were also aware that a minority of states insisted that the operative standard was the disappointment of consumer expectations.\textsuperscript{33} Without having yet undertaken a thorough canvassing of all states, we had assumed that no jurisdiction would knowingly embrace an amorphous, jury-whim approach and that one or more of the following explanations accounted for all such judicial references to consumer expectations: (1) references to “reasonable expectations” incorporated risk-utility balancing, and thus the standard to which courts referred was, in actuality, a fault-based standard; (2) the courts that referred to consumer expectations did so only in the context of self-defeating designs that caused products to malfunction; or (3) even if the references to expectations were not limited to reasonable expectations, and even if the references were made in the context of classic design litigation not involving product malfunctions, trial courts sent design claims to juries only when plaintiffs produced credible proof of reasonable alternative designs that would have avoided the plaintiffs’ harm.

In addition to these common-sense assumptions regarding the prevailing case law, we also knew that virtually every major torts scholar who had looked carefully at the issue of design defect over the past several decades had embraced risk-utility balancing and had rejected the consumer expectations test as unworkable and unwise.\textsuperscript{34} A small handful of writers, including two who wrote advocacy pieces only after the

\begin{thebibliography}{99}
\bibitem{33} See infra notes 188-200 and accompanying text.
\end{thebibliography}
Restatement revision project was well under way, urged adoption of the consumer expectations test. These authors insisted that the risk-utility standard lacked support in the case law and placed an unfair burden on plaintiffs by requiring them to provide technical proof that a safer, harm-preventing alternative design would have been feasible. 35 The consumer expectations test was fair, they argued, because all that it required plaintiffs to prove was that the product, even if reasonably safe, had been instrumental in causing them to suffer harm.

Lending an aura of plausibility to these otherwise implausible anti-risk-utility arguments was the fact that the Supreme Court of Connecticut purported to reject the Restatement’s reasonable-alternative-design standard in 1997, while we were still working with a tentative draft of the relevant section. The plaintiff in Potter v. Chicago Pneumatic Tool Co., 36 an industrial injury case, had proven several alternative designs and clearly would have reached the jury under the Restatement rule; the issue on appeal was how to instruct the jury after a trial almost entirely devoted to how the defendant could have designed the product more safely so as to avoid causing the plaintiff injury. 37 Although a majority approved an opinion that explicitly rejected the new Restatement’s approach in the abstract, it recognized an exception for complex cases that came so close to actually embracing the Restatement’s approach that a concurring justice chastised the majority for seemingly contradicting itself. 38 At the time, the Connecticut decision seemed so out of place in the factual context of the actual case as to appear artificially contrived in an effort to embarrass the Restatement project. Interestingly, our recent research for this Article reveals that no plaintiff in a reported case in Connecticut has ever reached the jury in a classic design case without proving that a safer, reasonable alternative design was available at time of sale. 39 It thus appears that the Connecticut high court could not have meant what it said in 1997 about there being no requirement that the availability of an alternative design be proven. But there it was—the Connecticut Supreme Court had gone out of its way to reject the tentative draft of our section on design defect. We could

36 694 A.2d 1319 (Conn. 1997).
37 See id. at 1324-25.
38 See id. at 1356 (Berdon, J., concurring) (“[A]dopting such a risk-utility test for ‘complex product designs’ sounds dangerously close to requiring proof of the existence of ‘a reasonable alternative design,’ a standard of proof that the court properly rejects today.”).
39 See infra notes 179-181 and accompanying text.
only hope that our reasoning and our research would persuade the American Law Institute membership that Connecticut’s contrived, abstract essay in support of a consumer expectations test had gotten it dead wrong.

The end-result of all these deliberations was section 2(b), which requires the plaintiff to prove that the manufacturer could have adopted a reasonable alternative design and that failure to do so renders the product not reasonably safe. Comment g to section 2 states explicitly that disappointment of consumer expectations, while relevant, does not provide an independent basis on which to find that a product design is defective.40 A Reporter’s Note explains that, while a small minority of states purport to adopt the consumer expectations test, a clear majority rely on a risk-utility/reasonable-alternative-design standard to determine whether a design is defective.41

B. Protecting Against Category Liability

The second major aspect of the Restatement’s treatment of liability for defective design concerned the need to protect against the possibility that the risk-utility approach would invite courts to condemn as defective entire categories of inherently dangerous products, even if those products could not be redesigned to be made safer.42 The idea behind category liability was that, under a negligence regime, a manufacturer could be found at fault for distributing certain inherently risky products in the first instance, even if those products could not be designed differently so as to make them safer.43 For example, alcoholic beverages must, almost by definition, contain alcohol to be attractive to those who desire to consume such products. Removing the alcohol does not merely make such beverages safer for those who consume them abusively, it also destroys their utility for everyone, including the significant majority who do not abuse them. American courts have never imposed category liability, mainly because they intuitively (and correctly) understand that it would constitute an abuse of judicial power to decide which broad categories of products should not be distributed at all. Such sweeping regulation, courts have concluded, should be left to legislatures to undertake.44 But if the new Restatement were overtly to

40 See Restatement (Third) of Torts: Prods. Liab. § 2 cmt. g (1998).
42 See supra note 11 and accompanying text.
43 Some advisers likened this form of distributor’s negligence to negligent entrustment. See Restatement (Second) of Torts § 390 (1965); Restatement (Third) of Torts: Prods. Liab. § 2 cmt. n (1998).
44 See, e.g., Rose v. Brown & Williamson Tobacco Corp., 855 N.Y.S.2d 119, 124-26 (N.Y. App. Div. 2008) (claim that negligent product design of regular cigarettes based on availability of “light” cigarettes with lower tar and nicotine was dismissed because “light” cigarettes are not a substitute for regular cigarettes and to impose liability would declare a whole category of
embrace a risk-utility standard in broad terms, we feared that our formulation might invite courts to look more kindly on the proposition that certain categories of products are sufficiently dangerous that it would be negligent to distribute them in the first instance.

Besides lawyers who represent plaintiffs in products liability litigation, who would have been delighted to see our Restatement project endorse the idea that broad categories of inherently risky products might be deemed defective even if no alternative designs could have reduced the risks, two groups of American Law Institute constituents with seemingly more objective, disinterested viewpoints supported formulations that we believed might encourage courts to embrace category liability. The first group urged us to replace the more specific, reasonable alternative design standard for defect with the broader principle of designs that presented unreasonable risks, and then explained in a comment that the best way to prove that a product design’s risks were unreasonable would be to prove that a reasonable, safer alternative design could have been adopted.\(^{45}\) The other group of seemingly disinterested critics urged that we include in the black letter explicit language making clear that a manufacturer could be found to be at fault for distributing certain highly-though-unavoidably-risky product designs in the first instance.\(^ {46}\) We resisted these suggestions on the ground that the clear implication would have been that a category of products might be found to present unreasonable risks even if those risks were not avoidable by the adoption of a safer alternative.

In the end, we responded to the entreaties from both of these camps of disinterested, otherwise supportive critics by retaining the “proof of a reasonable alternative design” formulation and addressing the substance of their concerns in comments. Comments a and d to section 2 make clear that the foundational principle for design and marketing liability is the unreasonable risk concept that underlies negligence,\(^ {47}\) and the last paragraph of comment n to section 2 explains that some negligent marketing doctrines, such as negligent entrustment, fall outside the reach of the \emph{Products Liability Restatement}.\(^ {48}\) Comment d to section 2 explicitly asserts that American courts have traditionally refused to impose category liability on “products that are generally available and widely . . . consumed, even if they pose substantial risks of harm.”\(^ {49}\)

\(^{45}\) Professor Harvey S. Perlman, a member of the A.L.I. Council and an advisor to our project, was most vocal in urging that we adopt as the design standard the basic normative principle underlying the concept of a reasonable alternative design.

\(^{46}\) Judge Robert E. Keeton (Advisor) and John P. Frank (Council Member) were the most vocal proponents of this position.

\(^{47}\) See \textit{Restatement (Third) of Torts: Products Liability} § 2 cmts. a, d (1998) (both refer explicitly to the negligence principle).

\(^{48}\) \textit{Cf. id.} § 2 cmt. n (1998); \textit{Restatement (Second) of Torts} § 390 (1965).

To the consternation of many American Law Institute members who supported our reasonable alternative design approach, we added comment e to section 2, recognizing the possibility that courts in the future might determine that certain categories of products, other than those “generally available and widely . . . consumed” alluded to in comment d, might be sufficiently dangerous and of such minimal social utility that they would be deemed defective even if no safer alternative design was available. Why did we include this comment that arguably contradicts comment d’s pronouncement against category liability? It will be observed that comment d makes clear that section 2(b) of the Restatement does not support category liability because American courts have never embraced it; and comment e speaks merely of the possibility that courts might encounter an unusual case in the future—it does not endorse or recommend the imposition of category liability. But if we were genuinely concerned with the possibility that the Restatement’s reliance on a risk-utility design standard might invite a movement toward category liability, why did we endorse the inclusion of comment e? Quite frankly, we were under significant pressure from critics, both interested and disinterested, to recognize that limited category liability was at least a logical implication of adopting a risk-utility approach to defective design. Thus, we decided to “bear hug” that possibility and hopefully disarm it by dealing with it forthrightly (and narrowly) in comment e. Whether or not it was an error in judgment at the time, we simply observe that our fears were unfounded—no court over the past ten years has relied on comment e to adopt category liability.

III. THE TREATMENT OF DESIGN DEFECT IN THE “REACHING CONSENSUS” ARTICLE

Having just published the Restatement with its “reasonable alternative design” requirement for design defects and its rejection of consumer expectations as a stand-alone test, why did we feel it was necessary in 1998 to publish an article claiming that consensus had been achieved? For one thing, it provided the opportunity to update the research reflected in the Reporters’ Note to section 2(b). We had finished the Note at least two years prior to publication. Perhaps more importantly, a law review article provided us the opportunity to explain

50 See id. § 2 cmt. c.
51 See supra note 44 and accompanying text.
52 The Reporters’ Note to comment e makes this clear. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 Reporters’ Note, cmt. e (1998).
53 McCarthy v. Olin Corp., 119 F.3d 148, 162, 173 (2d Cir. 1997) (Calabresi, J., dissenting) (citing comment e and arguing that category liability might apply to “Black Talon” bullets, which were designed to expose razor sharp claws upon impact to create “hideous, gaping wounds”); Parish v. Jumpking, Inc., 719 N.W.2d 540, 545 (Iowa 2006) (court rejected the application of comment e to declare a trampoline to be a manifestly unreasonable product).
ourselves more openly, free from the understandable constraints we had worked under as ALI Reporters. Moreover, an article in a law review with good circulation would help spread the word more quickly and widely than would the publication of the new Restatement by itself, however auspicious an event that may have been.

Because the instant Article undertakes a thorough, state-by-state review of American law governing product design liability through early 2009, we would like briefly to critique the 1998 article. (Thus, even if we identify shortcomings in the earlier effort, our research for this Article will leave no doubt whatever as to where our courts stand on the relevant issues.) In writing the instant Article, we have debated between us whether “consensus” was the right word choice for the earlier piece. Certainly we intended then (and intend now) to convey the message that our courts overwhelmingly embrace a risk-utility/reasonable-alternative-design approach to determining whether the plaintiff should reach the jury with a claim of defective design. However, to the extent that our use of the word “consensus” implied that the courts recognize this reality self-consciously and rhetorically, we may have overstated our position. Then and now, some of the courts that regularly and routinely require plaintiffs to adduce plausible proof of a feasible alternative design insist that such proof is not always necessary and explain what they are doing in terms of vindicating consumer expectations. Based on reported decisions, plaintiffs rarely, if ever, reach the jury in a classic design case without proof of a feasible alternative design; 55 but a minority of courts cling to the myth of strict design liability by clinging rhetorically to the consumer expectations rubric.

The thoroughness of our research for the instant Article suggests the other basis on which the 1998 article may have fallen a bit short. Rather than undertake a state-by-state review of the relevant law, as we do here, in our earlier article we chose representative examples with which to reveal the then-current patterns of judicial and legislative decisions. Our current research confirms that our previous assessments were accurate. But in addition to being current, the research supporting this Article is much broader and deeper. We turn now to examine the case law that has developed since the publication of the Products Liability Restatement in 1998.

54 Although Restatement reporters speak for themselves in their Notes—the comments are official and speak for the Institute—we felt constrained to avoid the kind of argumentation that the law review format allowed.
55 See infra notes 57-189 and accompanying text.
56 See infra notes 152-202 and accompanying text.
IV. DESIGN DEFECTS IN THE COURTS: A LOOK AT THE LAST DECADE

In the ensuing sections we shall demonstrate the overwhelming judicial support for the risk-utility/alternative design standard for classic design defect cases. We shall begin by showcasing two states (Illinois and Missouri) that say that they do not adopt the reasonable alternative design standard and show that the rhetoric of these opinions belies the reality that a reasonable alternative design is necessary to make out a case in those jurisdictions. We shall then turn to the twenty-five states whose opinions rather clearly indicate support for section 2(b) of the Restatement. Finally, we shall examine the jurisprudence of other states whose law on the standard for design defect is somewhat varied, but at bottom requires proof of a reasonable alternative design in cases other than those where an inference of defect can be made because the product caused injury when put to its manifestly intended function.

A. Consumer Expectations Rhetoric and Reality: The Illinois Experience

If one were to choose a poster child for the proposition that empty rhetoric continues to influence how courts articulate the standard for design defect, the recent decision of the Supreme Court of Illinois in Mikolajczyk v. Ford Motor Co. would be it. Some brief history is in order. In Lamkin v. Towner, decided in 1990, the Supreme Court of Illinois adopted a two-pronged test for design defect. A plaintiff can make out a case for defective design if the product either fails to meet consumer expectations or does not meet risk-utility standards. Since Lamkin, in a series of decisions, the Illinois court has wavered back and forth regarding the appropriate role of each test. Finally, in Mikolajczyk the court sought to set the record straight. James Mikolajczyk, the driver of a 1996 Ford Escort, suffered severe, irreversible brain trauma when the defendant, a drunk driver, rear-ended his car at high speed.

59 Id. at 457.
60 See, e.g., Calles v. Scripto-Tokai Corp., 864 N.E.2d 249, 258-59 (Ill. 2007) (court concluded that utility lighter was not categorically exempt from risk-utility test merely because product posed an obvious danger to children under a consumer expectations test; plaintiff therefore had opportunity to prevail under the risk-utility test even if she failed the consumer expectations test); Blue v. Envtl. Eng’g, Inc., 828 N.E.2d 1128, 1143-47 (Ill. 2005) (court discussed applicability of section 2(b) to design defect claims based on negligence and strict liability); Hansen v. Baxter Healthcare Corp., 764 N.E.2d 35, 46 (Ill. 2002) (court affirmed judgment for plaintiff based on both risk-utility test and consumer expectation test when an intravenous catheter that caused fatal air embolism could have been designed more safely at low cost and had been marketed as safety device and did not present obvious danger). For discussion of the pre-Mikolajczyk debate over design defect tests in Illinois, see Aaron D. Twerski, Chasing the Illusory Pot of Gold at the End of the Rainbow: Negligence and Strict Liability in Design Defect Litigation, 90 MARQ. L. REV. 7 (2006).
Mikolajczyk’s widow brought an action in strict liability against Ford Motor Co. and Mazda Motor Corp., claiming that the driver’s seat was defectively designed in that it propelled her husband rearward, causing him to hit his head on the backseat.61

Defendants introduced evidence that the seat in the Ford Escort met risk-utility standards and provided greater overall safety than an alternative design.62 Plaintiff insisted that the jury be allowed to conclude that the seat design was defective if it failed to meet consumer expectations.63 Defendants urged the court to adopt section 2(b) of the Products Liability Restatement.64 The court denied defendants’ request on the ground that doing so would require a plaintiff “to plead and prove the existence of a feasible alternative design in every case.”65 Then, in an interesting turnaround, the court said:

Although we have declined to adopt section 2 of the Products Liability Restatement as a statement of substantive law, we do find its formulation of the risk-utility test to be instructive. Under section 2(b) the risk-utility balance is to be determined based on consideration of a “broad range of factors,” including . . . the nature and strength of consumer expectations regarding the product, including expectations arising from product portrayal and marketing . . . .

We adopt this formulation of the risk-utility test and hold that when the evidence presented by either or both parties supports the application of this integrated test, an appropriate instruction is to be given at the request of either party. If, however, both parties’ theories of the case are framed entirely in terms of consumer expectations, including those based on advertising and marketing messages, and/or whether the product was being put to a reasonably foreseeable use at the time of the injury, the jury should be instructed only on the consumer-expectation test.

Adoption of this integrated test resolves the question of whether the answer to the risk-utility test “trumps” the answer to the consumer-expectation test.

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62 Id. at *26. The court offered the following summary of defendants’ argument that the seat was safe:

[D]efendants claim the evidence showed that the designers of the CT20 seat had to take into account all of the various types of possible collisions (front-end, rear-end, side, rollover) that could occur at a wide range of speeds, and with occupants of different sizes, who may or may not be properly using their seatbelts, positioned at various seats in the vehicle . . . . If the court had given the tendered nonpattern risk-utility instruction instead of the pattern instruction, defendants posit, the jury would have been directed to weigh this evidence, including expert testimony that the yielding seat that caused James’s death might nevertheless have been a safer alternative for other drivers in other types of collisions. Defendants also point to testimony by one of their own experts that the yielding driver’s seat may have prevented fatal or more serious injury to the backseat passenger even while causing more serious injury to James.

Id.
63 Id.
64 Id. at *14 (“The rule advocated by defendants is contained in section 2(b) of the Products Liability Restatement . . . .”).
65 Id. at *15.
because the latter is incorporated into the former and is but one factor among many for the jury to consider.66

Rhetoric aside, what is the bottom line of Mikolajczyk? From a functional standpoint, it would appear that the consumer expectations test is a dead letter in Illinois. In any case in which a plaintiff seeks to proceed solely under the consumer expectations test, a defendant need only counter with risk-utility evidence to cause the court to apply the factors set forth in section 2, comment f. Under that test, consumer expectations are but one factor among other risk-utility factors to be considered in deciding whether a product is unreasonably dangerous. Conversely, when a defendant defends on the ground that a product meets consumer expectations, perhaps because the risks are obvious, a plaintiff need only introduce risk-utility evidence for the court to apply risk-utility balancing. The only cases in which risk-utility balancing will not come into play are those in which a product fails to perform its manifestly intended function and in which defective design can be inferred from the fact of injury. There can be no rational risk-utility defense to a product that simply cannot do what it was designed to do. If the steering mechanism of a car fails when it is driven out of the dealership, one cannot say it was reasonably designed to fail in this manner. That contingency is, however, covered by section 3 of the Restatement, which allows a court to apply a res ipsa-like inference of defect when defect can easily be inferred from the mere occurrence of the accident.67

Two matters deserve comment. First, even if consumer expectations cannot serve as the sole test for defect, they are certainly relevant to risk-utility balancing. Thus, how a product is perceived by consumers implicates how the product will be used and ultimately affects the probability that the product may cause harm. The Learned Hand risk-utility formula takes into account both the probability and gravity of the harm and weighs both of these factors against the burden of taking precaution against the harm. As the Illinois court correctly observes, reasonable consumer expectations are one factor among many in deciding whether a product is unreasonably dangerous.68 Second, a product that fails reasonable consumer expectations may still meet risk-utility norms. Indeed, with regard to the Ford Escort, the court noted that a consumer might reasonably expect that the driver’s seat would not collapse upon impact and cause serious injury.69 Nonetheless, it may be that the seat utilized by Ford is the one that provides the greatest overall

66 Id. at *22 (internal citations omitted and second emphasis added).
68 Mikolajczyk, 2008 WL 4603565, at *22.
69 Id. at *23 (“Rear-end collisions are reasonably foreseeable and the ordinary consumer would likely expect that a seat would not collapse rearward in such an accident, allowing the occupant to sustain massive head injury.”).
safety and that an alternative design that would have saved the plaintiff from injury in the rare case of a high-speed, rear-end collision would present greater dangers to occupants of the Ford Escort in collisions of lesser intensity that occur with much greater frequency. It was for that reason that the court insisted that the Mikolajczyk case be retried and that the jury be given a risk-utility instruction in which consumer expectations are taken into consideration as a relevant, but not a controlling, factor.

Now to the big question. Why did the Illinois court not adopt section 2(b) as the standard for design defect, utilizing the factors set forth in comment f in deciding whether the manufacturer should have adopted a reasonable alternative design? One answer might be that, desiring to retain the consumer expectations test in cases where risk-utility evidence is not forthcoming from either side, the court felt constrained to reject section 2(b), which it said insists that a plaintiff present evidence of a reasonable alternative design as a *sina qua non* in every design defect case. As a practical matter in cases where risk-utility evidence is presented by either party, the factors set forth in comment f are all relevant to whether an alternative design is reasonable and should have been adopted. Thus, the court’s rejection of section 2(b) has little meaning.

A second answer might be that the court was scared off by plaintiff’s argument that requiring a reasonable alternative design was a new invention foisted onto plaintiffs by the Reporters of the *Products Liability Restatement* and was somehow harsher than risk-utility balancing. This view has been voiced by other courts. It is dead wrong. In any risk-utility balancing the answer depends on whether there was a safer alternative available that would have been preferable. Those courts that profess to do risk-utility balancing and yet take the position that the availability of a reasonable alternative design is only one relevant factor in risk-utility balancing fail to understand the basics of risk-utility analysis. Under risk-utility balancing in products litigation, a product may be found to be unreasonably dangerous in only two ways: (1) the product should have been more safely designed; or (2) the product

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70 See supra note 62.

71 *Mikolajczyk*, 2008 WL 4603565, at *29 (“Although defendants were not prevented from introducing evidence regarding the risks and benefits of the alternative designs that were feasible at the time, and were not prevented from arguing to the jury that, on balance, the CT20 seat was not ‘unreasonably dangerous’ because it prevented more injuries than it caused, the jury was specifically instructed to focus its deliberations solely on whether the seat was unsafe when put to a reasonably foreseeable use. The lack of a risk-utility instruction . . . prejudiced defendants’ ability to obtain a full, fair, and comprehensive review of the issues by the jury.”).

72 Id. at *14-15.

73 See, e.g., Green v. Smith & Nephew AHP, Inc., 629 N.W.2d 727, 751 (Wis. 2001) (“[W]e are . . . troubled by the fact that 2(b) sets the bar higher for recovery in strict products liability design defect cases than in comparable negligence cases.”).
category should not have been marketed at all. The first conclusion depends on whether a reasonable alternative design was available. The second conclusion clearly implicates product category liability. Earlier we established that American courts have almost universally rejected category liability. Thus, if a court is employing risk-utility balancing, it can only be asking whether a reasonable alternative design should have been adopted.

In any event, under the analysis in Mikolajczyk the reality is that, if risk-utility evidence is introduced by either side, the judge will give the case to the jury with a risk-utility instruction patterned after comment f. The defendant will argue that it correctly chose a cost-effective, reasonably safe design, and the plaintiff will insist that a reasonable alternative was available that could have avoided or reduced the injury. Any plaintiff who shows up in court knowing full well that the defendant will introduce risk-utility evidence that supports the product design must be ready to counter with evidence that a reasonable alternative was available. The burden of proof on risk-utility, according to the Illinois court, lies with the plaintiff. Reasonable alternative design is not an idea conjured up by the Restatement drafters. It lies at the very heart of risk-utility balancing.

B. Liability Without Rhetoric: The Missouri Experience

Missouri is an interesting example of a state that, while disavowing reliance on the Products Liability Restatement, nevertheless requires plaintiffs to establish a reasonable alternative design in order to make out a prima facie case of design defect. In a series of cases, the Supreme Court of Missouri has specifically rejected the consumer expectations test,79 risk-utility balancing,80 and the Restatement test requiring proof of a reasonable alternative design.81 Instead, a jury is to be instructed only that liability for defective product design depends on a finding that the product is unreasonably dangerous.82 Yet, both state and federal court decisions in Missouri uphold jury verdicts whenever the

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74 See OWEN, PRODUCTS LIABILITY LAW, supra note 9, § 8.5.
75 See supra note 11 and accompanying text.
76 See supra notes 42-53 and accompanying text.
78 OWEN, PRODUCTS LIABILITY LAW, supra note 9, §§ 8.4-8.5.
79 Nesselrode v. Executive Beechcraft, Inc. 707 S.W.2d 371, 377-78 (Mo. 1986) (en banc) (rejecting consumer expectations test for jury instructions).
80 Newman v. Ford Motor Co., 975 S.W.2d 147, 152-54 (Mo. 1998) (en banc) (rejecting risk-utility balancing for jury instructions).
81 Rodriguez v. Suzuki Motor Corp., 996 S.W.2d 47, 64-65 (Mo. 1999) (en banc) (rejecting reasonable alternative design in favor of “unreasonably dangerous” instruction).
82 Id. at 65.
plaintiff proves a reasonable alternative design, reverse summary judgments in favor of defendants whenever plaintiffs proffer credible evidence of a reasonable alternative design, and grant summary judgment for defendants whenever plaintiffs fail to produce credible evidence of a reasonable alternative design.

Often the grant of summary judgment in Missouri is predicated on the failure of plaintiff’s expert to meet Daubert criteria. This is odd on the face of it—if it is not necessary to prove a reasonable alternative design, why should an expert’s opinion on the feasibility of an alternative design be necessary? If a plaintiff can establish a case merely by asserting that the product is unreasonably dangerous, why should a jury not be permitted to decide that issue sans expert testimony on the

83 Bass v. Gen. Motors Corp., 150 F.3d 842, 844-45, 851 (8th Cir. 1998) (court affirmed jury verdict in favor of plaintiff who claimed that his head hit the car window during a collision because the seat belt mechanism was defectively designed in that it allowed too much slack to develop; a design that would have created more tension between the belt and the body of the plaintiff would have averted plaintiff’s head injuries); Peters v. Gen. Motors Corp., 200 S.W.3d 1, 17-20 (Mo. Ct. App. 2006) (jury verdict in favor of plaintiff claiming design defect in the cruise-control mechanism of a 1993 Oldsmobile that caused the car to go out of control upheld; plaintiff introduced sufficient expert testimony of alternative design of the cruise-control mechanism that would have avoided the accident); Redfield v. Beverly Health & Rehab. Servs., Inc., 42 S.W.3d 703, 710 (Mo. Ct. App. 2001) (court upheld jury verdict in favor of plaintiff’s decedent against the manufacturer of a ventilator that failed causing death to plaintiff; plaintiff introduced evidence that the ventilator was unreasonably dangerous because it did not have a redundant backup breathing system).

84 Pritchett v. Cottrell, Inc., 512 F.3d 1057 (8th Cir. 2008) (court reversed summary judgment for defendant on claims of plaintiff truck drivers that the ratchet system used to tie down new automobiles on transport trailers was defective and caused them serious injuries; though under both Missouri and Kansas law [whose laws applied to the respective plaintiffs] plaintiff is not required to prove a reasonable alternative design, the plaintiffs’ expert opinion set forth several practical alternative designs for ratchet mechanisms that were safer and would have avoided the plaintiffs’ injuries); Sappington v. Skyjack, Inc., 512 F.3d 440 (8th Cir. 2007) (after noting that Missouri does not require testimony of a reasonable alternative design, the court reversed the district court’s grant of summary judgment to defendant on claim that a “scissors lift” should have been designed with greater stability so that it would not tip over when the rear wheels dropped off a concrete floor into the hold; plaintiff’s case met Daubert standards because there was evidence that at the time the product was manufactured the technology existed to produce a more stable lift that would have avoided the plaintiff’s death); Anderson v. F.J. Little Mach. Co., 68 F.3d 1113 (8th Cir. 1995) (court reversed trial court’s grant of summary judgment in favor of defendant where plaintiff suffered injuries when his hand was caught while trying to wipe the rollers clean when a metal straightening machine was running because plaintiff’s expert had testified in a deposition that the machine could have been equipped with an interlock barrier guard which would have prevented the unsafe cleaning of the rollers of the machine while it was in operation).

85 Jaurequi v. Carter Mfg. Co., 173 F.3d 1076 (8th Cir. 1999) (court upheld grant of summary judgment for defendant on the grounds that the plaintiff’s expert’s suggested alternative design of an “awareness barrier” to the corn head of a combine did not meet Daubert reliability criteria; plaintiff was injured when he got swept into the combine by feeding the combine from the front though he was warned never to do so); Shaffer v. Amada Am. Inc., 335 F. Supp. 2d 992 (E.D. Mo. 2003) (defendant granted summary judgment against plaintiff’s claim that a press brake machine was defectively designed causing plaintiff to lose multiple fingers when his hand got caught between the lower ram of the machine and the upper die; plaintiff’s expert’s proffered alternative design did not meet Daubert criteria and was inadmissible); Pillow v. Gen. Motors Corp., 184 F.R.D. 304 (E.D. Mo. 1998) (defendant granted summary judgment against plaintiff’s design defect claim that GM van, on impact with another vehicle, transmitted forces to the braking system, causing the brake pedal to violently thrust rearward; plaintiff’s expert’s alternative design failed to meet Daubert criteria and was inadmissible).

86 See supra note 85.
feasibility of the proposed alternative design? Where the jurisprudence of a state seeks to escape the conundrum of any theoretical structure, yet the cases are replete with discussions of a reasonable alternative design as the criterion for the validity of the cause of action, the lesson is clear. Courts, with or without a theoretical structure for defective design, focus on reasonable alternative design as the crucial element in deciding the bona fides of a design defect case.87

C. Reasonable Alternative Design Is the Strong Majority Rule for Classic Design Defect Cases

Having staked out the position that, notwithstanding confusing rhetoric, plaintiffs do not reach juries in classic design defect cases without offering evidence of a reasonable alternative design, we now turn our attention to those states that have clearly adopted the view that a reasonable alternative design is necessary to establish a prima facie case of design defect. Given how deeply entrenched section 402A is in the case law, we are gratified to see the large number of courts that have said that plaintiff must present proof of a reasonable or feasible alternative design. Some have done so by legislative mandate, but the large majority has done so by judicial decision. Some critics have sought to delegitimize statutory provisions that require proof of a reasonable alternative design as nothing more than reactionary “tort reform” accomplished at the bidding of business interests.88 However, when legislation is balanced, backed by the overwhelming body of American scholars89 and part of a growing body of case law that is supportive, pejorative name-calling rings hollow. Thus, the five states that by statute

87 Pritchett, 512 F.3d at 1063, 1066 (plaintiff was not required to prove a reasonable alternative design though Court reversed summary judgment for defendant on grounds that there were several practical and safer alternative designs for ratchet mechanism); Skyjack, 512 F.3d at 443, 446-48 (plaintiff’s testimony of a reasonable alternative design was not required though Court reversed summary judgment for defendant on grounds that there was a reasonable alternative design available for “scissors lift”). In two Missouri Appellate Court decisions, the courts did not require the plaintiffs to prove a reasonable alternative design but gave heavy credence to the availability of a reasonable alternative design. See Smith v. Brown & Williamson Tobacco Corp., 275 S.W.3d 748 (Mo. Ct. App. 2008) (court upheld jury verdict for plaintiff on grounds that Kool Menthol cigarettes were unreasonably dangerous; plaintiff was not required to prove a reasonable alternative design though the court concluded that evidence demonstrated that specific design choices by defendant had the potential to affect plaintiff’s health during the time period she smoked); Thompson v. Brown & Williamson Tobacco Corp., 207 S.W.3d 76, 95-96 (Mo. Ct. App. 2006) (court found that plaintiff did not have to prove a reasonable alternative design and held that the evidence went beyond a categorical attack on cigarettes; there was sufficient evidence for the jury to conclude that the products were unreasonably dangerous as designed since plaintiff had submitted proof that tobacco companies made specific design choices that had the potential to affect plaintiff’s health during the time period he smoked).

88 See, e.g., Larry S. Stewart, Reaffirming Strict Liability for Product Design Cases, TRIAL MAG., Nov. 2008, at 11 n.15. This theme has been repeated on numerous occasions at symposia and seminars.

89 See supra note 33.
require proof of a reasonable alternative design—Louisiana, \(^{90}\) Mississippi, \(^{91}\) New Jersey, \(^{92}\) North Carolina, \(^{93}\) and Texas \(^{94}\)—represent one-fifth of the twenty five states that we count in support of the Products Liability Restatement’s position.

We shall not burden the reader with a state-by-state discussion of the decisions in the twenty jurisdictions whose common law decisions support the proposition that a reasonable alternative design is necessary in a classic design defect case. The notes in the margin will have to bear the weight of accomplishing that task. We note the following jurisdictions that support the thesis: Alabama, \(^{95}\) Delaware, \(^{96}\) District of

\(^{90}\) LA. REV. STAT. § 9:2800.56 (West 1998) (The statute provides that “[a] product is unreasonably dangerous if, at the time the product left its manufacturer’s control: (1) There existed an alternative design for the product that was capable of preventing the claimant’s damage.”). Under Louisiana’s statute, failure to make out the statutory elements will result in a grant of summary judgment for the defendant. *Id.*; see, e.g., Morgan v. Gaylord Container Corp., 30 F.3d 586, 590 (5th Cir. 1994) (plaintiff was injured when an allegedly defective pump leaked water causing her to slip and fall; summary judgment granted because plaintiff’s experts did not testify that an alternative design existed when the product left the defendant’s control and did not testify as to the effect of the suggested alternative design on the utility of the pump).

\(^{91}\) MISS. CODE. ANN. § 11-1-63(a), (f) (2008). To make out a prima facie case for design defect, a plaintiff must prove that a reasonable alternative design was available. Failure to proffer a credible reasonable alternative design will result in summary judgment in favor of the defendant. *See, e.g.*, Johnson v. Davidson Ladders, Inc., 403 F. Supp. 2d 544, 549-50, 552 (N.D. Miss. 2005), *aff’d*, 193 Fed. App’x. 349 (5th Cir. 2006) (claimant asserted that a stepladder suffered from design defect that caused the claimant’s accident, resulting in injury; court granted summary judgment to defendant when plaintiff “offered no evidence relative to the effectiveness of the alternative design in reducing the severity or frequency of accidents”); Clark v. Brass Eagle, Inc., 866 So. 2d 456, 461 (Miss. 2004) (plaintiff hit in the eye in a paintball game alleged defective design against the paintball gun manufacturer; summary judgment granted to defendant when plaintiff did not introduce evidence of feasible alternative design).

\(^{92}\) N.J. STAT. ANN. § 2A:58c-3 (West 2000); *see, e.g.*, Cavanaugh v. Skil Corp., 751 A.2d 518, 521 (N.J. 2000) (court compared New Jersey statute, which puts the burden on the defendant to prove there was a lack of feasible alternative design for a defense, and section 2(b) of Products Liability Restatement, which puts the burden of proof on the plaintiff). The Cavanaugh court concluded that “[t]he plaintiff, under New Jersey law, is usually required to show the existence of a reasonable alternative design. But where the defendant shows that there exists no design alternative which was practical and technically feasible, the jury need not weigh the plaintiff’s proposed design against the defendant’s.” *Id.*

\(^{93}\) N.C. GEN. STAT. ANN. § 99B-6 (West 2000); *see, e.g.*, Dewitt v. Eveready Battery Co., 550 S.E.2d 511, 518-19 (N.C. Ct. App. 2001), *aff’d*, 565 S.E.2d 140 (N.C. 2002) (court upheld summary judgment for defendant when plaintiff proffered an alternative design to batteries that had leaked onto his skin and caused alkaline burns, when the court did not find that the alternative design was practical, safer, or likely to have prevented the harm to the plaintiff).

\(^{94}\) TEX. CIV. PRAC. & REM. CODE ANN. § 82.005 (Vernon 2005). Texas courts have demanded that evidence of a proffered safer alternative be backed by expert testimony that evaluates the economic feasibility of the alternative design and the correlative risks that the alternative design presents to the user. *See, e.g.*, Smith v. Louisville Ladder Co., 237 F.3d 515, 518-20 (5th Cir. 2001) (applying Texas law) (court reversed jury verdict for plaintiff because plaintiff’s expert never evaluated the risks of the proposed alternative design); Smith v. Aqua-Flo, Inc., 23 S.W.3d 473, 478 (Tex. App. 2000) (plaintiff must establish not only technical feasibility but also economic feasibility of a safer alternative design; court upheld directed verdict in favor of manufacturer).

\(^{95}\) Alabama unequivocally requires proof of a reasonable alternative design in design defect cases. Summary judgment has been granted for defendant in numerous cases where this requirement is not met. The leading case is *General Motors Corp. v. Edwards*, 482 So. 2d 1176 ( Ala. 1985), stating that:
In order to prove defectiveness, the plaintiff must prove that a safer, practical, alternative design was available to the manufacturer at the time it manufactured the automobile. The existence of a safer, practical, alternative design must be proved by showing that: (a) The plaintiff’s injuries would have been eliminated or in some way reduced by use of the alternative design, and that; (b) taking into consideration such factors as the intended use of the vehicle, its styling, cost, and desirability, its safety aspects, the foreseeability of the particular accident, the likelihood of injury, and the probable seriousness of the injury if that accident occurred, the obviousness of the defect, and the manufacturer’s ability to eliminate the defect, the utility of the alternative design outweighed the utility of the design actually used.

Id. at 1191. This rule has been consistently applied in the Alabama courts. See Townsend v. Gen. Motors Corp., 642 So. 2d 411, 423 (Ala. 1994) (summary judgment granted for defendants as plaintiff’s expert testimony did not establish viability of an alternative design of a compaction unit on a garbage truck); Beech v. Outboard Marine Corp., 584 So. 2d 447, 450 (Ala. 1991) (In answering a question certified by the United States District Court, the Alabama Supreme Court held that failure to prove that a “safer, practical, alternative design was available” was a bar to a cause of action for defective design under both the Alabama Extended Manufacturer Liability Doctrine (AEMLD) and negligence.). Cases decided after the adoption of the Products Liability Restatement continue to require proof of a reasonable alternative design to make out a prima facie case under AEMLD. See, e.g., Flemister v. Gen. Motors Corp., 723 So. 2d 25, 27-28 (Ala. 1998) (“APJI [Alabama Pattern Jury Instructions] requires a jury to determine, using a risk/utility balancing process, whether a plaintiff alleging a lack of crashworthiness has shown that a safer, practical alternative design existed that would have eliminated or reduced the plaintiff’s injuries if it had been used.”).

Allen v. Int’l Bus. Machs. Corp., No. Civ.A. 94-264 JJF, 1997 WL 34501372, at *1 (D. Del. Dec. 18, 1997). In granting summary judgment for defendant-manufacturer of computer keyboards when there was no evidence that the plaintiff’s proffered alternative design of a computer keyboard would prevent or lessen carpal tunnel syndrome, the Court concluded that “a product is defective in design where it is not reasonably fit for its intended purpose and where the design has created a risk of harm which is so probable that an ordinary prudent person, acting as the product’s manufacturer, would pursue a different available design to substantially lessen the probability of harm.” Id. at *45 (emphasis added); Nacci v. Volkswagen of Am., Inc., 525 A.2d 617, 620 (Del. Super. Ct. 1974) (“[T]he proper test is whether the design has created a risk of harm which is so probable that an ordinarily prudent person, acting as a manufacturer, would pursue a different available design which would substantially lessen the probability of harm.”) (emphasis added).

In Warner Fruehauf Trailer Co. v. Boston, 654 A.2d 1272 (D.C. 1995), the court stated that to establish design defect, “[i]n general, the plaintiff must ‘show the risks, costs and benefits of the product in question and alternative designs[,]’ and ‘that the magnitude of the danger from the product outweighed the costs of avoiding the danger.’” Id. at 1276 (citing Hull v. Eaton Corp., 825 F.2d 448, 453-54 (D.C. Cir. 1987)); accord Artis v. Corona Corp. of Japan, 703 A.2d 1214, 1215 (D.C. 1997).

In Banks v. ICI Americas, Inc., 450 S.E.2d 671, 674 (Ga. 1994), the court adopted risk-utility balancing as the governing test for design litigation, stating:

[T]he reasonableness of choosing from among various alternative product designs and adopting the safest one if it is feasible is considered the “heart” of design defect cases, since it is only at their most extreme that design defect cases reflect the position that a product is simply so dangerous that it should not have been made available at all.

Id. (emphasis added) (citation omitted). The position adopted by the Georgia high court recognizes that, except for the “most extreme” instance, when a court determines that the product is so dangerous that it should not have been sold at all, it is necessary to prove a reasonable alternative design. See id. This position is supported by section 2(b) and comment e thereto. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) & cmt. e (1998).

Although section 34-20-4-1 of the Indiana Code adopts the consumer expectation test, the Code specifically provides that, for liability to attach in cases where there is an alleged design defect or failure to warn, “the party making the claim must establish that the manufacturer or seller
failed to exercise reasonable care under the circumstances in designing the product or in providing the warnings or instructions.” Ind. Code Ann. § 34-20-2-2 (LexisNexis 2008). Even prior to 1998, when the express requirement that negligence is the governing rule in design defect and failure to warn cases took effect, Indiana case law required proof of a reasonable alternative design to make out a case for design defect. See, e.g., Jackson v. Warrum, 535 N.E.2d 1207, 1220 (Ind. Ct. App. 1989) (court held that a “burden of proof scheme” required that “plaintiff must prove that a feasible safer alternative product design existed”); see also Whitted v. Gen. Motors Corp., 58 F.3d 1200, 1206 (7th Cir. 1995) (applying Indiana law) (Although Indiana statute sets forth a consumer expectation test, “[t]o allege that a manufacturer breached its duty to design a safe product under strict liability, a claimant must offer a safer, more practicable product design than the design in question. Accordingly, since [plaintiff] failed to present evidence that the product was flawed in its design and he failed to illustrate that a better design was cost-effective, summary judgment was properly issued as to the claim of design defect.”) (citation omitted); Pries v. Honda Motor Co., 31 F.3d 543, 545 (7th Cir. 1994) (applying Indiana law) (in crashworthiness case where issue was safety of automobile design, court cited to Restatement (Third) of Torts: Products Liability § 2(b) & cmt. c (Tentative Draft No. 1, 1994) and said “[t]o demonstrate a defect, the plaintiff must compare the costs and benefits of alternative designs”); Miller v. Todd, 551 N.E.2d 1139, 1141-42 (Ind. 1990) (applying risk-utility analysis); Rogers v. R. J. Reynolds Tobacco Co., 557 N.E.2d 1045, 1051 n.6 (Ind. Ct. App. 1990), aff’d in part and vacated in part, 745 N.E.2d 793 (Ind. 2001) (“A defective design is one which makes the product inadequate or unsafe relative to alternate design choices.”).

100 See, e.g., Wright v. Brooke Group Ltd., 652 N.W.2d 159, 169, 181-82 (Iowa 2002) (Court adopted sections 1 and 2 of the Products Liability Restatement; Restatement design standards under section 2(b) apply whether the claim is brought under negligence, strict liability or the implied warranty of merchantability).

101 In Toyota Motor Corp. v. Gregory, 136 S.W.3d 35, 42 (Ky. 2004), the Kentucky Supreme Court reviewed a set of early design defect cases, such as Jones v. Hutchinson Manufacturing, Inc., 502 S.W.2d 66 (Ky. 1973), and Ingersoll-Rand Company v. Rice, 775 S.W.2d 924 (Ky. Ct. App. 1988). The court, citing to Restatement (Third) Torts: Products Liability § 2 cmt. d (1998), said Kentucky law “stands for the proposition that design defect liability requires proof of a feasible alternative design.” Toyota Motor Corp., 136 S.W.3d at 42. Applying that principle to the case at bar, the court said:

[The elements of a prima facie crashworthiness claim are: (1) an alternative safer design, practical under the circumstances; (2) proof of what injuries, if any, would have resulted had the alternative, safer design been used; and (3) some method of establishing the extent of enhanced injuries attributable to the defective design.

Id. at 41; see also Burke v. U-Haul Int’l, Inc., 501 F. Supp. 2d 930, 933 (W.D. Ky. 2007) (“In the typical design defect claim Kentucky law requires proof of a feasible alternative design.”) Defendant’s motion for judgment n.o.v. denied because plaintiffs “met the requirement of showing a feasible alternative.”); Fritz v. Campbell Hausfeld/Scott Fetzer Co., No. 05-360-JBC, 2007 WL 1558509, at *1, *3-4 (E.D. Ky. May 29, 2007), aff’d, 279 Fed. App’x. 333 (6th Cir. 2008) (summary judgment granted to manufacturer of pressure washer; the design alternatives introduced by plaintiff supported the technological feasibility of the alternative design but did not address many factors necessary to determine the issue of whether the product that caused the injury was unreasonably dangerous); Estate of Bigham v. DaimlerChrysler Corp., 462 F. Supp. 2d 766, 779 (E.D. Ky. 2006) (summary judgment granted to defendant in crashworthiness case because of plaintiff’s failure to establish a reasonable alternative design); Caudill v. Toyota Motor Corp., No. Civ.A. 04-333-DLB, 2005 WL 3149311, at *4 (E.D. Ky. Nov. 23, 2005) (summary judgment granted to defendant in crashworthiness case; plaintiff failed to introduce “competent evidence[] that a feasible, alternative, safer design existed”).

102 See St. Germain v. Husqvarna Corp., 544 A.2d 1283, 1285 (Me. 1988) (court rejected consumer expectations test and adopted risk-utility balancing as the standard for determining defective design). The St. Germain court concluded, “In actions based upon defects in design, negligence and strict liability theories overlap in that under both theories the plaintiff must prove that the product was defectively designed thereby exposing the user to an unreasonable risk of harm. Such proof will involve an examination of the utility of its design, the risk of the design and the feasibility of safer alternatives.” Id. (quoting Stanley v. Schiari Mobile Homes, 462 A.2d 1144, 1148 (Me. 1983)). At least one federal court has held that Maine requires proof of a reasonable alternative design. See Reali v. Mazda Motor of Am., Inc., 106 F. Supp. 2d 75, 80-81 (D. Me. 2000) (“'[In
Maine, a plaintiff in a design defect case must prove that an alternative design is feasible and safer.


In an early case based on a negligence theory, Uloth v. City Tank Corp., 384 N.E.2d 1188 (Mass. 1978), the court held that there is “a case for the jury if the plaintiff can show an available design modification which would reduce the risk without undue cost or interference with the performance of the machinery.” Id. at 1193. In a case decided the same year, Back v. Wickes Corp., 378 N.E.2d 964 (Mass. 1978), the court held that Massachusetts law of warranty was “congruent in nearly all respects with the principles expressed in Restatement (Second) of Torts § 402A (1965),” id. at 969, and went on to hold that in a design case it would put heavy emphasis on the “mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design.” Id. at 970 (quoting Barker v. Lull Eng’g Co., 573 P.2d 443 (Cal. 1978)). Some twelve years later in Kotler v. American Tobacco Co., 926 F.2d 1217 (1st Cir. 1990), vacated, 505 U.S. 1215 (1992), on the issue of federal preemption in the field of cigarette labeling, the court discussed requirements of proof in a design defect case and said,

[w]e are aware of no Massachusetts case in which liability attached in the absence of evidence that some different, arguably safer, alternative design was possible. In a design defect case premised on negligence, the existence of a safer alternative design is a sine qua non for the imposition of liability. . . . It follows, we think, that a design defect case premised on breach of warranty is, in Massachussets, similarly dependent on proof of the existence of a safer alternative design—a design which reasonably could, or should, have been adopted.

Id. at 1225 (citations omitted). A similar view is expressed in Johnson v. Brown & Williamson Tobacco Corp., 122 F. Supp. 2d 194, 207 (D. Mass 2000) (applying Massachusetts law) (“In the tobacco context, as with design defect cases premised on negligence, a plaintiff alleging breach of warranty based on design defect must first plead that the tobacco in the cigarettes consumed was itself defective, and then offer proof of a safer alternative design which could reasonably have been adopted.”) (citation omitted); see also O’Neil v. Electrolux Home Prods., Inc., No. 06-10433-DPW, 2008 WL 2066948, at *7 (D. Mass. May 14, 2008) (breach of implied warranty claim against lawn mower manufacturer survived motion for summary judgment because plaintiff introduced credible evidence of safer alternative design that would have prevented the injury); Alves v. Mazda Motor of Am., Inc., 448 F. Supp. 2d 285, 298-99 (D. Mass. 2006) (applying Massachusetts law) (claim that defectively designed airbag caused plaintiff’s blindness dismissed on summary judgment). In Alves, the court found that the plaintiff’s experts did not meet Daubert criteria but explained that even if the expert testimony had been admissible, claims of implied warranty and negligence would be dismissed since the experts offered “no evidence on the mechanical feasibility of any alternative design, the costs of such a design or the consequences of such a design.” Id. at 299.

Michigan has explicitly rejected the consumer expectations test as the general standard for defective design and has adopted a pure risk-utility analysis for design defect cases, regardless of whether the case was based on strict liability (or implied warranty of merchantability) or negligence. See Prentis v. Yale Mfg. Co., 365 N.W.2d 176, 184 (Mich. 1984). As a practical matter, the plaintiff cannot establish a prima facie case of design defect without producing evidence of a reasonable alternative design. In Owens v. Allis-Chalmers Corp., 326 N.W.2d 372 (Mich. 1982), the failure of the plaintiff to produce evidence of the practicality and cost-effectiveness of a proffered alternative design was grounds for upholding a directed verdict for the defendant. Id. at 378-79; accord Scott v. Allen Bradley Co., 362 N.W.2d 734, 737 (Mich. Ct. App. 1984) (“Owens established that the plaintiff must present evidence concerning the magnitude of the risks involved and the reasonableness of any proposed alternative design.”). The Michigan Court of Appeals in Reeves v. Cincinnati, Inc., 439 N.W.2d 326 (Mich. Ct. App. 1989), summarized the elements of a prima facie case of failure to provide adequate safety devices:

[A] prima facie case of a design defect premised upon the omission of a safety device requires first a showing of the magnitude of foreseeable risks, including the likelihood of occurrence of the type of accident precipitating the need for the safety device and the severity of the injuries sustainable from such an accident. It secondly requires a showing
of alternative safety devices and whether those devices would have been effective as a reasonable means of minimizing the foreseeable risk of danger. This latter showing may entail an evaluation of the alternative design in terms of its additional utility as a safety measure and its trade-offs against the costs and effective use of the product.


In Holm v. Sponco Manufacturing, Inc., 324 N.W.2d 207, 212-13 (Minn. 1982), the Minnesota court rejected the consumer expectations test and adopted risk-utility balancing as the governing rule for design defect litigation. Minnesota recognizes that, in general, the plaintiff has the burden of showing a reasonable, safer alternative design, but notes that there may be rare cases in which that requirement does not apply. Thus, in Kallio v. Ford Motor Co., 407 N.W.2d 92 (Minn. 1987), the court stated that, in establishing that a product was unreasonably dangerous, “a factor bearing upon the . . . requirement will be the existence or nonexistence of a feasible alternative design. . . . [T]he plaintiff ordinarily has the burden of showing the existence of an alternative design that was safer.” Id. at 96 (emphasis added). Amplifying this point in a lengthy footnote, the court said,

Examination of our cases . . . alleg[ing] defective design demonstrates that, as a practical matter, successful plaintiffs, almost without fail, introduce evidence of an alternative safer design. See, e.g., Bilotta v. Kelley Co., 346 N.W.2d 616, (Minn. 1984) (plaintiff presented evidence of manufacturer’s actual alternative design of dockboard); Hudson v. Snyder Body, Inc., 326 N.W.2d 149 (Minn. 1982) (plaintiff presented evidence that a portion of the release mechanism of a hydraulic bed dumptruck was superfluously long creating the defect); Busch v. Busch Constr., Inc., 262 N.W.2d 377 (Minn. 1977) (plaintiff presented evidence that a turn signal’s use of a plastic yoke inside a lock steering column required a design allowing a greater clearance radius than the manufacturer’s design had allowed); McCormack v. Hanksraft Co., 278 Minn. 322, 154 N.W.2d 488 (Minn. 1967) (plaintiff presented evidence that the cover of a vaporizer should have been secured such that it would prevent water in the vaporizer’s jar from simultaneously discharging if the vaporizer should tip over).

Id. at 96 n.6 (emphasis omitted).

The Minnesota high court in Kallio did not require that in all cases a reasonable alternative design be presented to the jury as an essential element in finding a defect. The court said that “[a]lthough normally evidence of a safer alternative design will be presented initially by the plaintiff, it is not necessarily required in all cases.” Id. at 96-97 (emphasis added). The court exemplified this exception by citing Wilson v. Piper Aircraft Corp., 577 P.2d 1322 (Or. 1978), stating that “[c]onceivably, rare cases may exist where the product may be judged unreasonably dangerous because it should be removed from the market rather than be redesigned.” Kallio, 407 N.W.2d at 97 n.8.

A fair reading of Minnesota law is that for the majority of design defect cases, proof of a reasonable alternative is necessary. It is not, however, necessary to instruct a jury on a reasonable alternative design requirement, though a general instruction on risk-utility is required by the court. In rare cases, when a product involves negligible utility and high risk, the reasonable alternative design requirement is not imposed. The position of the Minnesota courts is thus fully consistent with both the black letter of section 2 and comments d, e, and f. A leading authority on Minnesota products liability law agrees. See generally Mike Steenson, A Comparative Analysis of Minnesota Products Liability Law and the Restatement (Third) of Torts: Products Liability, 24 WM. MITCHELL L. REV. 1 (1998).
Cases decided post-adoption of the Products Liability Restatement are in accord. See, e.g., Wagner v. Hesston Corp., 450 F.3d 756, 760 (8th Cir. 2006) (applying Minnesota law) (court noted that to satisfy the requirement that a product be unreasonably dangerous, “the plaintiff ordinarily has the burden of showing the existence of an alternative design that was safer” (quoting Kallio, 407 N.W.2d at 96)). The court upheld the district court’s grant of summary judgment because plaintiff’s suggested alternative design did not meet Daubert standards. See id. at 761; Young v. Pollock Eng’g Group, Inc., 428 F.3d 786, 789 (8th Cir. 2005) (applying Minnesota law). “Only in rare cases do defective-design claims succeed without showing a safer design. ‘Conceivably, rare cases may exist where the product may be judged unreasonably dangerous because it should be removed from the market rather than be redesigned.’” Young, 428 F.3d at 791 (citation omitted). The Young court reversed the district court’s grant of summary judgment to defendant because there was ample evidence of a reasonable alternative design. Id. at 791; see also Solo v. Trus Joist MacMillan, No. Civ. 02-2955 (RHK/RLE), 2004 WL 524898, at *11-12 (D. Minn. Mar. 15, 2004) (plaintiff failed to provide evidence of a feasible alternative safer design for a furnace as required by Minnesota law; defendant entitled to summary judgment); Bruzer v. Danek Med., Inc., No. Civ. 3-95-971/RHKJMM, 1999 WL 613329, at *5 (D. Minn. Mar. 8, 1999) (applying Minnesota law) (defendant entitled to summary judgment on claim that medical device was defectively designed because plaintiff failed to provide evidence of reasonable alternative design and product was not one of rare cases where product should not have been marketed at all).

Montana courts have few decisions dealing with the issue of the standard for design defect. However, the few cases extant support the proposition that to maintain a claim of design defect a plaintiff must prove that a reasonable alternative design could have been adopted that would have reduced the harm. In Rix v. General Motors Corp., 723 P.2d 195 (Mont. 1986), the court said that “a design is defective if at the time of manufacture an alternative designed product would have been safer than the original designed product and was both technologically feasible and a marketable reality.” Id. at 202. Earlier in the decision, the court emphasized that this rule applied when “a manufactured product is claimed to be unreasonably dangerous because a safer alternative was available to the manufacturer.” Id. The court left open the question of how it would rule if no alternative design was technologically feasible. Id. at 201 (citing O’Brien v. Muskin Corp., 463 A.2d 298, 306 (N.J. 1983), superseded in part by statute, N.J. STAT. ANN. § 2A:58c-3 (West 2000), as recognized in Dewey v. R.J. Reynolds Tobacco Co., 577 A.2d 1239 (N.J. 1990), in which the court held that a design could be found to be defective even if no feasible alternative was available). Even if the Montana court were to follow O’Brien, in the ordinary design defect case, a reasonable alternative design would have to be proven; O’Brien, on its own terms, allows for dispensing with the alternative design requirement only when the product has minimal social utility. See id. (Some products “are so dangerous and of such little use that under the risk-utility analysis, a manufacturer would bear the cost of liability of harm to others.”); see also Preston v. Mont. Eighteenth Judicial Dist. Court, 936 P.2d 814, 820 (Mont. 1997) (“[E]vidence of alternative designs available prior to the manufacture of the N12 [model pneumatic roofing nailer] is not only relevant, but necessary, to [plaintiff’s] products liability claim and, therefore, the District Court is clearly proceeding under a mistake of law in precluding discovery of alternative design evidence . . . .”). Krueger v. Gen. Motors Corp., 783 P.2d 1340, 1345 (Mont. 1989) (court reiterated the need for a reasonable alternative design).

The leading case in New Mexico is Brooks v. Beech Aircraft Corp., 902 P.2d 54 (N.M. 1995). Brooks attributes time-of-trial knowledge to defendant, but, given that knowledge, applies a risk-utility test to the issue of design defect. In Brooks, the New Mexico high court stated that it would charge a manufacturer with time-of-trial knowledge of risk regardless of whether it was available to defendant at time of sale. Nonetheless, the court clearly adopted a risk-utility analysis as the grounds for deciding whether a product was unreasonably dangerous. Id. at 61-62. It should be noted that the court said:

Under the current product liability jury instructions, SCRA 1986, 13-1401 to 13-1433 (Repl.Pamp.1991), the jury is instructed that a supplier’s liability is measured by “an unreasonable risk of injury resulting from a condition of the product or from a manner of its use.” UJI 13-1406. As to either flaw or design, the jury is informed that “[a]n unreasonable risk of injury is a risk which a reasonably prudent person having full knowledge of the risk would find unacceptable.” UJI 13-1407. Lastly, the jury is instructed specifically that in determining whether a product design poses an unreasonable risk of injury, “[y]ou should consider the ability to eliminate the risk without seriously impairing the usefulness of the product or making it unduly expensive.” Id. By requiring the jury to make a risk-benefit calculation, these instructions adequately
define “defect” so as to focus jury attention on evidence reflecting meritorious choices made by the manufacturer on alternative design and so as to minimize the risk that the public will be deprived needlessly of beneficial products for the sake of compensating injured victims.

. . . . . . As observed above, our existing uniform jury instructions allow proof and argument on all of the factors suggested by the Restatement (Third) of Torts as relevant in determining whether the omission of a reasonable alternative gave rise to an unreasonable risk of injury. See Restatement (Third) of Torts: Products Liability § 2, cmt. d, at 19-20 (Tentative Draft No. 1, 1994); Duran, 101 N.M. at 747, 688 P.2d at 784. The distinction between the negligence approach proposed by the Restatement and strict liability is the time frame in which the risk-benefit calculation is made.

Id. at 61-63. The court then concluded,

If in some future case we are confronted directly with a proffer of evidence on an advancement or change in the state of the art that was neither known nor knowable at the time the product was supplied, we may at that time reconsider application of a state-of-the-art defense to those real circumstances, properly developed under the proffer with applicable briefs and argument.

Id. at 63. Several decisions since Brooks emphasize the need for a reasonable alternative design as part of the plaintiff’s prima facie case. In Smith v. Bryco Arms, 33 P.3d 638 (N.M. Ct. App. 2001), plaintiff sued a gun manufacturer for injuries he suffered when a handgun was negligently discharged. The plaintiff alleged that safety features were available that would have indicated to the user that the gun was loaded and should not be fired. In reversing the trial court’s grant of summary judgment to the defendant, the court said:

Whether the type of misuse evident in this case was foreseeable, whether the existing features of the J-22 are sufficiently safe, and whether it was feasible without impairing the utility of the gun or being unduly expensive for Bryco and Jennings to incorporate the advocated safety devices and/or warnings into the design of the J-22, are all issues for the jury to decide.

Id. at 650. Most persuasive is the decision of the federal district court in Morales v. E.D. Etnyre & Co., 382 F. Supp. 2d 1278 (D. N.M. 2005), in which the Court predicted that the New Mexico Supreme Court would adopt RESTATEMENT OF TORTS (THIRD): PRODS. LIAB. § 2(b). The court said:

Etnyre contends that the Plaintiffs failed to make a prima facie showing to satisfy the elements for a design defect case in accordance with the Restatement (Third) of Torts: Products Liability. The Court agrees that, if the Supreme Court of New Mexico were presented with the precise issue in this case, it would most likely adopt the Restatement (Third) of Torts: Products Liability. Accordingly, the Court will assume that the Restatement (Third) of Torts: Products Liability governs this action and that the Restatement (Third) is the controlling law for the Plaintiffs’ claims based on defective design.

Before the ALI issued [sic] considered or issued the Restatement (Third), New Mexico had adopted the “risk-utility” test. The Court believes that test required the plaintiff to prove the existence of an “alternative design” to determine whether the defendant defectively designed a product. Thus, to the extent that a plaintiff could come to court and merely criticize a product, the Court believes that the New Mexico law required the plaintiff to propose an alternative design.

Morales, 382 F. Supp. 2d at 1283. It should be noted that whether a reasonable alternative design is required is an issue separate and apart from the question of whether a manufacturer should be charged with the knowledge of a risk-avoidance mechanism that was not known at the time of manufacture but was known at the time of trial. As set forth earlier, the New Mexico Supreme Court left open the “state of art” question for resolution at a later date. In any event, at the very least, the New Mexico court seems to require a reasonable alternative design that could be implemented at the time of trial.
Rhode Island, South Carolina, Virginia, and West Virginia. We will, however, comment on the views of three states that we count as supportive that deserve special comment.

Although the Supreme Court of Rhode Island has not yet held that a reasonable alternative design is required, in an important opinion the high court has cited to the language of section 2(b) in reversing a directed verdict on the ground that plaintiff had shown that a reasonable alternative design was available. In Buonanno v. Colmar Belting Co., 733 A.2d 712 (R.I. 1999), plaintiff, an employee of New England Ecological Development, Inc., observed that one of the conveyor belts was running off track. Plaintiff turned off the machine and climbed onto a catwalk to determine if the conveyor belt was obstructed. While plaintiff was standing on the catwalk, someone restarted the machine. Somehow, plaintiff lost his balance and thrust his arm into the “nip point” of the conveyor system. Buonanno, 733 A.2d at 713. The primary issue on appeal was whether the distributors of component parts of the nip points were entitled to summary judgment since they only sold the components for a system that was fully integrated at the plant. In a lengthy analysis, the court adopted section 5 of the Restatement (Third) Products Liability, which states that the manufacturer of a component part is not liable unless the component part “is defective in itself” or the seller or distributor of the component “substantially participates in the integration of the component into the design of the product.” Id. at 716 (quoting RESTATEMENT (THIRD) TORTS: PRODS. LIAB. § 5 (1998)) (emphasis omitted). With regard to one defendant (Colmar), the court found that there was evidence that could support a jury finding that the distributor was “substantially involved” in the integration of the component into the final product. Id. at 717. With regard to a second defendant the court observed:

[W]e are persuaded that a genuine issue of material fact may exist with respect to whether the pulley’s design was defective as a result of [the component manufacturer’s] failure to produce a reasonable alternative design that may have reduced or avoided the foreseeable risk of harm suffered by Buonanno, which would render the product defective “in itself” and “at the time of sale or distribution.” Specifically, the Restatement (Third) Torts § 2(b) provides that a product is defective when:

“the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe.”

Although this issue was not actually litigated by the parties, the record is clear that Buonanno produced evidence that a safer design of the pulley was available. Specifically, in his deposition, John Brunaccini, Colmar’s president, testified that [the component part maker] manufactured (for other customers on a “made-to-order-basis”), a wing pulley that had steel welded around the circumference of the wings, and that it manufactured this design at the same time that it manufactured the pulley in question. Brunaccini also indicated that there was a design known as a “spiral wing pulley” which had circular pieces wound around the pulley that would cover “the whole thing.” Accordingly, we are satisfied that a genuine issue of material fact exists as to whether this was a reasonable alternative design within the meaning of the Restatement. If so, the question remains as to whether the foreseeable risks of harm posed to plaintiff could have been reduced or avoided had the alternative design been available and offered . . . . We recognize that it may not have been economically feasible . . . to manufacture a wing pulley with this additional guarding for this particular use and such a factor would bear significantly upon the reasonableness of this alternative design. These determinations, however, are to be determined by a fact finder and are not suitable for summary judgment.

Buonanno, 733 A.2d at 717-18. A fair reading of Buonanno is that Rhode Island has adopted not only section 5 of the Restatement, but also section 2(b). The court, in seeking to define whether the wing pulley was “defective in itself,” clearly relies on the Restatement definition of design defect.

An early decision requiring a reasonable alternative design for a design defect is Bragg v. Hi-Ranger Inc., 462 S.E.2d 321, 330 (S.C. Ct. App. 1995) (directed verdict for defendant manufacturer because plaintiff failed to introduce evidence of a “feasible design alternative”). Since then, several federal courts applying South Carolina law have concluded that proof of a reasonable alternative design is mandatory in a design defect case. See, e.g., Cohen v. Winnebago Indus., Inc.,
state court decisions indicate that Virginia would require proof of a reasonable alternative design; the district court granted defendant summary judgment because the plaintiff had failed to provide expert testimony that the alternative design was feasible. The court said:

> "The argument lacks merit, because providing evidence of the existence of an alternative, feasible design is part of the plaintiff’s products liability case under South Carolina law; and hence the instruction was appropriate."); Campbell v. Gala Indus. Inc., No. Civ.A.6:04-2036-RBH, 2006 WL 1073796, at *4 (D.S.C. Apr. 20, 2006) (applying South Carolina law) (defendant’s motion for summary judgment on claim that centrifugal dryer was defectively designed denied because limitation of liability was "fair and just"); Disher v. Synthes (U.S.A.), 371 F. Supp. 2d 764, 767-68, 771 (D.S.C. 2005) (defendant manufacturer of titanium humeral nail that fractured after implant granted summary judgment because under South Carolina law it is crucial that a plaintiff show that a ‘‘feasible’’ or workable, design alternative exists under the circumstances’’); Little v. Brown & Williamson Tobacco Corp., 243 F. Supp. 2d 480, 495 (D.S.C. 2001) (‘‘While there is no explicit statement including proof of a safer alternative design as an element of a product liability case, clearly South Carolina courts have found that failure to provide such proof can doom a case as a matter of law.’’).

While state courts have not articulated a clear test for design defect, several federal district court decisions indicate that Virginia would require proof of a reasonable alternative design as a current design, primie facie case. In Kesler v. Crown Equipment Corp., Civ. No. 93-0644-R, 1994 WL 782904, at *1, *3 (W.D. Va. Jul. 5, 1994), aff’d, 51 F.3d 266 (4th Cir. 1995), the federal district court granted defendant summary judgment because the plaintiff had failed to provide expert testimony that the alternative design was feasible. The court said:

> Even if expert testimony were not required, Kesler’s challenge to the alleged design defect misses the mark. Essentially, Kesler contends that it was technologically feasible to install a guardrail and to use a harness rather than a belt. A feasible design, however, is not necessarily a desirable design. Suggested alterations must be “not only technically feasible but also practicable in terms of cost and the over-all design and operation of the product.” Allen v. Minnstar, Inc., 8 F.3d 1470, 1479 (10th Cir. 1993) (Allen required proof of reasonable alternative design). Although Kesler’s suggested changes are likely practicable in terms of cost, Crown’s manager of product engineering testified that those changes were not practicable given the nature of the work stockpicker operators perform and the stockpicker’s overall function, design and operation.

Id. at *3. More recently, in Tunnell v. Ford Motor Co., 385 F. Supp. 2d 582, 583 (W.D. Va. 2005), the court held that the trial court’s exclusion of plaintiff’s expert witness as to the alleged defectiveness of a Jaguar for its failure to have a battery cutoff device, which would have prevented a fire after a collision, was not error and that it was proper to grant the defendant-manufacturer a directed verdict. We set forth the court’s analysis at length because it so clearly demonstrates the court’s reliance on section 2(b) of the Restatement and its comments as the correct interpretation of Virginia law:

Defectiveness analysis considers whether a product is “unreasonably dangerous for ordinary or foreseeable use.” Alevromagiros v. Hechinger Co., 993 F.2d 417, 420 (4th Cir. 1993). As discussed in the Memorandum Opinion, this “foreseeable use” standard necessarily requires experts to take a broad view of the product they analyze. Because the foreseeable uses of some products are wide-ranging, a product may require multiple-and potentially competing-design elements to protect against the various foreseeable uses of the product. Precisely because of this fact, one design element protecting against a foreseeable use can easily frustrate or even impair the value of another measure protecting against a different foreseeable use. For this reason, a product designer may argue in its defense that a proposed alternative design actually increases the risk that an injury will result from a different, but equally foreseeable, use of the product. When such an argument is made, a plaintiff’s expert cannot simply make a defectiveness judgment based upon only one particular type of accident. Rather, he must analyze whether the current design, taken as a whole, reasonably protects against the other injuries that could occur due to foreseeable uses. This result is a necessary consequence of the “foreseeable use” standard because any other standard would render a designer susceptible to inconsistent judgments on defectiveness. In one lawsuit, the designer could be liable for failing to include a certain protective device; in another, he could be liable for choosing to include it. Here, Ford unquestionably argued that Wallingford’s proposed device would impose safety risks rendering the Mustang more dangerous. Because Wallingford
Arkansas statutorily embraces the consumer expectations test. However, in *Dancy v. Hyster Co.*, the court held that unless the case is never addressed the question of whether the vehicle taken as a whole was unreasonably dangerous for ordinary or foreseeable uses, his opinion was meaningless on the issue of defectiveness.

Ultimately, the preceding analysis merges with the issue Plaintiff raises in his motion regarding the risk-benefit analysis. The risk-benefit analysis is not, as Plaintiff argues, some additional technical hurdle that this Court is imposing where none existed before. Rather, it is a basic concept imbedded in any defectiveness analysis, requiring that a proposed alternative design actually cure a product of its alleged defects. Contrary to Plaintiff’s contention, Virginia, along with the Third Restatement of Torts, does require evidence from a plaintiff that an alternative design truly provides more benefits than risks.

Although the Third Restatement does not require a plaintiff “to establish with particularity the costs and benefits associated with adoption of the suggested alternative design” in light of the “inherent limitations on access to relevant data,” it nevertheless clearly does contemplate that a plaintiff will produce some affirmative evidence as to the risk-benefit analysis. As Plaintiff acknowledges, the Restatement is quite clear on this point:

> When evaluating the reasonableness of a design alternative, the overall safety of the product must be considered. It is not sufficient that the alternative design would have reduced or prevented the harm suffered by the plaintiff if it would have introduced into the product other dangers of equal or greater magnitude.

Restatement (Third) of Torts: Products Liability § 2 cmt. f (1997). Plaintiff acknowledges that some jurisdictions have interpreted the Third Restatement to require proof than [sic] an alternative design has passed a risk-benefit analysis, but he argues that neither the Virginia Supreme Court nor the Virginia General Assembly has expressly adopted the Third Restatement. Even assuming arguendo that Virginia has rejected express adoption of the Third Restatement in its entirety, however, this fact alone does not suggest that principles from the Third Restatement are not integrated in Virginia common law. As with any area of law, persuasive authority in the form of case law from other jurisdictions and restatements is instructive in identifying Virginia common law rules.


113 127 F.3d 649 (8th Cir. 1997).
one in which the plaintiff can draw a res ipsa-like inference of defect, the plaintiff must prove that a safer alternative design was available. In that case plaintiff was injured when a lift-truck overturned, pinning his right foot and leading to the amputation of his right leg below the knee. Dancy sued the lift-truck manufacturer alleging defective design because the truck did not have a cage or guard around the compartment to protect the operator from injury. The district court found that the plaintiff's expert testimony as to an alternative design did not meet Daubert criteria. Without credible evidence as to the alternative design the defendant was entitled to summary judgment. The court said:

Plaintiff does not contend that the lift truck malfunctioned in any way; he contends the lift truck was not designed properly because it lacked a safety device. Lay jurors would tend to understand products that do not work; they are not likely to possess “common understanding” about how products are designed. We cannot expect lay jurors to possess understanding about whether the mesh guard envisioned by Dr. Forbes would be capable of withstanding the force involved in a fall and be effective in protecting Plaintiff from the injury he received. . . . We cannot expect a lay juror to know whether the mesh guard itself would cause more injuries than it creates by, for instance, breaking and puncturing the lift truck’s operator. Although Dancy does not have the burden of proving that his “alternative safer design was available and feasible in terms of cost, practicality and technological possibility,” French v. Grove Mfg., Co., 656 F.2d 295, 297 (8th Cir. 1981), he still has the burden of proving the existence of a defect by showing that a safer alternative design actually exists. He cannot carry this burden without proving that his proposed design will actually work, and we believe the answer to this question is beyond the ken of lay jurors.

Several other federal court decisions relying on Dancy have granted summary judgment because plaintiff failed to proffer credible expert testimony as to the availability of a practical safer alternative design. In a recent case, Freeman v. Caterpillar Industrial, Inc., the court noted that although plaintiff is not required to prove the economic feasibility of an alternative design as part of her prima facie case, if “defendant comes forward with evidence to demonstrate the prohibitive cost, impracticality, or technological unfeasibility” of the alternative design, the case need

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114 Id. at 651-54.
115 Id. at 652-53.
116 Id. at 653-54 (emphasis added).
117 See, e.g., Anderson v. Raymond Corp., 340 F.3d 520 (8th Cir. 2003) (relying on Dancy, the Court held that the plaintiff’s expert did not meet Daubert criteria and absent expert testimony on a safer alternative design, the plaintiff could not make out a prima facie case, and defendant was therefore entitled to summary judgment); Jones v. Gott Corp., 4:00CV00279 GTE, 2001 U.S. Dist. LEXIS 26252, at *4, 6 (W.D. Ark. Sept. 6, 2001) (defendant was granted summary judgment against a claim that a plastic container was defectively designed when it did not contain a flame arrester, thus allowing gasoline in the container to spray out and burn the plaintiff; plaintiff’s expert did not meet Daubert criteria and without that testimony, plaintiff could not meet its burden of proving that a safer alternative existed).
119 Id. at *20.
not be submitted to a jury “because there is a point at which it must be said that the alternative design will not work.” Thus, notwithstanding that an Arkansas statute embraces the consumer expectations test, the courts have required the plaintiff to provide evidence of a workable alternative design. And, if a defendant demonstrates that the proffered alternative design is not economically feasible, the plaintiff will suffer either summary judgment or a directed verdict. Although the Arkansas test for design defect does not line up in all its particulars with section 2(b) of the Products Liability Restatement, it is a far cry from a strict liability consumer expectations test. Plaintiff is required to proffer a technologically feasible, safer alternative design and, even when proven, it can be defeated by evidence that it is not economically feasible.

Utah, also, has a statute that predicates liability on a product being “dangerous to an extent beyond which would be contemplated by the ordinary and prudent buyer, consumer, or user of that product in that community.” Notwithstanding this statutory language, the court in Brown v. Sears, Roebuck & Co. held that “[t]he statute does not create a cause of action” but instead limits the plaintiff’s right to recover to cases where the product fails to meet consumer expectations. In addition, however, a plaintiff must show that a reasonable alternative design was available at the time the product was put into commerce. Once again a court has held that consumer expectations language in a statute is not determinative. Instead the court, citing to the Products Liability Restatement, held that to make out a prima facie case for design defect, a plaintiff must present credible evidence of a reasonable alternative design.

Finally, we include New York among the jurisdictions that require proof of a reasonable alternative design. The leading case espousing this view is Voss v. Black & Decker Manufacturing Co., a landmark case in New York products liability jurisprudence. Products Liability Restatement.

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120 Id. at *21.
121 Under section 2(b), the plaintiff has the burden of proving that the reasonable alternative design is technologically and economically feasible.
122 UTAH CODE ANN. § 78B-6-702 (2008).
123 328 F.3d 1274 (10th Cir. 2003).
124 Id. at 1278-79 (“The statute does not create a cause of action. It sets limits on any cause of action created by some other source of law. It states that in a products liability suit, a product will be regarded as defective only if at the time of sale the product was ‘unreasonably dangerous’ . . . .”).
125 Id. at 1279 (“The statute . . . imposes a necessary condition for a cause of action. The statute does not state what is sufficient for a cause of action. Because Utah does not have another statute setting forth the elements of a products liability cause of action, the sufficient conditions for such a cause of action must come from the common law . . . . This circuit . . . has interpreted Utah law to require that the plaintiff prove the practicability of a safer design.”).
126 Id.; see also RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. d (1998).
127 Brown, 328 F.3d at 1279 (describing risk-utility/alternative design test used in Allen v. Minnstar, Inc., 8 F.3d 1470, 1472 (10th Cir. 1993)).
Liability cognoscenti may counter that in *Denny v. Ford Motor Co.*, the New York Court of Appeals gave explicit recognition to the consumer expectations test as a method for establishing design defect. To be sure, in *Denny* the court approved a separate instruction based on the failure of the product to meet consumer expectations because the product in question, a small utility vehicle, was marketed for highway driving. The court noted that the vehicle was reasonably safe as an “off-road” vehicle but that, when traveling at normal highway speeds, its center of gravity was such that it was prone to roll-over accidents, thus disappointing consumer expectations. The role of marketing as the lynchpin for use of the consumer expectations test was emphasized by Judge Guido Calabresi in a subsequent decision, *Castro v. QVC Network, Inc.* In that case, defendant advertised a roasting pan on a TV home-shopping channel as suitable for cooking a twenty-five pound turkey. Plaintiff bought the roasting pan and used it to prepare a twenty-five pound turkey on Thanksgiving. She was injured when she attempted to remove the turkey from the pan. While wearing insulated mittens, she gripped the pan’s handles with the first two fingers of each hand. She could not use more than two fingers because that was the maximum grip allowed by the small size of the handles. As she removed the pan, the turkey tipped toward her, spilling hot drippings and fat onto her foot and ankle causing second- and third-degree burns. The plaintiff had pled claims in strict liability in tort (risk-utility) and breach of implied warranty of merchantability (consumer expectations). The federal district court applying New York law instructed only on the strict tort claim. The jury found for the defendant. In reversing for failing to give the consumer expectations instruction, Judge Calabresi noted that “in *Denny*, the Court of Appeals pointed out that the fact that a product’s overall benefits might outweigh its overall risks does not preclude the possibility that consumers may have been misled into using the product in a context in which it was dangerously unsafe.” If not for the specific representation as to its suitability for roasting a twenty-five pound turkey, it was a safe roasting pan. However, Judge Calabresi noted:

But, it was also the case that the pan was advertised as suitable for a particular use—cooking a twenty-five pound turkey . . . . The product was, therefore, sold as appropriately used for roasting a twenty-five pound turkey.

In such circumstances, New York law is clear that a general charge on strict products liability based on the risk-utility approach does not suffice. The jury

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130 *Id.* at 738.
131 *Id.* at 732-33.
132 *Id.* at 732.
133 139 F.3d 114, 118-19 (2d Cir. 1998).
134 *Id.* at 115-16.
135 *Id.* at 118.
could have found that the roasting pan’s overall utility for cooking low volume foods outweighed the risk of injury when cooking heavier foods, but that the product was nonetheless unsafe for the purpose for which it was marketed and sold—roasting a twenty-five pound turkey and, as such, was defective under the consumer expectations test. That being so, the appellants were entitled to a separate breach of warranty charge. 136

In a footnote, Judge Calabresi noted that in both Denny and Castro the product had been marketed as suitable for “dual purposes” but, in fact, was dangerous for use in one of the modes. 137

Given the explicit representations in Denny and Castro, they might be better classified as express warranty claims. But whether classified as consumer expectations or express warranty they represent a tiny share of New York design defect cases. Once one gets past the few instances where explicit representations support the use of the consumer expectations test, 138 the case law in New York is replete with decisions by courts that defendants are entitled to summary judgment because plaintiffs failed to introduce credible evidence of a reasonable alternative design. 139 The constancy and volume of decisions to that effect leave little doubt as to the law applicable in New York in classic design cases.

136 Id. at 119.
137 Id. at n.11.
138 See supra notes 128, 132 and accompanying text.
139 A substantial number of decisions set forth the requirement of a reasonable alternative design as a prerequisite for a prima facie case of defective design. See, e.g., Rypkema v. Time Mfg. Co., 263 F. Supp. 2d 687, 692 (S.D.N.Y. 2003) (summary judgment granted to defendant against plaintiff’s claim that aerial lift bucket was defectively designed because under New York law “plaintiff is required to prove the existence of a feasible alternative” design; plaintiff’s expert failed to show the practical availability of such an alternative design); Crespo v. Chrysler Corp., 75 F. Supp. 2d 225, 228 (S.D.N.Y. 1999) (court granted defendant’s motion to vacate jury verdict against plaintiff’s claim that an airbag was defectively designed, citing RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2, cmt. f (1998), and held that plaintiff must prove a reasonable alternative design that would be safer for all users and it is not sufficient if the alternative design would have preexisted the plaintiff’s injury); Deere v. Goodyear Tire & Rubber Co., 175 F.R.D. 157, 161-62 (N.D.N.Y. 1997) (defendant tire company granted summary judgment against plaintiff’s claim that he was injured by explosion of defectively designed tire because plaintiff did not establish reasonable alternative design as required under New York law); Voss v. Black & Decker Mfg. Co., 450 N.E.2d 204, 208 (N.Y. 1983) (“The plaintiff . . . is under an obligation to present evidence that the product, as designed, was not reasonably safe because there was a substantial likelihood of harm and it was feasible to design the product in a safer manner. . . .”); Magadan v. Interlake Packaging Corp., 845 N.Y.S.2d 443, 445 (App. Div. 2007) (summary judgment for defendant upheld on claim that a book stitcher was defectively designed since “plaintiff failed to raise an issue of fact as to whether at the time the stitcher was manufactured, it was feasible to design it in a safer manner); Felix v. Akzo Nobel Coatings, Inc., 692 N.Y.S.2d 413, 415 (App. Div. 1999) (granting summary judgment because “there was no competent evidence set forth by the plaintiff that there was an alternative, safer design and the evidence clearly indicates the volatile solvent contained in the defendant’s quick-drying lacquer sealer is critical to the product’s performance”); Perez v. Radar Realty, No. 24414/1998, 2005 WL 946710 (N.Y. Sup. Ct. Apr. 5, 2005), aff’d, 824 N.Y.S.2d 87 (App. Div. 2006) (summary judgment for defendant in a design defect claim against manufacturer of quick-drying lacquer sealer that injured plaintiff when it caught fire since there was no feasible alternative proffered by plaintiff that would meet the performance standards of the defendant’s product); see also Clinton v. Brown & Williamson Holdings, Inc., 498 F. Supp. 2d 639 (S.D.N.Y. 2007) (summary judgment granted to defendant on plaintiff’s claim that cigarettes were not reasonably safe when subject to risk/utility balancing). The court in Clinton began its analysis by saying:
D. Risk-Utility Balancing: Reasonable Alternative Design Not Required

We have already noted that unless a jurisdiction is prepared to adopt category liability, the inevitable conclusion that one must draw from adopting risk-utility balancing is that plaintiff must prove a reasonable alternative design. When one does risk-utility balancing one must judge the product on trial and compare it with some hypothetical design that could have been adopted. Reasonable alternative design is the answer to the comparative balancing process; it is not a factor in the equation as to whether the product was reasonably designed.

Thus, states like Colorado, Illinois, New Hampshire, and Nevada may say that reasonable alternative design is not a sine qua non.
non to make out a prima facie case for design defect. However, in these states, all classic design cases in which plaintiff has reached the jury are cases in which plaintiff has proved an alternative design. No plaintiff has ever reached the jury in the absence of such proof. The interesting question is why would courts make such a serious theoretical error? Why would they insist that reasonable alternative design is only a relevant factor in risk-utility balancing when, in actuality, they treat it as controlling?

One reason is that many courts have relied on a highly influential article published in 1973 by the late Dean and Professor John Wade. In that article, Wade set forth seven risk-utility factors that should be considered in deciding whether a product design is unreasonably dangerous. One of the Wade factors is the availability of a safer design: “[t]he availability of a substitute product would meet the same need and not be as unsafe.” In a different setting, we observed that Wade was referring to the empirical question as to whether an alternative design was technologically feasible, whereas the issue of reasonable alternative

Camacho v. Honda Motor Co., 741 P.2d 1240, 1246-47 (Colo. 1987). While proof of a reasonable alternative design is part of Colorado’s risk-utility standard, it “is not always necessary.” See Armentrout, 842 P.2d at 185 n.11 (citing Wilson v. Piper Aircraft Corp., 577 P.2d 1322, 1328 n.5 (Or. 1978)). Thus, according to Wilson and as cited by the high court, it would appear that the only exceptions to the reasonable alternative design requirement in Colorado are those cases where the product has negligible utility and high risk.

141 See supra Part IV.A.

142 In Vautour v. Body Masters Sports Industries, Inc., 784 A.2d 1178 (N.H. 2001), the court adopted the risk-utility approach as the governing standard for design defect litigation. It held, however, that it was not incumbent on the plaintiff to prove a reasonable alternative design as part of its prima facie case. The court rejected the reasonable alternative design requirement of the Products Liability Restatement as placing too heavy a burden on the plaintiff. Instead, whether a reasonable alternative design was available would be one of many factors to be taken into consideration in deciding whether a product was defective. Id. at 1182; see also Price v. BIC Corp., 702 A.2d 330, 332 (N.H. 1997) (failure to incorporate child-proof features in cigarette lighter to be governed by risk-utility analysis). It is worthwhile to note that although the court held that proof of a reasonable alternative design is not required in each of the above cases, plaintiff offered proof of a reasonable alternative design to support its position that the product was defective and unreasonably dangerous. Vautour, 784 A.2d at 1184; see also Collins v. Tool Exch. L.L.C., No. Civ. 01-302-M, 2002 WL 31395929, at *2 (D.N.H. Oct. 16, 2002) (summary judgment on design defect claim denied; plaintiff noted three design defects, the elimination of which would have rendered power saw safer).

143 Although Nevada courts have referred to the failure of a design to meet reasonable consumer expectations in explaining pro-plaintiff decisions, they have done so in cases involving product malfunctions. See, e.g., Ginnis v. Mapes Hotel Corp., 470 P.2d 135, 137-38 (Nev. 1970). In more recent decisions, the Supreme Court of Nevada has made clear that plaintiffs may reach the jury by proving that an alternative design was available at time of sale, although “[a]lternative design is [only] one factor for the jury to consider when evaluating whether a product is unreasonably dangerous.” McCourt v. J.C. Penney Co., Inc., 734 P.2d 696, 698 (Nev. 1987); see also Robinson v. G.G.C. Inc., 808 P.2d 522, 525-26 (Nev. 1991) (holding that the failure to admit evidence of alternative design was grounds to reverse jury verdict for defendant). Notwithstanding this “only one factor” language in McCourt, no case in Nevada has been found, not involving product malfunction, in which a plaintiff has reached the jury with a design claim without proof of a reasonable alternative design.


145 Wade, supra note 144, at 837.
design looks to the normative question as to whether the alternative design should have been implemented. However, that just makes the problem worse. How can the technological feasibility of an alternative design simply be a factor in deciding whether a product is defectively designed? As noted earlier, if there is no technologically feasible alternative, then the plaintiff perforce is attacking the product category. We are constrained to conclude that Wade was simply wrong in listing the availability of an alternative design as one factor among many in deciding whether a product design is unreasonably dangerous. A partial defense for Wade may be that in 1973 the issue of product category liability, although an early concern of products liability scholars at the time section 402A was adopted, was not on his radar screen. We reinvigorated the issue and popularized the phrase “category liability” in an article published in 1991; since then, scholars and courts have discussed the subject. Wade could not have been sensitive to the possibility that his formulation might lead to category liability.

We conclude that the view that a court can embrace risk-utility balancing and yet insist that the availability of a reasonable alternative design is simply one factor in the equation has no practical significance. The only cases in which plaintiffs successfully dodge summary judgment without proof of a reasonable alternative design are those covered by section 3 of the Restatement, which allows a plaintiff to draw an inference of defect when the product fails in its manifestly intended function.

146 See Henderson & Twerski, Achieving Consensus, supra note 2, at 888-89.
148 See Henderson & Twerski, Closing the Frontier, supra note 11, at 1297.
reasonable alternative need be proffered.\textsuperscript{153} It may be that some courts are put off by the language of section 2(b), which seems to mandate a reasonable alternative design in all product design cases. Both section 2, comment f,\textsuperscript{154} and section 3, comment b,\textsuperscript{155} make it exquisitely clear that the Restatement does not mandate that result. In short, in jurisdictions that use risk-utility balancing as the test for design in classic design defect cases, no decisions have been reported in which plaintiffs have been able to reach juries without evidence that a reasonable alternative design was available that would have reduced or eliminated the risk of injury.

\textsuperscript{153} Restatement (Third) of Torts: Prod. Liab. § 3 cmt. b (1998) (“[W]hen the incident . . . is one that ordinarily occurs as a result of product defect, and evidence in the particular case establishes that the harm was not solely the result of causes other than product defect . . . . it should not be necessary for the plaintiff to incur the cost of proving whether the failure resulted from a manufacturer defect or from a defect in the design of the product.”).

\textsuperscript{154} Section 2, comment f provides:

While a plaintiff must prove that a reasonable alternative design would have reduced the foreseeable risks of harm, Subsection (b) does not require the plaintiff to produce expert testimony in every case. Cases arise in which the feasibility of a reasonable alternative design is obvious and understandable to laypersons and therefore expert testimony is unnecessary to support a finding that the product should have been designed differently and more safely. For example, when a manufacturer sells a soft stuffed toy with hard plastic buttons that are easily removable and likely to choke and suffocate a small child who foreseeably attempts to swallow them, the plaintiff should be able to reach the trier of fact with a claim that buttons on such a toy should be an integral part of the toy’s fabric itself (or otherwise be unremovable by an infant) without hiring an expert to demonstrate the feasibility of an alternative safer design. Furthermore, other products already available on the market may serve the same or very similar function at lower risk and at comparable cost. Such products may serve as reasonable alternatives to the product in question.

\textsuperscript{155} Id. § 2 cmt. f.

Section 3, comment b allows an inference of design defect without proof of a reasonable alternative design:

Although the rules in this Section, for the reasons just stated, most often apply to manufacturing defects, occasionally a product design causes the product to malfunction in a manner identical to that which would ordinarily be caused by a manufacturing defect. Thus, an aircraft may inadvertently be designed in such a way that, in new condition and while flying within its intended performance parameters, the wings suddenly and unexpectedly fall off, causing harm. In theory, of course, the plaintiff in such a case would be able to show how other units in the same production line were designed, leading to a showing of a reasonable alternative design under § 2(b). As a practical matter, however, when the incident involving the aircraft is one that ordinarily occurs as a result of product defect, and evidence in the particular case establishes that the harm was not solely the result of causes other than product defect existing at time of sale, it should not be necessary for the plaintiff to incur the cost of proving whether the failure resulted from a manufacturing defect or from a defect in the design of the product. Section 3 allows the trier of fact to draw the inference that the product was defective whether due to a manufacturing defect or a design defect. Under those circumstances, the plaintiff need not specify the type of defect responsible for the product malfunction.

\textsuperscript{155} Id. § 3 cmt. b.
E. The Two-Prong Test for Defect

Some jurisdictions apply a two-prong test for defect under which a plaintiff can establish design defect by demonstrating either that (1) the product failed to meet consumer expectations; or (2) the product failed to meet risk-utility standards. Arizona, Alaska, California, Connecticut, Florida, Hawaii, Ohio, Oregon, Puerto Rico, Tennessee, and Washington appear to fall in this camp.

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1. if the plaintiff demonstrates that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, or
2. if the plaintiff proves that the product’s design proximately caused his injury and the defendant fails to prove, in light of the relevant factors discussed above, that on balance the benefits of the challenged design outweigh the risk of danger inherent in such design.

Barker, 573 P.2d at 457-58. In General Motors Corp. v. Farnsworth, 965 P.2d 1209, 1220 (Alaska 1998), the Supreme Court of Alaska reaffirmed its use of the consumer expectations test without requiring proof of a reasonable alternative design.

158 See Barker, 573 P.2d at 457-58; see also discussion accompanying notes infra 170-174.

159 See Potter v. Chicago Pneumatic Tool Co., 694 A.2d 1319, 1333-34 (Conn. 1997); see infra notes 176-178 and accompanying text.

160 Florida case law supports the two-prong test for defect. See, e.g., Force v. Ford Motor Co., 879 So. 2d 103, 105 (Fla. Dist. Ct. App. 2004). A large number of cases that rely on the consumer expectations test are cases that would be decided identically under section 3 of the Products Liability Restatement. As the court notes in Force, Florida law is not clear as to the line of demarcation between cases that can be decided under the consumer expectations test and those which require risk-utility balancing. Id. at 106-07. The court does, however, note that there are cases of such complexity that the ordinary consumer would not know what to expect and would require risk-utility balancing to set the standard for defect. Id. at 109. From the onset the Florida courts acknowledged that the consumer expectations test is problematic in classic design defect cases. In the much cited case of Cassisi v. Maytag Co., 396 So. 2d 1140 (Fla. Dist. Ct. App. 1981), the court said:

The consumer expectation standard, though adequate to identify unintended manufactured defects, is more difficult to apply as to the other two generally recognized types of product defects: (1) design defects—those which are due to design error because unforeseen hazards accompany normal use of the product created according to design, and (2) defects resulting from misinformation or inadequate warnings. As to the last two defects, the standard is said to be a very vague and imprecise one because the ordinary consumer cannot be said to have expectations as to safety regarding many features of complexly made products that are purchased, such as the risk of fire from the way gasoline tanks are installed in cars, or the magnitude of risks involved in vehicles overturning. Due to the difficulty in applying the consumer expectation standard to all types of product defects, many thoughtful commentators have suggested that it should be rejected, particularly as to those defects arising from design, in favor of a test that would weigh the utility of the design versus the magnitude of the inherent risk.

Id. at 1145. More recently, in Liggett Group, Inc. v. Davis, 973 So. 2d 467, 473-74 (Fla. Dist. Ct. App. 2007), the issue before the court was whether it should adopt section 2(b) of the Products Liability Restatement in the context of a claim alleging a design defect in cigarettes. The court found that plaintiff had not presented evidence of a reasonable alternative design and upheld a jury verdict.
based on the consumer expectations test. \textit{Id}. The case was appealed to the Florida Supreme Court and it at first accepted jurisdiction to review the intermediate appellate court’s decision. See Liggett Group Inc. v. Davis, 997 So. 2d 400, 401 (Fla. 2008). Then after oral argument, the court declined jurisdiction. \textit{Id}. Florida law thus remains uncertain as to when it is proper to use the consumer expectations test and when a case requires risk-utility balancing.

\textbf{161} Acoba v. Gen. Tire Co., 986 P.2d 288, 304 (Haw. 1999). Though the \textit{Acoa} court said that plaintiff could proceed under both consumer expectations and risk/utility, plaintiff introduced evidence of a design alternative that would have avoided the injury. \textit{Id}

\textbf{162} Ohio has a bifurcated statute governing design-based liability. The statute, Ohio Rev. Code Ann. § 2307.75 (A)-(F), provides two avenues for imposing design-based liability. “[A] product design is in a defective condition to the user or consumer if (1) it is more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, or (2) if the benefits of the challenged design do not outweigh the risk inherent in such design.” Knitz v. Minster Mach. Co., 432 N.E.2d 814, 818 (Ohio 1982). Despite presenting alternate bases of design-based liability, subsection (F) provides:

\begin{quote}
A product is not defective in design or formulation if, at the time the product left the control of its manufacturer, a practical and technically feasible alternative design or formulation was not available that would have prevented the harm for which the claimant seeks to recover compensatory damages without substantially impairing the usefulness or intended purpose of the product.
\end{quote}


\textbf{163} Oregon Rev. Stat. § 30.920 (2007) adopts section 402A, including comments a through m, as the law governing products liability in Oregon. In \textit{McCathern v. Toyota Motor Corp.}, 23 P.3d 320, 329-30 (Or. 2001), the Oregon Supreme Court said that it was bound by the legislative determination set forth in section 402A, comment i (consumer expectations test). The court then said:

\begin{quote}
Plaintiff acknowledges that evidence related to risk-utility balancing of that kind may be necessary to show that a product failed to perform as safely as an ordinary consumer would have expected. However, plaintiff disputes the Court of Appeals’ holding that, under the consumer expectations test, a plaintiff \textit{must} introduce such evidence. \textit{See McCathern}, 160 Or. App. at 211, 985 P.2d 804 (proof of safer practicable alternative design essential to consumer risk-utility theory). According to plaintiff, evidence related to risk-utility balancing, as described above, is required only under the now-defunct reasonable manufacturer test. \textit{See Wilson v. Piper Aircraft Corporation}, 282 Or. 61, 67-69, 577 P.2d 1322 (1978) (relying on \textit{Phillips}’s reasonable manufacturer test; requiring that, when risk-utility balancing and proof of design alternative are necessary, proof must include evidence that alternative design was practicable).

We agree that evidence related to risk-utility balancing, which may include proof that a practicable and feasible design alternative was available, will not \textit{always} be necessary to prove that a product’s design is defective and unreasonably dangerous, \textit{i.e.}, that the product failed to meet ordinary consumer expectations. However, because the parties did not dispute that evidence related to risk-utility balancing was necessary in this case, we leave for another day the question under what circumstances ORS 30.920 requires a plaintiff to support a product liability design-defect claim with evidence related to risk-utility balancing of the kind discussed above.
\end{quote}

\textit{McCathern}, 23 P.3d at 331-32.

\textbf{164} In \textit{Collazo-Santiago v. Toyota Motor Corp.}, 149 F.3d 23, 24 (1st Cir. 1998), involving a claim that an airbag in an automobile was defectively designed, the federal court of appeals reviewed Puerto Rico’s products liability law in affirming a verdict and judgment for the plaintiff-appellee. The court’s Erie-educated guess regarding Puerto Rican law, based on prior decisions by the Supreme Court of Puerto Rico, was that the two-prong approach adopted in California in \textit{Barker v. Lulå Engineering Co.}, 573 P.2d 443 (1978), applied. \textit{Collazo-Santiago}, 149 F.3d at 25-26. Notwithstanding expert testimony from defendant’s witnesses that the benefits of the airbag
To the extent that these states utilize risk-utility balancing, we have already demonstrated that it inevitably leads to requiring proof of a reasonable alternative design.\textsuperscript{167} The questions of real import concern how the courts administer the consumer expectations test. What are the parameters of the test? By what barometer does one measure whether consumer expectations have been disappointed? Unless the consumer expectations test is carefully cabined, it is open to telling criticisms. First, for many products, consumers do not have clear expectations as to how the product will perform when subjected to a broad range of uses. Second, under the consumer expectations test, defect and causation are merged. Plaintiffs need only allege disappointment of expectations and injury. Third, since risk-utility is not an issue, the product as designed may provide greater overall safety than an alternative product that would meet consumer expectations and would have avoided a particular plaintiff’s harm. Fourth, consumer expectations may vary; thus placing outweighed its risks overall and that no reasonable alternative design was feasible, the First Circuit Court of Appeals concluded that after the plaintiff proved that deployment of the airbag caused the second-degree burns to the plaintiff’s face, “the burden shifted to the defendant to establish that the benefits of the design outweighed its risks . . . .” Id. at 27-28. More recently, in Fremaint v. Ford Motor Co., 258 F. Supp. 2d 24, 26, 30-31 (D.P.R. 2003), the federal district court, applying Puerto Rican law, granted summary judgment for defendant in a case involving second-collision injuries suffered in a single-car accident. The court held that the consumer expectation prong of the \textit{Barker} two-prong approach did not apply because the case involved complex technical matters of automobile design, and the plaintiff failed to introduce expert testimony to establish that an alternative, safer design was feasible that would have avoided plaintiff’s injuries in the accident. \textit{Id.} at 29-30.

\textsuperscript{165} \textit{Jackson v. Gen. Motors Corp.}, 60 S.W.3d 800 (Tenn. 2001); \textit{see also} discussion \textit{infra} notes 181-186 and accompanying text.

\textsuperscript{166} \textit{WASH. REV. CODE} § 7.720.030(3) (1981) imposes strict liability for design defects and provides that “[i]n determining whether a product was not reasonably safe under this section, the trier of fact shall consider whether the product was unsafe to an extent beyond that which would be contemplated by the ordinary consumer.”

It would at first blush seem that Washington allows a plaintiff to prevail under a pure consumer expectations test. However, in several cases the court has included risk-utility factors as necessary to determine whether plaintiff meets the consumer expectations test. \textit{See, e.g.}, \textit{Bruns v. PACCAR, Inc.}, 890 P.2d 469 (Wash. Ct. App. 1995), where the court said:

Alternatively, the plaintiff may establish manufacturer liability by showing the product was unsafe as contemplated by a reasonable consumer. RCW 7.72.030(3). Several factors contribute to this consumer expectation determination, including “[t]he relative cost of the product, the gravity of the potential harm from the claimed defect and the cost and feasibility of eliminating or minimizing the risk.”

\textit{Id.} at 474 (quoting \textit{Seattle-First Nat’l Bank v. Tabert}, 542 P.2d 774 (Wash. 1975) (en banc)); \textit{see also} \textit{Higgins v. Intex Recreation Corp.}, 99 P.3d 421 (Wash. Ct. App. 2004), where the court said:

In determining the reasonable expectations of the ordinary consumer, a number of factors must be considered. The relative cost of the product, the gravity of the potential harm from the claimed defect and \textit{the cost and feasibility of eliminating or minimizing the risk may be relevant in a particular case. In other instances the nature of the product or the nature of the claimed defect may make other factors relevant to the issue.}

\textit{Id.} at 426 .

\textsuperscript{167} \textit{See supra} notes 73-78 and accompanying text.
the manufacturer in the impossible position of being subject to liability no matter how the product is designed.

For these reasons, courts in these two-prong states have been very sensitive to the limitations of the consumer expectations test and have confined its application to cases that instantiate res ipsa-like product failures i.e., where a product fails to perform its manifestly intended function. We have made reference to section 3 of the Products Liability Restatement earlier in this paper. At this juncture we set it out in full.

§ 3. Circumstantial Evidence Supporting Inference of Product Defect

It may be inferred that the harm sustained by the plaintiff was caused by a product defect existing at the time of sale or distribution, without proof of a specific defect, when the incident that harmed the plaintiff:

(a) was of a kind that ordinarily occurs as a result of product defect; and

(b) was not, in the particular case, solely the result of causes other than product defect existing at the time of sale or distribution.168

To the extent that a court recognizes that if a product does not fall within section 3 the plaintiff must establish that the product fails to meet risk-utility norms, the law of that jurisdiction is perfectly congruent with the Products Liability Restatement. For example, in its leading case Dart v. Wiebe Mfg.,169 the Arizona Supreme Court noted that the consumer expectations test is adequate for manufacturing defect cases but will only “sometimes work well” in design cases, as consumers will very often not know what to expect of a complex or unfamiliar design. More recently in Golonka v. General Motors Corp.,170 the Arizona Court of Appeals reiterated that the consumer expectations test works well for manufacturing defect cases and has “limited utility” in design defect cases where risk-utility standards must govern.171 California, the originator of the two-prong test in Barker v. Lull Engineering Co.,172 later found it necessary in Soule v. General Motors Corp.173 to explain that the consumer expectations test is very limited in scope. The court said:

As we have seen, the consumer expectations test is reserved for cases in which the everyday experience of the product’s users permits a conclusion that the product’s design violated minimum safety assumptions, and is thus defective regardless of expert opinion about the merits of the design . . . .174 [T]he jury may not be left free to find a violation of ordinary consumer expectations whenever it chooses. Unless the facts actually permit an inference that the product’s performance did not meet the minimum safety expectations of its

169 709 P.2d 876, 878 (Ariz. 1985) (en banc).
171 Id.
172 573 P.2d 443 (Cal. 1978).
173 882 P.2d 298 (Cal. 1994).
174 Id. at 308.
ordinary users, the jury must engage in the balancing of risks and benefits required by the second prong of Barker.\footnote{Id. at 309.}

In two telling footnotes the court outlined the proper role of each of the two prongs. As to the consumer expectations test, the court said the following:

For example, the ordinary consumers of modern automobiles may and do expect that such vehicles will be designed so as not to explode while idling at stoplights, experience sudden steering or brake failure as they leave the dealership or roll over and catch fire in two-mile-per-hour collisions. If the plaintiff in a product liability action proved that a vehicle’s design produced such a result, the jury could find forthwith that the car failed to perform as safely as its ordinary consumers would expect, and was therefore defective.\footnote{Id. at 308 n.3.}

The Court went out of its way in rejecting the attempt by plaintiff to broaden the scope of the consumer expectations test saying:

Plaintiff insists that manufacturers should be forced to design their products to meet the “objective” safety demands of a “hypothetical” reasonable consumer who is fully informed about what he or she \textit{should} expect. Hence, plaintiff reasons, the jury may receive expert advice on “reasonable” safety expectations for the product. However, this function is better served by the risk-benefit prong of Barker. There, juries receive expert advice, apply clear guidelines, and decide accordingly whether the product’s design is an acceptable compromise of competing considerations.\footnote{Id. at 308 n.4.}

Connecticut, as we explained earlier, has formally rejected the \textit{Products Liability Restatement} test for design defect. Yet it limits its consumer expectations test to cases where an ordinary consumer is “able to form expectations of safety.”\footnote{Potter v. Chicago Pneumatic Tool Co., 694 A.2d 1319, 1333 (Conn. 1997).} In cases involving issues of complex product design, the court admits that risk-utility balancing must be utilized in order to decide whether a design is defective. As noted earlier, in \textit{Potter v. Chicago Pneumatic Tool Co.},\footnote{Id.} the seminal Connecticut case pronouncing this two-prong analysis, the plaintiff presented evidence of several reasonable alternative designs that were readily available and that would have minimized or eliminated the injury to the plaintiff. Since \textit{Potter}, the Connecticut cases in which the consumer expectations test has been applied by state and federal courts are all res ipsa-like cases in which the inference of defect was entirely appropriate under section 3 of the Restatement.\footnote{Hartford Fire Ins. Co. v. DENT-X Int’l, Inc., No. 3:05CV1019 (TPS), 2007 U.S. Dist. LEXIS 20858 (D. Conn. Mar. 23, 2007); Moran v. E. Equip. Sales, Inc., 818 A.2d 848 (Conn. App. Ct. 2003); Martone v. C. Raimondo & Sons Constr., No. CV000704975S, 2002 WL 31234758 (Conn. Super. Ct. Aug. 28, 2002).}
Tennessee’s Product Liability Act embraces a two-prong test for design defect similar to the tests in Arizona and California. In *Jackson v. General Motors Corp.*,181 the Tennessee Supreme Court held that the consumer expectations test was not limited to the malfunction of simple products but could apply to complex products as well. It will be noted, however, that the court also observed that “plaintiffs, in cases involving highly complex products,” will often be unable “to establish that the product is dangerous to an extent beyond that which would be contemplated by an ordinary consumer.”182 This caveat was applied in *Brown v. The Raymond Corp.*,183 where a plaintiff was driving his forklift when he collided with a forklift driven by another employee. The wheel well of the other employee’s forklift entered the operator compartment of the plaintiff’s forklift, crushing his left foot. Plaintiff’s expert testified that the defendant’s forklift was defectively designed because the company could have eliminated the hazard of its forklift’s wheel intruding into the compartment of another. The trial court found that the plaintiff’s expert testimony did not meet *Daubert* standards and was inadmissible.184 Plaintiff argued that even though he had not satisfied the risk-utility prong for design defect, he was entitled to take the case to the jury under the consumer expectations test.185 In rejecting the plaintiff’s argument, the court noted that, notwithstanding the broad language in *Jackson* that the consumer expectations test could be applied to complex products, the requirement that the product be more dangerous than expected by the ordinary consumer could not be met in this case.186 The complexity of the product would not allow for such an inference of defect.

We need not deluge the reader with cases in which the courts have held that the consumer expectations test is inappropriate and the case requires risk-utility balancing. If one needs reminding, the *Soule* case in California was a crashworthiness case in which the court held that the consumer expectations test was improper and required risk-utility balancing.187 As we see it, most cases in which the courts have imposed liability under consumer expectations and have not required risk-utility balancing are cases that would have met the test set forth in section 3 of the *Products Liability Restatement*. A few cases may be found in which courts, in our opinion, have given an overly broad reading to the

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181 60 S.W.3d 800 (Tenn. 2001).
182 *Id.* at 806.
183 432 F.3d 640 (6th Cir. 2005).
184 *Id.* at 642-43.
185 *Id.* at 644.
186 *Id.*
187 *Soule v. Gen. Motors Corp.*, 882 P.2d 298, 309 (Cal. 1994) (“Unless the facts actually permit an inference that the product’s performance did not meet the minimum safety expectations of its ordinary users, the jury must engage in the balancing of risks and benefits . . . .”).
consumer expectations test. Would results in those states that have given a broader reading to consumer expectations than is to our liking have been different had the court applied the language of section 3? That is hard to tell. The res ipsa doctrine has had an accordion-like quality to it and courts have at times given it an expansive reading. One fact is undeniable. Those courts that have opted for a two-prong test for design defect manifest by that doctrinal choice that they understand that the consumer expectations test has serious limitations and cannot be the exclusive test for design liability. Although we do not formally count them as states that agree with the Products Liability Restatement, the reality is that when one considers sections 2 and 3 together and lines them up with the law of: (1) the states that require proof of a reasonable alternative design; (2) the states that profess to apply risk-utility balancing; and (3) the two-prong states, the consensus that support the general approach of the Products Liability Restatement is overwhelming. We never anticipated that we would persuade states to speak in the same dialect. But they are, in fact, speaking in one common language.

F. The Pure Consumer Expectation States

A handful of states embrace the consumer expectations test as the sole standard for defect. Thus, Kansas, Maryland, Nebraska, Oklahoma, and Wisconsin all profess allegiance to the consumer

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188 See, e.g., Bresnahan v. Chrysler Corp., 38 Cal. Rptr. 2d 446 (Ct. App. 1995) (plaintiff was injured when her car was rear-ended and the air bag inflated in a low speed collision; court held that plaintiff was entitled to go to the jury on consumer expectations theory and that risk-utility evidence as to the effectiveness of air bags was not relevant); Force v. Ford Motor Co., 879 So. 2d 103 (Fla. Dist. Ct. App. 2004) (consumer expectations test appropriate for injury allegedly caused by a defective seatbelt shoulder harness). But see Pruitt v. Gen. Motors Corp., 86 Cal. Rptr. 2d 4 (Ct. App. 1999) (On facts similar to Bresnahan, the appellate court upheld a trial court finding that the consumer expectations test was inappropriate.). For other cases indicating that California courts generally read the consumer expectations test narrowly, see HENDERSON AND TWERSKI, supra note 9, at 287.

189 See OVEN, PRODUCTS LIABILITY LAW, supra note 9, § 2.5; DAN B. DOBBS, THE LAW OF TORTS §§ 154-55 (2000); PROSSER AND KEETON, THE LAW OF TORTS § 39 (1984); HENDERSON & TWERSKI, supra note 9, at 176.

190 See Delaney v. Deere & Co., 999 P.2d 930 (Kan. 2000). Answering a certified question from the U.S. Court of Appeals for the Tenth Circuit, the Kansas high court announced that it rejected the Restatement (Third) standard and “adopted the consumer expectations test . . . .” Id. at 946. It should be borne in mind that in Delaney, the plaintiff had clearly proven a reasonable alternative design case sufficient to reach the jury under the Restatement (Third) section 2(b) test.

191 See infra note 193 and accompanying text.


193 In Kirkland v. General Motors Corp., 521 P.2d 1353, 1360 (Okla. 1974), the court adopted the consumer expectations test. There is a dearth of Oklahoma cases utilizing the consumer expectations test in classic design defect cases. The consumer expectations test has been applied to section 3 res ipsa-like cases. See, e.g., Dutsch v. Sea Ray Boats, Inc., 845 P.2d 187, 190 (Okla. 1992).

194 In Vincer v. Esther Williams All-Aluminum Swimming Pool Co., 230 N.W.2d 794 (Wis. 1975), Wisconsin adopted the consumer expectations test. More recently, in Green v. Smith &
For almost two decades, Maryland utilized risk-utility balancing and required proof of a reasonable alternative design to make out a prima facie case of design defect. Then, in what appeared to be an abrupt reversal in Halliday v. Sturm, Ruger & Co., the Supreme Court embraced the consumer expectations test. Plaintiffs’ decedent, a three-year old boy, shot himself while playing with his father’s handgun. The gun was sold with a lock box in which to store the gun, the magazine, and a padlock for the box. The instruction manual set forth multiple warnings about storing the handgun with special cautionary instructions about storing the gun away from children. There were also warnings that ammunition should be stored separately from the firearm. The boy’s father disregarded virtually every one of the warnings. Rather than putting the gun in the lock box, he placed it under his mattress and kept the loaded magazine on a bookshelf in the same room so that it was visible and accessible to his son. The child found the gun and the magazine. From watching television he knew how to load the magazine into the gun. While playing with the loaded handgun, he shot and killed himself.

Plaintiff alleged that the gun was defective and unreasonably dangerous, suggesting a host of alternative designs that would have substantially reduced the likelihood that a young child could fire the gun. After a lengthy discussion of earlier Maryland cases, the court concluded that it would not apply a risk-utility standard to handguns and would bar the action because the gun met consumer expectations. The court said:

It is clear that under the consumer expectations test that . . . no cause of action had been stated in this case. There was no malfunction of the gun; regretfully it worked exactly as it was designed and intended to work and as any ordinary consumer would have expected it to work. The gun is a lawful weapon and was lawfully sold. What caused this tragedy was the carelessness of [the] father in leaving the weapon and the magazine in places where the child was able to find them, in contravention not only of common sense but of multiple warnings given to him at the time of purchase.

196 792 A.2d 1145 (Md. 2002).
197 Id. at 1148.
198 Id. at 1158.
The court then noted that, given the controversy surrounding the risk-
utility standard of the *Products Liability Restatement* and given the fact
that the legislature had enacted its own standard for the sale and
distribution of handguns, it would not adopt the risk-utility test for
handguns.199

Although the consumer expectations test is generally considered
to be more favorable to plaintiffs, a rigorous application of the test as the
sole grounds for deciding defect would result in negating legitimate
plaintiffs’ claims when a product satisfies consumer expectations,
perhaps because the risks are obvious, but could be made safer by
adopting reasonable alternative designs.200 Nonetheless, in comments
written shortly after Halliday, we predicted that Maryland courts would
revert to risk-utility balancing in classic design defect cases by declaring
that consumers have a right to expect reasonably designed products.201

Several post-Halliday cases have proven our prediction to be accurate.202
Although the consumer expectations test may occasionally be used as a
shield against liability, when the issue is whether a product was
reasonably designed, Maryland courts will resort to risk-utility balancing
and will not simply allow a plaintiff to recover based on disappointed
consumer expectations.

CONCLUSION

One may quibble with our assessments here and there regarding
whether one state or another has fully adopted risk-utility/reasonable
alternative design as the standard for design defect liability. But in the
broad view of the national landscape set forth in this Article, there is
little doubt that risk-utility balancing has carried the day.203 The

199 Id. at 1159 ("Given the controversy that continues to surround the risk-utility standard
articulated for design defect cases in § 2 of the RESTATEMENT (THIRD), we are reluctant at this point
to cast aside our existing jurisprudence in favor of such an approach on any broad, general basis . . . .
So far, the Legislature has chosen not to place these burdens on gun manufacturers but has attempted
to deal with the problem in other ways. We shall respect that policy choice.").

2007) (summary judgment granted to defendant against claim that a lawnmower was defectively
designed because dangers were known to a reasonable consumer); Halliday, 792 A.2d at 1158.

201 See JAMES A. HENDERSON, JR. AND AARON D. TWERSKI, PRODUCTS LIABILITY:
PROBLEMS AND PROCESS 266-67 (5th ed. 2004).

202 Higginbotham v. KCS Int’l, 85 F. App’x 911 (4th Cir. 2004) (utilizing risk-utility
balancing in deciding that swim ladder of a yacht was not defectively designed); Celmer v.
for summary judgment to manufacturer of trampoline relying on risk-utility balancing to show that
an alternative design was available that would have prevented plaintiff’s injury); Hoon v. Lightolier,
in Maryland design defect litigation and citing to section 2(b) of Products Liability Restatement),
rev’d on other grounds, 876 A.2d 100 (Md. 2005).

203 The issue is still unclear in only six states: Pennsylvania, Idaho, North Dakota, South
Dakota, Wyoming, and Vermont.

Whether Pennsylvania will adopt section 2 of the *Products Liability Restatement* will
shortly be decided by the Pennsylvania Supreme Court. The issue is before them in Bugosh v. I.U.
The law on design defect in North Dakota is similarly sparse. N.D. CENT. CODE §§ 28-01.3-05 to 28-01.3-06(4) (2006) set forth the consumer expectations test as the test for defect. The first case, see Johnson v. Am. Motors Corp., 225 N.W.2d 57 (N.D. 1974), involved a driver and passenger of an automobile who were incinerated when the gasoline tank exploded when struck from behind by another automobile. Id. at 59. The lower court granted summary judgment for the manufacturer, holding that the manufacturer was under no duty to make the automobile accident-proof. Id. at 62. On appeal, the high court reversed and remanded, indicating that the issue—whether a reasonable alternative design to the gasoline tank would have prevented the injury—was for the trier of fact. While the high court in Johnson adopted strict liability in tort, the standard applied was a negligent design. Id. at 65. The second case, see Endresen v. Scheels Hardware & Sports Shop, Inc., 560 N.W.2d 225 (N.D. 1997), involved a man who was permanently blinded in his right eye when his handgun exploded when he attempted to shoot an overloaded cartridge. Id. at 227. The lower court, without a jury, granted judgment for the plaintiff in the amount of $259,079.21. Id. An expert for the plaintiff testified that the use of reloaded ammunition was a common and foreseeable practice. Id. Further, the expert testified that other brands of firearms were designed to withstand reloaded ammunition. Id. Given that there is no judicial interpretation of the statute and that the few cases dealing with design defect were supported by reasonable alternative design, we believe that the standard for design defect is undecided in North Dakota. Many Idaho cases deal with the issue of when courts may draw an inference of defect without having to prove a specific defect. These are invariably res ipsa-like cases that are totally consistent with section 3 of the Products Liability Restatement. See, e.g., Fitting v. Dell Catalog Sales USA, No. CV-06-23-S-LMB, 2008 U.S. Dist. LEXIS 41946 (D. Idaho May 21, 2008); Bachman FXC Corp., No. CV-06-140-2-JLQ, 2007 U.S. Dist. LEXIS 20938 (D. Idaho Mar. 21, 2007); Mortenson v. Chevron Chem. Co., 693 P.2d 1038 (Idaho 1984). Few cases deal with the standard of design defect. Aside from noting that Idaho adopted section 402A for both manufacturing and design defects, see Rindlisbaker v. Wilson, 519 P.2d 421 (1974), the cases do not address the standard for design defect. However, in Pate v. Columbia Machine, Inc., 930 F. Supp. 451 (D. Idaho 1996), plaintiff’s hand was crushed when he sought to break up a jam in a block splitter. Id. at 455; see also Curtis v. DeAtley, 663 P.2d 1089 (Idaho 1983) (housekeeper injured when the chandelier she was cleaning fell on her); court reversed trial court’s grant of directed verdict against the distributor because the plaintiff’s expert suggested two alternative designs that would have prevented the accident). Wyoming has few cases discussing the issue of the standard for deciding design defect cases. However, in Campbell v. Studer, Inc., 970 P.2d 389, 392 (Wyo. 1998), the court cited to the text of section 2(b) in deciding a design defect case. Plaintiff had been thrown from an asphalt compactor and was killed with the compactor rolled over him. Plaintiff’s expert posited an alternative design on the grounds that the expert’s testimony was insufficient to support the proposition that the alternative design was practical. After citing to section 2(b) the court said:

The requirement that plaintiff show the existence of a reasonable alternative design as an element of her claim has been the subject of extensive debate. Comments b and e to this section, however, suggest an alternative design may not be necessary in every design defect case. We need not enter the debate at this time because Campbell’s allegations clearly rest on her contention that a feasible alternative design was available.

Id. at 392 n.1. It is important that the court noted to the comments to section 2(b) that indicate that the Products Liability Restatement does not always require proof of a reasonable alternative design. This would indicate that the court understands the subtlety of the Restatement and would be more likely to adopt it. Nonetheless, in our opinion, we would categorize Wyoming as a state that is leaning toward adoption of Restatement section 2(b) and its comments. Not many Vermont cases, both on the state and federal level, deal directly with the standard for design-based liability. Vermont adopted the doctrine of strict products liability in 1975, in accordance with the RESTATEMENT (SECOND) OF TORTS § 402A (1965). See Zaleskie v. Joyce, 333 A.2d 110, 113-14 (Vt. 1975). Subsequent high court decisions indicate that design-based
overwhelming majority of cases that rely on consumer expectations as the theory for imposing liability do so only in res ipsa-like situations in which an inference of defect can be drawn from the happening of a product-related accident. We do not disagree with those holdings. Indeed, section 3 of the Products Liability Restatement enthusiastically supports the principle that there is no need to prove a reasonable alternative design when a product fails to perform its manifestly intended function.204

Putting legal theory aside, the simple reality is that plaintiffs base their design defect claims on the availability of a reasonable alternative design. They are compelled by logic to do so. They must be able to explain to juries what is wrong with a product. The only way to do so is to posit a better, safer design. When their experts falter in providing credible evidence that a reasonable alternative design was available, they almost always face Daubert challenges. If they do not survive the Daubert challenge, they cannot fall back on the consumer expectations test. Where plaintiffs cannot establish product malfunction they must establish that the product failed to meet the risk-utility standard. They live or die by their ability to establish a reasonable alternative design. The test for design defect set forth in the Products Liability Restatement merges sound legal theory and actual litigation practice. It will stand the test of time.

jurisprudence in Vermont remains largely undeveloped. See Farnham v. Bombardier, Inc., 640 A.2d 47 (Vt. 1994); see also Webb v. Navistar Int'l Transp. Corp., 692 A.2d 343 (Vt. 1996). Farnham involved a plaintiff who suffered a head injury when he was thrown off his snowmobile while driving at high speeds. Farnham, 640 A.2d at 48. Plaintiff claimed that the snowmobile was defectively designed with regard to its ability to break at high speeds. Id. The lower court granted summary judgment for the defendant in a strict products liability action. Id. On appeal, the high court affirmed, citing the open and obvious nature of the risk involved in addition to the failure of the plaintiff's expert to establish a design defect. Id. at 49. The high court did not address nor expand upon any of the customary design-based tests.

204 See supra note 151.
NOTES
Dirty Digits
THE COLLECTION OF POST-CUT-THROUGH DIALED DIGITS UNDER THE PEN/TRAP STATUTE

INTRODUCTION

Telephone users commonly pay outstanding bills or verify bank account balances by navigating an automated system and entering the appropriate digits. In some cases, a caller might dial digits to input personal information, such as a social security number or a pin number to access confidential accounts. Nevertheless, many telephone users would be disturbed to learn that law enforcement agencies may record and store indefinitely all of the digits dialed from a specific telephone without a warrant, without notification to the user, and without a showing of probable cause.

The device that enables law enforcement agencies to collect the outgoing digits a telephone user dials is called a pen register. Though at one time pen registers exclusively monitored telephones, today pen registers monitor communications conducted over a variety of electronic media. In the case of telephones, a pen register can record both the digits dialed to connect a telephone call to its destination and the digits dialed after connection occurs, such as those dialed to navigate automated

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1 In re United States for Orders (1) Authorizing the Use of Pen Registers and Trap and Trace Devices and (2) Authorizing Release of Subscriber Info. (E.D.N.Y. I), 515 F. Supp. 2d 325, 328 (E.D.N.Y. 2007). Because the names of the published orders this Note discusses are unwieldy, this Note will refer to the orders by the jurisdiction in which they were decided. Where a district has published more than one order, roman numerals indicate the chronological order in which the orders were issued.


3 Id. at 117. Pen registers perform the inverse function of trap-and-trace devices, which collect information about all calls received by a particular telephone. Id. The Pen/Trap Statute regulates both pen registers and trap-and-trace devices. See 18 U.S.C. §§ 3121-3127 (2006) (“Pen/Trap Statute”). The statutory definition of a pen register is located in 18 U.S.C. § 3127(3) (“Definition”) and discussed in more detail in Parts I.A and I.C.

4 See infra notes 25-27 and accompanying text.
menus. These latter digits are known as “post-cut-through dialed digits” (“PCTDDs”).

To date, researchers have failed to develop technology that can effectively screen PCTDDs that contain a telephone user’s substantive information, such as account or PIN numbers, from PCTDDs that do not contain substantive information, such as digits the user dials after being connected to a calling card company, which are technically PCTDDs but may also represent the actual destination of the telephone call. Therefore, when using a pen register to collect all digits dialed by a particular telephone user, law enforcement agencies inevitably collect all PCTDDs dialed by the user to navigate automated systems, even when those digits contain the user’s substantive information.

Between 2006 and 2008, six courts issued pen register orders denying the government’s application to install and use a pen register to collect all PCTDDs dialed by a subject telephone. Principally, this Note extracts from this series of pen register orders the three unique interpretations of the Pen/Trap Statute that informed the courts’ conclusions. Next, by analyzing those three perspectives in light of both the statutory text and the legislative history of the Pen/Trap Statute, this Note ultimately argues that the collection of PCTDDs that contain the substantive content of telephone users’ communications runs afoul of

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5 See infra Part I.A. for a more detailed discussion of pen registers. See also U.S. Telecom Ass’n. v. FCC, 227 F.3d 450, 462 (D.C. Cir. 2000).
7 In re United States for Orders (1) Authorizing the Use of Pen Registers and Trap and Trace Devices and (2) Authorizing Release of Subscriber Info. (E.D.N.Y. I), 515 F. Supp. 2d at 332 n.5; see also U.S. Telecom, 227 F.3d at 462 (“Some post-cut-through dialed digits are telephone numbers, such as when a subject places a calling card, credit card, or collect call by first dialing a long-distance carrier access number and then, after the initial call is ‘cut through,’ dialing the telephone number of the destination party.”).
8 Each published pen register order denied a law enforcement agency’s application to record all digits dialed from a specific telephone using a pen register. See In re United States for an Order Authorizing the Use of a Pen Register and a Trap and Trace Device on Wireless Tele. Bearing Tele. No. [Redacted], Subscribed to [Redacted] (E.D.N.Y. III), No. 08 MC 0595, 2008 U.S. Dist. LEXIS 101364, at *15-*16 (E.D.N.Y. Dec. 15, 2008); In re United States for an Order Authorizing the Use of Two Pen Register and Trap and Trace Devices (E.D.N.Y. II), No. 08-308, 2008 U.S. Dist. LEXIS 97359, at *26 (E.D.N.Y. Nov. 22, 2008); In re United States for an Order: (1) Authorizing the Installation and Use of a Pen Register and Trap and Trace Device, and (2) Authorizing Release of Subscriber and Other Info. (S.D. Tex. II), No. H-07-613, 2007 U.S. Dist. LEXIS 77635, at *34-*35 (S.D. Tex. Oct. 17, 2007); E.D.N.Y. I, 515 F. Supp. 2d at 339; In re Application of United States for an Order Authorizing (1) Installation and Use of a Pen Register and Trap and Trace Device or Process, (2) Access to Customer Records, and (3) Cell Phone Tracking (S.D. Tex. I), 441 F. Supp. 2d 816, 837 (S.D. Tex. 2006); In re United States for an Order Authorizing the Installation and Use of an Elec. Computerized Data Collection Device Equivalent to a Pen Register and Trap and Trace Device, No. 06:06-mj-1130 (M.D. Fla. June 20, 2006) (order affirming partial denial of application for the installation and use of pen register and trap and trade device). To date, no court has published an order granting such a request, although presumably such orders are granted routinely.
both the Pen/Trap Statute and the Fourth Amendment of the United States Constitution and should be prohibited.

Specifically, in Part I, this Note briefly reviews relevant background information about pen register technology, as well as the common-law and statutory provisions that restrict the use of pen registers and the collection of content by law enforcement agencies. In Part II, this Note emphasizes the interplay between two provisions of the Pen/Trap Statute—18 U.S.C. § 3121(c) and 18 U.S.C. § 3123(7)—which has given rise to the three prominent and conflicting interpretations of the Pen/Trap Statute. By viewing these interpretations in light of traditional canons of statutory interpretation and the statute’s legislative history, Part II concludes that the Pen/Trap Statute should not be viewed as authorizing the use of pen registers to collect PCTDDs that contain content. Specifically, because the Fourth Amendment most likely protects PCTDDs that contain content, the canon of constitutional avoidance suggests that future courts should interpret the Pen/Trap Statute to prohibit the collection of PCTDDs that contain content.

Building on Part II’s discussion, Part III.A presents this Note’s primary conclusion, which is that the statutory ambiguity should be cured by either amending or eliminating 18 U.S.C. § 3121(c). Part III.B briefly summarizes suggestions made by other commentators who have advocated general amendments to the Pen/Trap Statute. Finally, Part IV reemphasizes the conclusion that the collection of content in the form of PCTDDs is unconstitutional and urges Congress to take steps to prevent the continuation of this practice.

I. THE RELATIONSHIP BETWEEN PEN REGISTERS AND THE COLLECTION OF CONTENT

Part I.A explains what a pen register is and traces its evolution from a device that originally assisted telephone service providers in the ordinary course of business, to a tool that law enforcement agencies routinely employ during investigations. Part I.B explores judicial limitations imposed on the government’s ability to intercept the content of electronic communications, including its use of pen registers, in a series of Supreme Court decisions. These decisions in turn have informed Congressional action with respect to pen registers, including the original passage of and later amendments to the Pen/Trap Statute, which Part I.C addresses in detail. The brief review of this well-trodden history sets the stage for Part II’s analysis of the recent pen register orders and the Pen/Trap Statute’s ambiguous text.

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9 U.S. CONST. amend. IV (“The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.”).
A. Identifying a Pen Register

Telephone service providers use pen registers in the ordinary course of business to perform monthly billing operations and to prevent illegal and fraudulent uses of telephone lines. Yet, as a result of the inherent value of the information that pen registers collect, pen registers are also important for law enforcement agencies conducting investigations into criminal activities. No available statistics tabulate the total number of pen register applications approved in the United States for law enforcement agents. However, one commentator estimated that in 2007 alone, that figure was at least 60,000.

Whether or not a particular device is a pen register depends on the exact capabilities of the device in light of the statutory definition of a pen register. Because technology and statutes constantly evolve, judicial conceptions and statutory definitions of a pen register have also changed over time. The current statutory definition of a pen register contains expansive language that resulted from amendments intended to allow pen registers to monitor activities conducted over a variety of digital mediums, including digital telephones, cellular phones, digital pagers, Internet browsing, and electronic mail. Yet, the earliest


11 See N.Y. Tel. Co., 434 U.S. at 177-78 (acknowledging congressional intent to treat the pen register as a permissible law enforcement tool); see also 86 Ops. Cal. Atty. Gen. 198, No. 03-406 at *2 (Dec. 18, 2003) (“The placement of pen registers and trap and trace devices allows law enforcement officers to obtain such information as the names of suspects in an investigation, the identities and relationship between individuals suspected of engaging in criminal activity, especially in conspiracies, and the location of fugitives.”).

12 Pen registers are approved on an individual basis by courts pursuant to ex parte requests by law enforcement agents. 18 U.S.C. § 3123(a). The Pen/Trap Statute imposes an obligation on the Attorney General to report to Congress each year the total number of pen registers for which agents of the DOJ applied. 18 U.S.C. § 3126. However, these reports are not publicly available and other authors have been unable to obtain them despite thorough efforts. See, e.g., Robert Ditzion, Electronic Surveillance in The Internet Age: The Strange Case of Pen Registers, 41 AM. CRIM. L. REV. 1321, 1347 n.162 (2004). Most evidence of the total number of pen register applications granted appears to be anecdotal. See Giardi, infra note 13, at 554; see also Carl S. Kaplan, Concern Over Proposed Changes in Internet Surveillance, N.Y. TIMES, Sept. 21, 2001, available at http://www.nytimes.com/2001/09/21/technology/21CYBERLAW.html?ex=1236315600&en=c0400d2e20e6291&ei=5070 (quoting former DOJ trial attorney who claimed to use pen registers to obtain non-content “hundreds of times”) (on file with author).


15 See infra Part I.B.

16 See infra Part I.C.

17 See Freiwald, supra note 14, at 982-86.

18 See infra Part I.C; see also 18 U.S.C. § 3127(3) (2006) (“[T]he term ‘pen register’ means a device or process which records or decodes dialing, routing, addressing, or signaling information transmitted by an instrument or facility from which a wire or electronic communication is transmitted . . . .”).
devices that Congress and courts considered to be pen registers lacked this wide scope of functions.

The primitive pen register of the 1960s attached to a telephone line and then generated a paper tape on which it printed dashes that correlated to the outgoing numbers the user dialed.\(^{19}\) Because at that time telephone users only used telephones to place phone calls, many believed that any device that detected the digits dialed to connect a call could not reveal the substantive information the user communicated during the call.\(^{20}\) Understandably, laws and attitudes failed to anticipate how the nature and use of communication devices, including telephones, would evolve and expand in the decades to follow.\(^{21}\)

Today, telephones serve many purposes aside from facilitating conversation.\(^{22}\) Similarly, a proliferation of digital devices with complex and innovative capabilities can monitor far more about a single telephone call than merely the digits the user dialed. Devices can easily capture the “time, date, and duration” of calls.\(^{23}\) In the case of a cellular telephone user, a pen register can supply information that can be used to calculate the user’s physical location or track the user’s movements in real time.\(^{24}\) Litigation has tested the outer boundaries of what devices are properly considered to be pen registers. For instance, plaintiffs have challenged the use by law enforcement agencies of pen registers to clone a suspect’s pager,\(^{25}\) track a suspect’s web site activity,\(^{26}\) or monitor the flow of e-mail traffic into and away from a particular e-mail account.\(^{27}\) In resolving plaintiffs’ claims, courts have crafted their views of which devices may qualify as pen registers in light of the statutory text. One court, for instance, speculated that a device that allowed its operator to eavesdrop on actual telephone conversations could fall within the statutory definition of a pen register, so long as the eavesdropping function was

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\(^{21}\) See In re United States for Orders (1) Authorizing the Use of Pen Registers and Trap and Trace Devices and (2) Authorizing Release of Subscriber Info. (E.D.N.Y.), 515 F. Supp. 2d, 325 328 (E.D.N.Y. 2007). But see Olmstead v. United States, 277 U.S. 438, 474 (1928) (Brandeis, J., dissenting) (“Ways may some day be developed by which the government, without removing papers from secret drawers, can reproduce them in court, and by which it will be enabled to expose to a jury the most intimate occurrences of the home. . . . Can it be that the Constitution affords no protection against such invasions of individual security?”).

\(^{22}\) For instance, the Apple i-Phone allows its user to browse the Internet, e-mail, download music, and utilize maps with GPS tracking, in addition to other features. See Apple-iPhone-Features, http://www.apple.com/iphone/features/ (last visited Feb. 9, 2009).

\(^{23}\) Freiwald, supra note 14, at 986.

\(^{24}\) The use of pen registers to track telephone users in real time is also controversial. See, e.g., Timothy Stapleton, Note, The Electronic Communications Privacy Act and Cell Location Data: Is the Whole More than the Sum of its Parts?, 73 BROOK. L. REV. 383, 385 (2007) (recommending that the Pen/Trap Statute be amended to prevent the use of a pen register to collect cell site data without a showing of probable cause).


\(^{26}\) United States v. Forrester, 512 F.3d 500, 504 (9th Cir. 2008).

\(^{27}\) Warshak v. United States., 532 F.3d 521, 524 (6th Cir. 2008).
inactive. Another court concluded that a device that monitored the URL addresses that the defendant visited, as well as the e-mail addresses of those to whom he sent messages, was a pen register. Recently, another court concluded that a device that collected content was statutorily precluded from being a pen register, even if the government stipulated that it would only decode pre-cut-through dialed digits.

In short, the classification of a device as a pen register is primarily functional, but not exclusively so. The analysis depends not only on the capabilities of a specific device in light of the statutory definition of a pen register, but also turns on the philosophy of the particular court applying that language to a particular device. Accordingly, both Congress and the courts play significant roles in determining whether a device is a pen register. Parts I.B and I.C explore those roles, respectively.

B. The Supreme Court’s Treatment of Content, Non-Content, and Pen Registers

The current statutory definition of a pen register provides that the information that a pen register records or decodes “shall not include the contents of any communication.” The term “contents” is a legal term of art with a meaning developed over time through both case law and legislation. In simplistic terms, the content of a particular electronic communication includes the substantive aspects of that communication, as distinguished from those attributes of the communication that relate exclusively to its facilitation. The digits dialed to connect a telephone call, the delivery address written on the outside of a mailed envelope, or the email address of the user to whom an email is sent all exemplify attributes that facilitate a communication, but which ordinarily do not reveal the substantive content of the communication.

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28 People v. Kramer, 706 N.E.2d 731, 737 (N.Y. 1998) (concluding that if a device’s digital and audio functions were “sufficiently discrete” and there was a “remote” likelihood of misuse, the presence of audio-capable technology would not disqualify the device from use as a pen register).

29 Forrester, 512 F.3d at 504.


31 See Freiwald, supra note 14, at 985-86.


34 Susan Freiwald usefully distinguishes between communication content and communication attributes. See Freiwald, supra note 14, at 953 (“[A]tributes [of a communication] include the existence, duration and . . . the identities of the parties to it, their physical locations and their electronic addresses.”).

35 See, e.g., United States v. Huie, 593 F.2d 14, 15 (5th Cir. 1979).

36 See United States v. Forrester, 512 F.3d 500, 510 (9th Cir. 2008).
This understanding of content can be traced back to 1967, when the Supreme Court held in *Katz v. United States* that the Fourth Amendment’s probable cause requirement applied to the substantive aspects of a telephone communication if the speaker’s expectation of privacy in his conversation was reasonable. The Fourth Amendment to the United States Constitution guarantees “[t]he right of the people to be secure in their persons, houses, papers and effects, against unreasonable searches and seizures.” In *Katz*, the Court considered whether the government had conducted an unreasonable search by electronically intercepting the dialogue of a telephone call that the defendant placed on a public telephone from within a telephone booth. The Court of Appeals had concluded that the government’s action was not a search for Fourth Amendment purposes because the government had not physically entered the telephone booth in order to intercept the communication. The Supreme Court rejected this conclusion, explaining that the Fourth Amendment protects “people—and not simply ‘areas’ against unreasonable searches and seizures.” The Court concluded that to apply the Fourth Amendment more narrowly would be to “ignore the vital role” of the telephone in modern life.

The concurring opinion by Justice Harlan fashioned a two-pronged test to determine whether a search was unreasonable. Courts later adopted this test as the standard for determining the legality of a search under the Fourth Amendment. Under this articulation, the Fourth Amendment protects parties who have either an objectively legitimate expectation of privacy, or a subjective expectation of privacy that “society is prepared to recognize as reasonable.” Applying this test to the defendant’s conversation in the telephone booth, Justice Harlan concluded that the defendant had a legitimate expectation that what he said to the other party during the call was private. Since his expectation of privacy was reasonable, the interception of the defendant’s

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38 *Id.* at 353-54.
39 U.S. CONST. amend. IV.
40 *Katz*, 389 U.S. at 348-50.
41 *Id.* at 348-49. This reasoning followed from early Supreme Court jurisprudence. See, e.g., *Olmstead v. United States*, 277 U.S. 438, 466 (1928) (concluding that warrantless wiretapping was not a search under the Fourth Amendment unless the defendant’s physical property had been invaded).
42 *Katz*, 389 U.S. at 353.
43 *Id.* at 352.
44 *Id.* at 361 (Harlan, J., concurring).
45 See, e.g., *Smith v. Maryland*, 442 U.S. 735, 740 (1979); see also *Kyllo v. United States*, 533 U.S. 27, 33 (2001) (concluding that the use of thermal imagery to measure heat emanating from within a private home constituted an unreasonable search under the Fourth Amendment); *California v. Ciraolo*, 476 U.S. 207, 213-15 (1986) (concluding that the warrantless observation of a private backyard did not constitute an unreasonable search under the Fourth Amendment).
46 *Katz*, 389 U.S. at 361 (Harlan, J., concurring) (quotation marks omitted).
47 See *id.*
communication constituted an unreasonable search under the Fourth Amendment.48

Congress responded to the *Katz* decision the following year by enacting Title III of the Omnibus Crime Control and Safe Streets Act of 1968,49 which provided statutory protection for the “content”50 of communications.51 Part I.C discusses this legislation in greater detail. In short, Title III, commonly known as the “Wiretap Act,” set forth procedures for obtaining authorization to intercept a wire or oral communication.52 Under Title III, after a government agent demonstrates probable cause in a federal court, the court may issue a warrant authorizing the government to intercept the content of a private communication falling under Title III.53 Title III incorporated the basic principle of *Katz* by defining content, “with respect to any wire, oral or electronic communication, [as] includ[ing] any information concerning the substance, purport or meaning of that communication.”54

In 1977, in *United States v. New York Telephone Co.*, the Court first considered the relationship between pen registers and the “content” protected by Title III.55 New York Telephone Company had resisted a directive from the FBI to install pen registers on two telephone lines the defendants used in an illegal gambling enterprise.56 Although the government possessed probable cause to believe that the defendants used the telephone lines illegally,57 the telephone company argued that the district court could only order it to furnish facilities and technical assistance to the government in connection with a wiretap order conforming to Title III.58 The Court rejected this argument and concluded that pen registers were not governed by Title III because they were incapable of “intercept[ing]” the content of wire or oral communications.59 Relying on the prevalent understanding at the time, the Court concluded that digits dialed into a telephone lacked the capacity to be substantive. Consequently, it followed that pen registers posed a lesser threat to privacy than traditional wiretaps because they

48 See id.
50 Id. § 2510(8) (defining “content”).
51 Id. § 2511 (prohibiting the interception and disclosure of wire, oral, or electronic communications).
52 See id. §§ 2510-2522.
53 Id. § 2518(1)(a)-(f), (3).
54 Id. § 2510(8).
56 Id. at 162.
57 Id. 161-62.
58 Id. at 162-63.
59 Title III defines “intercept” as the “aural or other acquisition” of content. 18 U.S.C. § 2510(4). Because a pen register does not monitor sound, the court concluded that a pen register cannot “intercept” content. *N.Y. Tel. Co.*, 434 U.S. at 166-67.
could not reveal substantive information about a telephone communication.  

In *New York Telephone*, the government possessed probable cause to believe that the defendants used telephone lines illegally. Consequently, the Court had no occasion to rule on the minimal showing of suspicion needed to justify the use of a pen register. However, the Court answered that open question in 1979 in the case of *Smith v. Maryland*. The defendant, Smith, appealed his robbery conviction on the grounds that the government’s investigation included the installation and use of a pen register to monitor his telephone use without a warrant. Writing for the Court, Justice Blackmun affirmed the decision by the Court of Appeals of Maryland, and held that Fourth Amendment protections do not apply to dialed digits. To reach this conclusion, the Court applied the *Katz* test and concluded that a telephone user does not have a legitimate expectation of privacy in dialed numbers because the user is aware that the telephone company monitors the numbers dialed to connect a telephone call. This holding reflected a basic tenet of the Court’s Fourth Amendment jurisprudence: an individual does not have a reasonable expectation of privacy in information that the individual voluntarily turns over or conveys to a third party. In revealing information to a third party, even on the assumption that it will be kept secret, one assumes the risk that that party may reveal that information to the government.

The Court identified several ways in which a telephone subscriber receives notice that a telephone company has facilities that enable it to document its subscribers’ dialing activities. The Court

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60 See id. at 168.
61 Id. at 162.
62 See id. at 165 n.7.
63 442 U.S. 735 (1979).
64 Id. at 737.
66 Smith, 442 U.S. at 742.
67 Id.
68 See id.
69 Id. at 743-44. Professor Orin S. Kerr refers to this principle as “the disclosure principle.” Orin S. Kerr, *Internet Surveillance Law After the USA Patriot Act: The Big Brother that Isn’t*, 97 NW. U. L. REV. 607, 628 (2003); see also Orin S. Kerr, *The Case for the Third-Party Doctrine*, 107 MICH. L. REV. 561, 561 (2009) (defending “the controversial rule that information loses Fourth Amendment protection when it is knowingly revealed to a third party”). The disclosure principle has guided judicial decision making in a variety of contexts. See, e.g., United States v. Miller, 425 U.S. 435, 442 (1976) (bank depositor’s records, including checks and deposit slips); United States v. Haie, 593 F.2d 14, 15 (5th Cir. 1979) (address information on outside of mailed envelope); Tyler v. Berd, 877 F.2d 705, 706-07 (8th Cir. 1989) (interception of content of telephone conversation on portable phone by radio in the vicinity).
70 *Smith*, 442 U.S. at 744 (quoting *Miller*, 425 U.S. at 442); see also United States v. Jacobsen, 466 U.S. 109, 117 (1984) (discussing the disclosure principle in connection with the seizure and search by federal agents of packages determined to contain cocaine).
71 A telephone user realizes that by dialing digits, those digits are conveyed to the telephone company in order to complete the call. The user also receives a monthly itemized bill that
emphasized that its conclusion did not rely on whether the telephone company in fact monitored any dialed digits, but rather rested on the petitioner’s knowledge that such a possibility existed. Because a telephone user has notice of the possibility of monitoring, the use of a telephone constitutes an assumption of risk by the user that digits dialed will not be secret from the telephone company, which might in turn reveal those numbers to the government. Even if an individual telephone user subjectively believed that dialed digits were private, that belief would be unreasonable and, under Katz, not protected by the Fourth Amendment. Thus, the Court held that “[t]he installation and use of a pen register . . . was not a search, and no warrant was required.”

Smith marked the last time that the Supreme Court considered the use of pen registers. Therefore, Smith’s holding—that the use of a pen register does not constitute a search and therefore does not require probable cause—remains relevant to that area of law today. However, as the next subsection addresses, Congress has acted on several occasions since Smith to craft and amend federal law in order to keep pace with evolving technology and the specific questions raised by the continued exception of pen registers from Title III’s warrant requirement.

C. The Evolution of the Pen/Trap Statute

The statutory scheme that regulates the use of pen registers can best be understood by examining in chronological order four public laws, including Title III of the Omnibus Crime Control and Safe Streets Act of 1968 ("Title III"), the Electronic Communications Protection Act of 1986 ("ECPA"), the Communications Assistance for Law Enforcement Act of 1994 ("CALEA"), and the USA PATRIOT Act of 2001, each

lists numbers dialed. Most telephone books also notify telephone users that the telephone company may monitor dialing activity to identify users that make improper phone calls, or to regulate or maintain the telephone line. Thus, a telephone user is on notice of the company’s ability to monitor dialed digits. Smith, 442 U.S. at 742-43. Today, these uses are statutorily preserved by an exception in 18 U.S.C. § 3121(b) (2006).

See Smith, 442 U.S. at 745.

Id. at 743.

Id. at 743-44. The court noted, however, that its conclusions applied as a result of the telephone company’s known practices, and therefore did not foreclose the reasonableness of the defendant’s expectation that the content of his telephone conversation would remain private. See id. at 743.

Id. at 745-46 (quotation marks omitted).

See, e.g., United States v. Forrester, 512 F.3d 500, 509 (9th Cir. 2008) (considering the application of Smith to the use of pen registers to record e-mail and Internet activities).


of which directly affected the use of pen registers. This Note takes the view that legislative history, particularly statements in committee reports or made by a bill’s sponsor, is relevant to courts that must apply a statute that, by its plain language, is ambiguous. The extent to which this sort of evidence should influence judicial decision making is often challenged by textualists, who take the view that the “text is the law.” Nevertheless, relevant examples of legislative history are interwoven with the history that this Part presents.

The evolution of the statutory scheme that regulates electronic surveillance, including the use of pen registers, has been fueled by Congress’ consistent desire to keep pace with the challenges posed by emerging technologies to traditional notions of privacy. By enacting Title III in 1968, Congress took a major step forward in its effort to protect electronic communications. The purpose of that bill was to become “the primary law protecting the security and privacy of business and personal communications.” However, Title III only provided protection for “oral” or “wire” communications that could “be overheard and understood by the human ear,” and which were transmitted over “common carriers.”

This changed in 1986 with the passage of the Electronic Communications Protection Act. The ECPA amended Title III to extend its protections to new forms of electronic communications. Members of Congress had become aware of dramatic technological changes that created new risks to the privacy and security of transmitted communications. The ECPA sought to prevent unauthorized interceptions of many different electronic communications in the same
way that Title III had done for oral and wire communications. The ECPA defined an “electronic communication” as “any transfer of signs, signals, writing, images, sounds, data, or intelligence of any nature transmitted in whole or in part by a wire, radio, electromagnetic, photoelectronic or photooptical system that affects interstate or foreign commerce.” This broad definition brought modern technologies, such as the Internet and e-mail, under Title III’s purview. Consequently, law enforcement agencies had to follow Title III’s procedures, including a showing of probable cause, in order to intercept the content of any electronic communication.

The ECPA also articulated federal guidelines for the installation and use of pen registers. In 1986, Congress viewed a pen register as a device that, in its limited capacity, could only record the telephone numbers to which a telephone user placed calls, yet could not capture any part of an actual telephone conversation. Consequently, the ECPA established separate and lower standards for the installation and use of pen registers than those that applied to content-intercepting devices under Title III. The distinct sections of the ECPA that regulate pen registers and trap-and-trace devices are referred to as the Pen/Trap Statute.

The standards that govern the installation and use of a pen register under the Pen/Trap Statute differ from those that govern content-intercepting devices under Title III in four ways that are relevant to this discussion generally, as well as to the statutory amendments that Part III of this Note suggests.

First, Title III applications must satisfy a higher standard of proof than pen register applications. Under 18 U.S.C. § 2518, a judge may only issue a wiretap warrant under Title III if the judge determines on the basis of the facts submitted by the applicant that there is probable cause to believe that “an individual is committing, has committed, or is

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91 Brown, 50 F.3d at 289.
93 See id. § 2518(1)(d), (3).
96 See 18 U.S.C. § 2511(2)(h)(i) (providing that the use of pen registers is not regulated by Title III).
97 See infra note 102 and accompanying text.
99 Compare 18 U.S.C. § 2518(1) (requiring extensive disclosure incident to a wiretap application including, among other things, full and complete statements of fact about the investigation and any alternative procedures employed to obtain the desired information without a wiretap), with id. § 3122(b) (requiring minimal disclosure incident to a pen register application, limited to the identity of the applicant and the agency conducting the investigation and a certification that the information sought is relevant to the investigation being conducted).
about to commit” a qualified offense.100 In contrast, a pen register application requires only that an attorney for the government certify to the court in writing and under oath that “the information likely to be obtained [by a pen register] is relevant to an ongoing criminal investigation being conducted” by the official’s agency.101 The lower standard of proof required for pen register applications is “far from burdensome.”102

Second, if an attorney for the government or a law enforcement official has made the proper certification to the court, then the court is compelled to order the installation and use of a pen register.103 This compulsory order leaves no room for judicial discretion in determining whether or not a pen register should be issued. A wiretap application, in contrast, is permissive. A federal judge has wide latitude for factual review in determining whether the particular facts support authorizing the interception of content.104

Third, the Pen/Trap Statute does not contain an exclusion requirement. As a result of this omission, evidence obtained pursuant to the wrongful or unlawful installation or use of a pen register may be admitted as evidence in a criminal case.105 The statute penalizes a knowing wrongdoer by authorizing the imposition by the court of either a fine or prison sentence, yet it has no effect on the fruit of such wrongdoing.106 This stands in contrast to the treatment of content wrongfully intercepted pursuant to Title III, which may be suppressed upon a petitioner’s motion.107

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100 Id. § 2518(3)(a).
101 Id. § 3122(b).
103 18 U.S.C. § 3123(a)(1)-(2); see also S. REP. No. 99-541, at 47 (1986), as reprinted in 1986 U.S.C.C.A.N. 3555, 3601 (“[Section 3123(a)] does not envision an independent judicial review of whether the application meets the relevance standard, rather the court needs only to review the completeness of the certification submitted.”); 147 CONG. REC. S10,990, S11,000 (daily ed. Oct. 25, 2001) (statement of Sen. Leahy) (“The court is required to issue an order upon seeing the prosecutor’s certification. The court is not authorized to look behind the certification to evaluate the judgment of the prosecutor.”).
104 18 U.S.C. § 2518(3) (providing that upon a satisfactory Title III application, a judge may enter a wiretap order) (emphasis added); see also United States v. Diaz, 176 F.3d 52, 110 (2d Cir. 1999) (discussing the circumstances under which a federal judge may authorize a wiretap order).
105 See, e.g., United States v. Fregoso, 60 F.3d 1314, 1320 (8th Cir. 1995); see also United States v. Thompson, 936 F.2d 1249, 1251-52 (11th Cir. 1991) (concluding that defendant could not show that Congress intended, either explicitly or implicitly, to provide suppression as a remedy for violation of the Pen/Trap Statute).
107 See id. § 2518(10)(a) (providing aggrieved party the right to move to suppress the fruits gathered pursuant to wiretap authorization that was unlawful due to either procedural or substantive misuse).
Fourth, Title III contains a minimization requirement. Under 18 U.S.C. § 2518(5), even where the government intercepts communications pursuant to a valid wiretap order, it must “minimize the interception” of irrelevant communications. Courts view this provision as requiring agents to take reasonable steps to avoid recording the content of communications that are not relevant to their investigations.

At the time of the ECPA’s passage, however, no such provision was incorporated into the Pen/Trap Statute. This omission may have been sensible given the fact that in 1986, neither courts nor Congress anticipated that the collection of dialed digits by a pen register could reveal more than the telephone number of the party to whom a call had been directed, which, under Smith, was not protected information.

By 1994, however, this view had changed markedly. That year, Congress passed CALEA in response to new challenges faced by law enforcement as a result of the “explosive growth” of wireless services and technologies, such as call forwarding, that had started to impede the government’s traditional wiretapping abilities. CALEA required the telecommunications network providers to develop the capacity to self-monitor their networks in order to expedite compliance with wiretap, pen register, or other court orders for electronic information. While expanding government access to electronic information, Congress also struggled to protect the reasonable expectation of privacy the law accorded to the content of electronic communications.

Section 207 of CALEA enacted 18 U.S.C. § 3121(c). Entitled “Limitation,” this section amended the Pen/Trap Statute by imposing a minimization requirement on the use of pen registers. The limitation, any agency authorized to install a pen register “shall use technology reasonably available to it that restricts the recording or

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108 See id. § 2518(5).
109 Id.
112 S.D. Tex. I 441 F. Supp. 2d 816, 826 (S.D. Tex. 2006); see also supra notes 75-76 and accompanying text.
116 Id. at 13 as reprinted in 1994 U.S.C.C.A.N. at 3493 (“CALEA seeks to balance three key policies: (1) to preserve a narrowly focused capability for law enforcement agencies to carry out properly authorized intercepts; (2) to protect privacy in the face of increasingly powerful and personally revealing technologies; and (3) to avoid impeding the development of new communications services and technologies.”); see also 47 U.S.C. § 1002(a)(4)(A) (2006) (emphasizing the importance of monitoring telecommunications networks “in a manner that protects . . . the privacy and security of communications and call-identifying information not authorized to be intercepted”).
decoding of electronic or other impulses to the dialing, routing, addressing, and signaling information utilized in the processing and transmitting of wire or electronic communications. 118 This new language reflected an emerging awareness of the fact that the digits a pen register collected could include content. 119

Divining the exact purpose behind the addition of the limitation, however, is no simple task. 120 Statements of purpose in the House Report 121 and statements by the bill’s sponsor, Senator Patrick Leahy, 122 indicate that Congress intended the limitation to protect the exercise of the government’s surveillance authority and may have contemplated allowing the government to collect PCTDDs that included content, so long as it endeavored to minimize content by using reasonably available technology. 123 On the other hand, statements of purpose 124 and statements

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119 During hearings in March, 1994, Senator Leahy and then FBI Director Louis Freeh discussed the fact that some PCTDDs contained content:

Sen. LEAHY: You say this proposal would not expand law enforcement’s authority to collect data on people, and yet if new technologies are used where we can dial up everything from a video movie to doing our banking over the phone, you are going to have access to a lot more data, just because the phone is being used.

Mr. FREEH: I do not want that access, and I am willing to concede that. What I want with respect to pen registers is the dialing information: telephone numbers which are being called, which I have now under pen register authority. As to the banking accounts and what movies somebody is ordering at Blockbuster, I do not want it, do not need it, and I am willing to have technological blocks with respect to that information, which I can get with subpoenas or another process. I do not want that in terms of my access, and that is not the transactional data that I need.


120 See infra Part II.C.
121 H.R. REP. No. 103-827, at 17, as reprinted in 1994 U.S.C.C.A.N. at 3497 (“[T]he bill . . . [e]xpressly provides that the authority for pen registers and trap and trace devices cannot be used to obtain tracking or location information, other than that which can be determined from the phone number . . . . Further, the bill requires law enforcement to use reasonably available technology to minimize information obtained through pen registers.”) (emphasis added).
122 140 CONG. REC. S11,055, S11,055-56, S11,059 (daily ed. Aug. 9, 1994) (“[T]he limitation requires that a] government agency authorized to install and use a pen register under this chapter or under State law, shall use technology reasonably available to it that restricts the recording or decoding of electronic or other impulses to the dialing and signaling information utilized in call processing.”); In re United States for Orders (1) Authorizing the Use of Pen Registers and Trap and Trace Devices and (2) Authorizing Release of Subscriber Info. (E.D.N.Y. I), 515 F. Supp. 2d 325, 333 (E.D.N.Y. 2007) (citation omitted).
124 See S. REP. No. 103-402, at 10 (1994) (“The bill further protects privacy by requiring telecommunications systems to protect communications not authorized to be intercepted and by restricting the ability of law enforcement to use pen register devices for tracking purposes or for obtaining transactional information.”).
by Senator Leahy in the Senate Report indicate that Congress intended the limitation to restrict the government’s access to transactional information, but are not amenable to an interpretation that views minimization favorably.

As Congress prepared to pass the USA PATRIOT Act of 2001 seven years later, Senator Leahy made several statements that appeared to support the view that he believed that Congress intended the limitation to prevent the collection of content. That year, Congress considered two proposed amendments to the Pen/Trap Statute, each of which prohibited the use of a pen register to collect content. To illuminate the necessity of the proposed amendments, Senator Leahy explained that although he had added the 1994 limitation after he “recognized that [pen registers] collected content and that such collection was unconstitutional on the mere relevance standard,” information obtained from the F.B.I. in June 2000 indicated that the limitation had not deterred law enforcement officials from collecting content with pen registers. The limitation did not have the effect of prohibiting the collection of content since, as the government argued, no technology was reasonably available that would allow it to distinguish PCTDDs that contained content from those that did not. Because it did not interpret the limitation’s prohibition to be absolute, the government had continued to collect content with pen registers in the same way that it had done for years.

In this context, Congress passed the PATRIOT Act, which, pursuant to § 216, amended two sections of the Pen/Trap Statute. First, § 216(a) amended 18 U.S.C. § 3121(c)—the 1994 limitation—to prohibit the collection of content pursuant to the installation and use of a pen register. As a result, the text of 18 U.S.C. § 3121(c) read and continues to read:

A government agency authorized to install and use a pen register or trap and trace device under this chapter or under State law shall use technology reasonably available to it that restricts the recording or decoding of electronic

128 147 CONG. REC. at S11,000 (statements of Sen. Leahy).
129 Id. (“[T]he FBI advised me in June 2000, that pen register devices for telephone services ‘continue to operate as they have for decades’ and that ‘there has been no change . . . that would better restrict the recording or decoding of electronic or other impulses to the dialing and signaling information utilized in call processing.’” (quoting FBI’s explanation to Senator Leahy)).
130 See id. For a summary of this same history, see Beryl A. Howell, Seven Weeks: The Making of the USA PATRIOT Act, 72 GEO. WASH. L. REV. 1145, 1198 (2004).
131 147 CONG. REC. at S11,000 (statements of Sen. Leahy).
or other impulses to the dialing, routing, addressing, and signaling information utilized in the processing and transmitting of wire or electronic communications so as not to include the contents of any wire or electronic communications.  

Section 216(c)(2) also modified 18 U.S.C. § 3127(3), which contains the statutory definition of a pen register. Specifically, Congress defined a pen register, for the first time, as a device that cannot collect content. The definition read and continues to read:

[T]he term “pen register” means a device or process which records or decodes dialing, routing, addressing, or signaling information transmitted by an instrument or facility from which a wire or electronic communication is transmitted, provided, however, that such information shall not include the contents of any communication . . . .

From this history, it is evident that when the 2001 amendments to the Pen/Trap Statute took effect, Congress was aware that PCTDDs could contain content. Further, Congress recognized that the government had interpreted the limitation that CALEA imposed in 1994 to authorize the collection of all PCTDDs in the absence of reasonably available technology to sort content from non-content. While amending the Pen/Trap Statute to include new prohibitions on content collection, Congress did not eliminate the “reasonably available technology” clause, which formed the basis of the government’s claimed authority to collect all PCTDDs. These observations are relevant to the analysis of the Pen/Trap Statute that courts have performed, which is discussed in Part II.

II. INTERPRETING THE PEN/TRAP STATUTE

Until 2006, no court directly addressed the question of whether the Pen/Trap Statute authorizes law enforcement agencies to collect PCTDDs that contain content. Between 2006 and 2008, six courts issued written orders that justified their decisions to deny the portion of a law enforcement agent’s ex parte application that sought to collect all

134 Id. § 3127(3).
135 Id. (emphasis added to reflect the 2001 amendment). The definition continues, “such term does not include any device or process used by a provider or customer of a wire or electronic communication service for billing, or recording as an incident to billing, for communications services provided by such provider or any device or process used by a provider or customer of a wire communication service for cost accounting or other like purposes in the ordinary course of its business.” Id. The PATRIOT Act also amended 18 U.S.C. § 3127(4), which defines trap and trace devices, to provide that a trap and trace device shall not collect the content of a communication. PATRIOT Act § 216(c)(3).
136 During this time, two courts referenced the PCTDD question in dicta. See U.S. Telecom Ass’n v. FCC, 277 F. 3d 450, 462 (D.C. Cir. 2000); see also In Re United States for an Order Authorizing the Use of a Pen Register and Trap on [xxx] Internet Service Account/User Name [xxxxxxxxxx@xxx.com], 396 F. Supp. 2d 45, 48 (D. Mass. 2005).
137 See supra note 8.
dialed digits from a telephone pursuant to the Pen/Trap Statute.\textsuperscript{138} Given the ex parte nature of each proceeding, the courts solicited amicus briefs to represent the interests of the telephone user. The six decisions reached inconsistent conclusions about whether the Pen/Trap Statute is ambiguous, whether canons of statutory interpretation are relevant to the question and, if so, how they apply, whether legislative history helps to answer the question, and whether the Fourth Amendment protects PCTDDs that contain content.\textsuperscript{139}

This Part approaches each question in turn. After identifying the different ways that the statute can be interpreted, Part II.A concludes that the plain language of the Pen/Trap Statute does not overwhelmingly lend support to any particular textual interpretation. As a result of this ambiguity, Part II.B applies traditional canons of statutory interpretation to the different interpretations of the Pen/Trap Statute. Although the canons lend support to the position that the Pen/Trap Statute does not authorize the collection of content, they ultimately fail to be entirely persuasive. Part II.C concludes that the legislative history of the Pen/Trap Statute is also not dispositive on the question of whether the statute authorizes the collection of minimal PCTDD content. However, Part II.D concludes that because society is prepared to recognize a reasonable expectation of privacy in PCTDDs that contain content, the canon of constitutional avoidance counsels against an interpretation that the Pen/Trap Statute authorizes the collection of content using a pen register.

A. The Plain Language of the Pen/Trap Statute

Following the cardinal rule of statutory interpretation, the opposing parties have argued that the plain language of the Pen/Trap Statute mandates a particular conclusion about the legality of collecting PCTDDs that contain content with a pen register.\textsuperscript{139} Consequently, three primary interpretations of the text have arisen, each of which fundamentally conflicts with the others. The role of the court in such circumstances is to determine whether the statute’s plain language supports one of the interpretations.\textsuperscript{140} This Part briefly summarizes the

\textsuperscript{138} That no court addressed this issue until five years after the passage of the PATRIOT Act may be partially attributed to the fact that pen register applications are ex parte proceedings that do not usually result in the publication of a written decision. 18 U.S.C. § 3123(a)(1) (2006). Further, because the court is not entitled to receive facts concerning the investigation beyond the investigator’s stipulation that the information sought to be collected is relevant, 18 U.S.C. § 3122(b) (2006), little has been documented about the number of pen register applications made and granted each year, or about the reasons that a particular court granted or denied an application. See, e.g., Ditzion, supra note 12, and accompanying text; see also Kevin S. Bankston, Only the DOJ Knows: The Secret Law of Electronic Surveillance, 41 U.S.F. L. REV. 589, 589-90 (2007).


\textsuperscript{140} See e.g., Barnhart v. Sigmon Coal Co., 534 U.S. 438, 450 (2002).
three perspectives in order to illustrate that the Pen/Trap Statute is ambiguous. Next, Part II.B critiques each perspective using traditional canons of statutory interpretation.

1. The Government’s Theory

The government has argued that the Pen/Trap Statute’s text authorizes the collection of PCTDDs that contain content. The government’s briefs express this theory in two assertions. First, the limitation in 18 U.S.C. § 3121(c) requires that if technology that can distinguish between content and non-content is reasonably available, then the government must use that technology to avoid collecting content. However, if technology that can screen content from non-content is not reasonably available, then the limitation permits the pen register to access content incident to its collection of non-content. Accordingly, the government views the limitation as an exception to the language in 18 U.S.C. § 3127(3) that provides that a pen register shall not collect the content of any communication.

2. The “Added Precaution” Theory

A contrary perspective adopted by some courts is that the limitation does not operate as an exception to the general prohibition on collecting content, but rather precludes the collection of all PCTDDs where the collection of content cannot be prevented. This theory can also be reduced to two assertions. First, if technology that is reasonably available to minimize the collection of content exists, then the government should use it to prevent the inadvertent collection of content. Second, if technology to screen content is not reasonably available, then the limitation prevents the collection of content.

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142 Thompson Memo, supra note 141, at 4 (articulating the DOJ’s position that the inadvertent collection of PCTDDs that contain content should be avoided but, where it occurs, the agent should not use the content affirmatively); see also Gov’t Brief, June ’07, supra note 141, at *1-2.

143 Gov’t Brief, June ’07, supra note 141, at *11.

144 Id. (“The [limitation] establishes ground rules governing circumstances in which it is difficult for the government to know in advance” whether pen register information represents content or non-content.).


government must use it.\textsuperscript{147} However, if no technology that is reasonably available can separate content from non-content, then the government may not collect PCTDDs.\textsuperscript{148} Under this theory, the limitation is only operative when technology that can screen content from non-content is reasonably available, in which instance the government must use it. Where such technology is not reasonably available, the limitation does not otherwise condone the use of a pen register to collect content.\textsuperscript{149} Thus, the limitation functions primarily as an “added precaution” to prevent content collection.\textsuperscript{150}

3. The “Preclusive Definition” Theory

A third perspective adopted by one court is similar to the second. Its proponents emphasize that under the definition of a pen register in 18 U.S.C. § 3127(3), it is unlawful for a pen register to record the content of a communication.\textsuperscript{151} If a device records PCTDDs that contain content, then that device is not a pen register.\textsuperscript{152} Under this theory, the limitation provision is not a factor in the analysis of whether in certain circumstances a pen register can collect PCTDDs that contain content, because as soon as a device collects content, the device is not a pen register, and the Pen/Trap Statute is no longer implicated.\textsuperscript{153}

4. Statutory Ambiguity

The next subsection demonstrates problems with each of these interpretations.\textsuperscript{154} At this point, it is only necessary to observe that each perspective is based on and equally supported by the plain language of the Pen/Trap Statute. This illuminates the fundamental flaw of the statute: it provides no guidance about the effect of an absence of reasonably available technology to effectively filter content from non-content. A more sensible approach is to view the first three theories

\textsuperscript{147} Id. at 825.
\textsuperscript{148} Id. at 825-26.
\textsuperscript{149} Id.; see also United States for an Order Authorizing the Installation and Use of an Elec. Computerized Data Collection Device Equivalent to a Pen Register and Trap and Trace Device, No. 06:06-mj-1130 at 5 (M.D. Fla. June 20, 2006) (“In the Court’s view, § 3121(c) operates as an additional privacy safeguard, rather than an enabling provision.”).
\textsuperscript{150} In re United States for an Order: (1) Authorizing the Installation and Use of a Pen Register and Trap and Trade Device, and (2) Authorizing Release of Subscriber and Other Info. (S.D. Tex. II), 2007 U.S. Dist. LEXIS 77635 at *31-32 (S.D. Tex. Oct. 17, 2007) (“The requirement to use ‘reasonably available technology’ is a supplement to the Government’s obligation not to collect contents with a pen register.”).
\textsuperscript{151} In re United States for an Order Authorizing the Use of a Pen Register and a Trap and Trace Device on Wireless Tele. Bearing Tele. No. [Redacted], Subscribed to [Redacted], Serviced By [Redacted] (E.D.N.Y. III), 2008 U.S. Dist. LEXIS 101364 at *8-*9 (E.D.N.Y Dec. 15, 2008).
\textsuperscript{152} Id. at *8-*9, *11.
\textsuperscript{153} See id. (denying government’s pen register application with no discussion of 18 U.S.C. § 3121(c)).
\textsuperscript{154} See infra Part II.B.
critically and conclude, as one court has done, that the Pen/Trap Statute is ambiguous. The language of the statute contradicts itself because the definition of a pen register includes an unconditional prohibition of the use of a pen register to collect content, yet the limitation provision appears to require only the use of reasonably available technology to prevent the collection of content.

B. Applying Canons of Statutory Interpretation to the Pen/Trap Statute

Canons of statutory interpretation are “rules of thumb” that courts apply to aid in statutory interpretation. Courts are not bound by the result that the application of a particular canon would produce. Further, the individual canons have been criticized for being easily countered. Nevertheless, courts continue to apply them routinely. Because the ambiguity inherent in the Pen/Trap Statute gives rise to several possible interpretations of its text, this Part will assess the effect of several applicable canons of construction on the three emergent interpretations.

The government’s interpretative theory is undesirable because it interprets statutory silence as modifying the plain commandment of 18 U.S.C. § 3127(3) that a pen register shall not collect content. To subscribe to the government’s view is to conclude that the limitation, which is only operative after the government has received authorization to use a pen register, alters the scope of what a pen register can do. Yet, the only way to reach the conclusion that the limitation alters the definition of a pen register is to rely on Congressional silence, which is generally undesirable. The statute fails to provide that the lack of reasonably available technology to sort content from non-content has any effect on the abilities of a pen register. This silence should not be interpreted as an implied exception to the clear commandment of 18

156 Id.
157 Id.
159 WILLIAM N. ESKRIDGE, JR., PHILIP P. FRICKEY & ELIZABETH GARRETT, CASES AND MATERIALS ON LEGISLATION STATUTES AND THE CREATION OF PUBLIC POLICY 849 (4th Ed. 2007).
161 See supra notes 141-145.
162 This canon of interpretation may be referred to as the “dog that did not bark.” Chisom v. Roemer, 501 U.S. 380, 396 n.23 (1991); see also Zuni Pub. Sch. Dist. No. 89 v. Dept. of Educ., 127 S. Ct. 1534, 1541-45 (2007).
164 See Chisom, 501 U.S. at 396.
U.S.C. § 3127(3), since it can be presumed that if Congress intended such an exception, it could easily have provided it explicitly. A second canon of interpretation advises courts to interpret an ambiguous statutory provision in a way that is consistent with the whole act of which it is a part. Under this canon, viewing the limitation as a prohibition of the collection of content where sorting technology is not reasonably available—the added precaution theory that some courts have adopted—is preferable to the government’s theory. Such an interpretation has the advantage of maintaining consistency within the Pen/Trap Statute, since it does not require inferring from statutory silence exceptions to the plain commandment in 18 U.S.C. § 3127(3). In this way, the interpretation minimizes the conflict between the limitation and the definition.

On the other hand, the precaution theory can be criticized on the grounds that adopting it renders the limitation mere surplusage. A separate canon of construction guides courts to avoid such a result, counseling against interpretations of statutory provisions that strip particular words of meaning. To conclude, as the precaution theory does, that the limitation operates to “supplement” the definition of a pen register is to say that the limitation merely reiterates, or repeats, what is written elsewhere. Yet such repetition is redundant. If a pen register by definition cannot collect content, then the limitation is unnecessary to the extent that it merely functions to remind courts that a pen register cannot collect content.

Formal logic is a useful way of illustrating the application of the canons of interpretation to the government’s theory and the precaution theory. As noted above, each perspective imposes a “gloss” onto the interplay between the two statutory provisions. Although the statute is not phrased in the form of an if-then conditional, both perspectives proceed from the assumption that it can be understood as such. For instance, both theories concur that under the statute, if technology to sort content from non-content is reasonably available, then the government must use it to prevent the collection of content (if X, then Y). Yet the

165 See, e.g., Landgraf v. USI Film Prods., 511 U.S. 244, 259-60 (1994).
169 See supra note 150 and accompanying text.
172 See supra notes 142-143, 147-148 and accompanying text.
173 Supp. Amicus Brief, July ’07, supra note 170, at *33-34.
two perspectives diverge with respect to the consequences that arise if no technology is reasonably available to perform the sorting (not X). The government’s theory concludes that if no technology exists, the government can collect content (if not X, then not Y). The precaution theory concludes that if no technology exists, the government cannot collect content (if not X, then Y). Yet both perspectives suffer from a logical fallacy.

By concluding that if not X, then not Y, the government’s perspective commits the common logical error of denying the antecedent. In an if-then conditional such as “if X then Y,” the negation of X has no bearing on whether or not Y obtains. It follows that in the Pen/Trap Statute, even if it is correct to reduce the statute to a conditional form, the absence of reasonably available technology (not X) does not require any particular result as to whether or not a pen register can collect content (maybe Y, but maybe not).

Similarly, under the precaution approach (if not X, then Y), X is stripped of any utility because Y remains constant whether or not the condition X is satisfied. Proponents of this theory argue that if technology is reasonably available (if X), then no content may be collected (then Y). But the same proponents also argue that if technology is not reasonably available (if not X), then no content may be collected (then Y). Because content may not be collected whether or not technology is reasonably available, it appears that there is no relationship between X and Y. This, in turn, reiterates the conclusion that under the precaution theory, the limitation is superfluous.

The definitional theory conflicts even more clearly with the canon against superfluities. As noted above, under the definitional theory, the limitation does not factor into the analysis of a pen register’s ability to collect content. As soon as a device collects data that includes content, the device is not a pen register. If the device is not a pen register, the limitation does not apply. There are no other circumstances in which the limitation would apply, because the limitation only applies to pen registers that collect data that might include content. Thus, this theory essentially writes the limitation out of the statute.

In sum, applying the canons of interpretation fails to cure the ambiguity of the Pen/Trap Statute because each of the three theories appears equally prone to criticism. Although one additional canon is

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174 ROBERT E. RODES, JR. & HOWARD POSPESEL, PREMISES AND CONCLUSIONS: SYMBOLIC LOGIC FOR LEGAL ANALYSIS 51 (1997) (“One who gives this argument a superficial examination may hold that it exhibits the form *modus tollens*. Closer inspection, however, will show that it is the counterfeit of *modus tollens*, the invalid pattern called the *fallacy of denying the antecedent*.”); see also Supp. Amicus Brief, July ’07, supra note 170, at *33-*34.

175 RODES & POSPESEL, supra note 174, at 51.

176 See supra note 147-148 and accompanying text.

177 See supra note 168 and accompanying text.

178 See supra note 153 and accompanying text.
discussed below in Part II.D, before proceeding to that discussion, Part II.C briefly examines the legislative history of the statute for additional signs of legislative intent.

C. The Legislative History of the Pen/Trap Statute

When confronted with an ambiguous statute, courts often resort to legislative history in order to ascertain the effect that Congress intended the statute to have.\textsuperscript{179} The process of using legislative history has its critics.\textsuperscript{180} Nevertheless, courts routinely resort to legislative history, despite academic critiques of its utility. Among proponents of legislative history, committee reports are generally viewed as the most persuasive form of legislative history.\textsuperscript{181} Statements made by individual senators are less persuasive than committee reports,\textsuperscript{182} however, statements made by a bill’s sponsor are typically considered more persuasive than the remarks of other Congressmen.\textsuperscript{183}

As noted previously, the legislative history of CALEA concerning the passage of the 1994 amendment that enacted the limitation is ambiguous.\textsuperscript{184} Statements in the Senate and House Reports and statements made directly by Senator Leahy\textsuperscript{185} alternate between indicating that the limitation envisioned minimal collection of content, and indicating that it did not.\textsuperscript{186} No clear answer to the question of whether Congress intended a pen register to collect PCTDDs that contain a minimal amount of content emerges by resorting to legislative history from 1994.

The legislative history related to the passage of the USA PATRIOT Act in 2001 is equally unhelpful. Unlike the 1994 amendments, no committee reports address the intended effect of the amendments of § 216.\textsuperscript{187} However, Senator Leahy made remarks bearing directly on the intended effect of § 216 on the Pen/Trap Statute.\textsuperscript{188}

\textsuperscript{179} See, e.g., Kosak v. United States, 465 U.S. 848, 855-57 (1984); see also In re Sinclair, 870 F.2d 1340, 1342 (7th Cir. 1989).

\textsuperscript{180} See SCALIA, supra note 82 and accompanying text; see also Piper v. Chris-Craft Indus., Inc., 430 U.S. 1, 26 (1977).

\textsuperscript{181} E SKRIDGE ET AL., supra note 159, at 981; see, e.g., Blanchard v. Bergeron, 489 U.S. 87, 91-96 (1989); United States v. UAW-CIO, 352 U.S. 567, 585-86 (1957).

\textsuperscript{182} Id. at 1000 (suggesting that the “statements by sponsors are given such deference in part because the sponsors are the most knowledgeable legislators about the proposed bill and in part because their representations about the purposes and effects of the proposal are relied upon by other legislators”).

\textsuperscript{183} See supra notes 117-125 and accompanying text.


\textsuperscript{185} See supra notes 120-125 and accompanying text.

\textsuperscript{186} Government’s Memorandum of Law in Support of Its Requests for Authorization to Acquire Post-cut-through Dialed Digits Via Pen Registers at 26-27, In re Orders (1) Authorizing Use of Pen Registers and Trap and Trace Services and (2) Authorizing Release of Subscriber
This legislative history can be viewed in two distinct ways. Both ways agree on certain fundamental points. First, it is evident that in 1994, members of Congress recognized that pen registers could collect content and that in 2001, members of Congress recognized that pen registers routinely did collect content. Second, it is evident that in 2001, members of Congress recognized that the government based its authority to collect PCTDDs that contained content on its interpretation of the 1994 limitation embodied in 18 U.S.C. § 3121(c). Third, it is evident that with these first two factors in mind, Congress enacted legislation that amended three provisions of the Pen/Trap Statute, including the limitation itself, with language that prohibited the use of a pen register to collect content.

With this in mind, it is possible to view the Pen/Trap Statute from an “aerial” perspective. The evolution of the statute over time—from its inception in 1986 to the 1994 and 2001 amendments—is consistent with a desire by Congress to protect the content of electronic communications despite the advent of new technologies that threatened that status. When Congress realized in 1994 that pen registers could collect content, it enacted the limitation. When Congress realized that the limitation did not prevent the collection of content in practice, it enacted three additional provisions intended to prohibit the collection of content. From this history, it is possible to conclude as a general matter that the three amendments point towards a singular conclusion, namely that, “interception of any communications content is not authorized, and technology must be used to insure that communications content is not collected.” If viewed in this way, the legislative history supports the denial of an application to install and use a pen register to collect all digits dialed from a subject telephone.

On the other hand, by placing more emphasis on the specific circumstances surrounding the 2001 amendments, arguments to the contrary emerge. It is apparent that in 2001, Senator Leahy believed that the collection of content by a pen register was unconstitutional. However, that Senator Leahy held this belief does not mean that each

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See e.g., Freeh Statement, supra note 119, and accompanying text.

147 CONG. REC. at S11,000 (statement of Sen. Leahy).

Id.

See supra notes 132-135 and accompanying text.


Id.

Id. at 827.


member of Congress shared it. In fact, Senator Leahy’s remarks indicate that during the process of reaching consensus on the provisions of the bill, he encountered and acquiesced to resistance to his efforts to add additional protection for PCTDDs that contain content. Examining the compromises made between parties with distinctly different viewpoints about a divisive issue is an important way of gauging the effect that Congress intended the statute to have.

For instance, Senator Leahy proposed that the PATRIOT Act should include specific definitions for the terms “routing” and “addressing” to ensure that courts did not interpret the terms so broadly that they included content. Yet, the Bush Administration and the Department of Justice “flatly rejected” that approach. Senator Leahy worried that the Administration’s desire to leave the terms undefined would fail to protect content. But Congress did not decide to include definitions in the statute. Instead, Congress and the Administration reached a compromise that included amending the definitions of a pen register and trap-and-trace device and the limitation to prohibit the collection of content. Thus, although Senator Leahy personally believed that content collection under the statute should be prohibited, his statements indicate that the statute did not follow a path that would have unequivocally achieved this effect. It follows that because the amendments represented a compromise between Senator Leahy and the Administration, they should not be viewed as adopting only Senator Leahy’s view and absolutely prohibiting the collection of content.

Driven by his concerns about content collection, Senator Leahy also sought to update and modify the judicial review procedure for obtaining authorization to install and use a pen register by requiring law enforcement agents to present details of their investigations to the judges who consider their applications. Senator Leahy did not argue that the relevance standard should be enhanced, but only that courts should learn more information about the underlying investigations. Again, Senator Leahy met with defeat. The Bush administration refused to capitulate, and Senator Leahy acquiesced, but nevertheless appeared satisfied with the final result. This progression carries two implications. First, it

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198 Id.
199 Id.
200 Id.
201 For a discussion that highlights the importance of identifying legislative compromises, see ESKRIDGE ET AL., supra note 159, at 67 (“[T]he existence of vetogates may tell statutory interpreters . . . to whom they should pay attention if they consult legislative history . . . . Legislative statements are most important when they reflect assurances by the enacting coalition—especially promises to or by gatekeepers—to enable the bill to pass through a vetogate.”).
202 147 CONG. REC. at S11,000 (statement of Sen. Leahy).
203 Id.; see also id. at S11,015 (statement of Sen. Leahy) (“It is not precisely the bill I would have written . . . . But it is a good bill. It is a balanced bill. . . . It is one that sets up the checks and balances necessary in a democratic society that allow us to protect and preserve our security but also protect and preserve our liberties.”).
appears that if the statute required more disclosure, then Senator Leahy would have been comfortable if courts continued to grant pen register applications on the low relevance standard, despite the fact that pen registers were known to collect content. Second, the legislation that finally passed did not reflect only Senator Leahy’s vision of how the statute would operate, but also took into account the perspective of the Bush Administration, which viewed the collection of PCTDDs that contain content favorably.

Lastly, Senator Leahy also acknowledged that the FBI had reported that it continued to collect content because there had been no change in technology that would “better restrict” the information collected so as to include only non-content. The FBI’s use of the phrase “better restrict” indicates that it sought to develop technology that would screen content more efficiently, but not completely. Yet despite being made aware of the FBI’s perspective, neither Senator Leahy nor Congress categorically rejected the possibility that a pen register could collect minimal content if technology could “better restrict” that process. Nor did Senator Leahy express any intention to modify or eliminate the limitation, which was known to be the basis of the government’s claimed authority to collect PCTDDs that contain content.

In sum, the legislative history of the Pen/Trap Statute is amenable to two interpretations. On the macro level, the evolution of the Pen/Trap Statute, culminating in the passage of three distinct amendments that prohibited the collection of content, supports the conclusion that Congress intended to prevent the collection of content by a pen register. On the micro level, the legislative history demonstrates that the amendments that emerged from the legislative process resulted from compromises between those who advocated greater protection for content and those who rejected greater protection for content. Thus, Congress did not intend the amendments to protect content completely. Because this history lends equal support to both outcomes, it cannot be dispositive on the question of whether the Pen/Trap Statute authorizes the collection of content with a pen register.

D. Applying the Canon of Constitutional Avoidance to the Pen/Trap Statute

A stronger argument in support of the conclusion that the Pen/Trap Statute does not authorize the collection of content lies in

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204 Id. at S11,000 (statement of Sen. Leahy).
205 Gov’t Brief, Jan. ’07, supra note 187, at *31-*32.
206 See, e.g., Landgraf v. USI Film Prods., 511 U.S. 244, 262-63 (1994) (refusing to view legislative history as dispositive of Congressional intent in the absence of evidence that members of Congress believed that they had reached a tacit agreement to a controversial issue).
applying the canon of constitutional avoidance. 207 This canon has been described as “the preeminent canon of federal statutory construction.” 208 It guides courts choosing between competing interpretations of a statutory text to choose an interpretation that avoids raising a constitutional question. 209 To apply the canon, a court need not determine that a particular statutory interpretation would undoubtedly conflict with the Constitution. Rather, a court must only conclude that the interpretation might be unconstitutional, and then avoid it. 210

Congress has historically gone to great lengths to ensure that the Fourth Amendment protects the content of electronic communications. 211 Further, the Supreme Court has given no indication that the content of electronic communications is entitled to less protection when it is conveyed over a telephone in the form of PCTDDs than when it is conveyed through other means that require compliance with Title III’s procedures. Nevertheless, the government has argued that a telephone user cannot maintain a reasonable expectation of privacy after entering such digits into an automated telephone system. 212 The government reaches this result by extending the holding in Smith. Under its view, a caller assumes the same risk with respect to PCTDDs as with respect to the digits dialed to connect a telephone call because both types of digits must be conveyed to the telephone company, which can in turn record all of the digits dialed. 213 It follows from this interpretation that no dialed digits are entitled to Fourth Amendment protection. 214

Yet at its outset, Smith acknowledged that its holding did not address the government’s ability to capture the content of communications. 215 Rather, Smith presupposed a context in which a pen register intercepted non-content digits voluntarily transmitted to a telephone company in order to complete a call, but could not intercept content. 216 The PCTDD issue today has arisen squarely outside Smith’s framework. It exists within a fundamentally different context and

207 In re United States for Orders (1) Authorizing the Use of Pen Registers and Trap and Trace Devices and (2) Authorizing Release of Subscriber Info. (E.D.N.Y. I), 515 F. Supp. 2d 325, 335 (E.D.N.Y. 2007).
210 Vermeule, supra note 208, at 1958.
211 E.D.N.Y. I, 515 F. Supp. 2d at 335-36; see also Kerr, supra note 69, at 630-31.
213 Id.
214 Id.
216 Id. at 741-42.
presents constitutional concerns that Smith did not foresee. Consequently, it is doubtful whether Smith’s holding governs the interception of content with a pen register at all. It is even more doubtful whether extending Smith in order to justify the collection of content under the Pen/Trap Statute would be constitutional, for the simple fact that Congress has repeatedly recognized that the Fourth Amendment protects the content of electronic communications. For these reasons, the government’s interpretation should be avoided under the canon of constitutional avoidance.

Even a court that applied Smith to PCTDDs would reach the same result. Smith applied the test articulated in Katz, which determines whether a particular form of electronic surveillance violates the Fourth Amendment. Under Katz, the person invoking Fourth Amendment protection must demonstrate a justifiable, reasonable, or legitimate expectation of privacy in the information sought to be protected. This inquiry is normally satisfied by demonstrating both that an individual exhibited an actual expectation of privacy, and also that the individual’s subjective expectation is one that society is prepared to recognize as reasonable.

In light of Katz, the government’s argument is unavailing because it fails to consider the actual nature of PCTDDs. Both Katz and Congress have emphasized that the content of a communication is entitled to Fourth Amendment protection. Despite the expectations of privacy that people maintain in their bank account numbers, social security numbers, or other private information, the government’s theory associates PCTDDs most closely with digits dialed to connect a call. Yet, when they contain substantive, private information, PCTDDs actually resemble the content that Katz sought to protect. When a telephone user enters PCTDDs to navigate an automated answering system, the PCTDDs are the equivalent of a conversation with an entity.

\[\text{\textsuperscript{217} See, e.g., 147 CONG. REC. S10,990, S11,000 (daily ed. Oct. 25, 2001) (statement of Sen. Leahy).}\]
\[\text{\textsuperscript{218} 18 U.S.C. § 2510(8) (2006); see also Supp. Amicus Brief, July '07, supra note 170, at *27-28.}\]
\[\text{\textsuperscript{219} See supra note 45 and accompanying text.}\]
\[\text{\textsuperscript{220} Smith v. Maryland, 442 U.S. 735, 739 (1979).}\]
\[\text{\textsuperscript{221} Id. But see id. at 740 n.5 (noting that “where an individual’s subjective expectations had been ‘conditioned’ by influences alien to well-recognized Fourth Amendment freedoms, those subjective expectations obviously could play no meaningful role in ascertaining what the scope of Fourth Amendment protection was”).}\]
\[\text{\textsuperscript{222} See supra notes 38, 50-51 and accompanying text.}\]
\[\text{\textsuperscript{223} In re United States for Orders (1) Authorizing the Use of Pen Registers and Trap and Trace Devices and (2) Authorizing Release of Subscriber Info. (E.D.N.Y. I), 515 F. Supp. 2d 325, 336 (E.D.N.Y. 2007).}\]
\[\text{\textsuperscript{224} Id.}\]
representative that would otherwise be protected.\textsuperscript{225} Without a wiretap order, a pen register cannot lawfully intercept the oral component of telephone conversations. Similarly, a pen register should not be able to intercept lawfully the functional equivalent of an actual conversation simply because it takes the form of a PCTDD.\textsuperscript{226} To conclude otherwise would interfere with telephone users’ legitimate expectation of privacy in PCTDDs that contain content.

Finally, in Smith, the Court rejected the petitioner’s privacy claim because it imputed to telephone users, as a class, notice that dialed digits may be monitored, which bolstered its conclusion that one who dials a telephone assumes a known risk that those digits might be provided to the government.\textsuperscript{227} Yet while the third-party disclosure principle supplies grounds for eliminating Fourth Amendment protection,\textsuperscript{228} its application in Smith rests on the assumption that a reasonable user will know that he is revealing information in a manner that can lead to its interception.\textsuperscript{229} It is a stretch to say that the telephone user assumes the risk that digits dialed into an automated system after being connected to the target number will be monitored by the telephone company,\textsuperscript{230} because the telephone user receives inadequate notice that such a risk exists.\textsuperscript{231} For instance, PCTDDs are not listed on monthly bills like digits dialed to connect a call.\textsuperscript{232} Nor would a telephone user have

\begin{footnotesize}
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\item[226] Id. at 1078. PCTDDs can also be analogized to the digits transmitted to pagers. E.D.N.Y. I, 515 F. Supp. 2d at 339. Courts considering the question have held that the Fourth Amendment protects digits transmitted to pagers. See, e.g., Brown v. Waddell, 50 F.3d 285, 294 (4th Cir. 1995).
\item[227] Smith v. Maryland, 442 U.S. 735, 743 (1979).
\item[228] See supra note 69-70 and accompanying text.
\item[229] Smith, 442 U.S. at 744 (“When he used his phone, petitioner voluntarily conveyed numerical information to the telephone company and ‘exposed’ that information to its equipment in the ordinary course of business.”).
\item[230] It is beyond the scope of this Note to evaluate a debate between the Federal Defenders of New York and the Government about whether the particular way in which PCTDDs are transmitted should factor into the determination of whether the Fourth Amendment protects them. Compare Supp. Amicus Brief, July ’07, supra note 170, at *5-*6 (distinguishing between the transmission of digits over the control channel and content channels), with Gov’t Brief, June ’07, supra note 141, at *9-*10 (minimizing the distinction between the control and content channels). For technical information about digital telephony technology, see Communications Assistance for Law Enforcement Act: Hearing Before the FCC (1999) (statement of Dave Yarbaugh, FBI Supervisory Special Agent), available at http://www.askcalea.net/lef/docs/990127-y.pdf; see also Communications Assistance for Law Enforcement Act: Hearing Before the FCC (1999) (statement of John W. Cutchi, FBI Electrical Engineer), available at http://www.askcalea.com/lef/docs/990127-c.pdf.
\item[231] Further, such a risk is not consonant with the expectations of privacy that the telephone user would retain if the same information was transmitted by conversation. On the other hand, that the Fourth Amendment would not protect digits dialed to connect a telephone call is consonant with the fact that automated dialing systems are the functional equivalent of live operators, to whom the user willingly revealed the destination telephone number. Smith, 442 U.S. at 744-45.
\item[232] Rosow, supra note 225, at 1078.
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any reason to expect a continued need for monitoring by the telephone company beyond the point of connection to a third party’s line.233

In Smith, the Court identified multiple ways in which the telephone user received notification of the telephone company’s capacity to monitor digits dialed to connect calls.234 Because it was reasonable to conclude that the telephone user received notice that such practices could occur, the Court concluded it was unreasonable to believe that a telephone user expected communications to be private.235 Yet the Court did not and has never held that a telephone user assumes the risk that communications may be revealed solely because the telephone company possesses the capacity or occasionally chooses to monitor electronic transmissions. Notice to the user—at least sufficient to impute knowledge—is also a necessary element of the assumption of risk argument. To conclude otherwise would achieve the result that Smith rejected by conditioning Fourth Amendment protection on the particular industry practices of the service provider, without regard for a reasonable user’s actual or imputed knowledge of those practices.236 By this logic, even the content of actual conversations could be revealed by a pen register, since the telephone company has the capacity to monitor conversations.237

In sum, telephone users have a reasonable expectation of privacy in PCTDDs that contain content. Society generally and Congress in particular have traditionally regarded the content of electronic communications as private. Further, telephone users do not voluntarily assume the risk that content transmitted via telephone in the form of a PCTDD will be revealed to the government. In light of this, the Fourth Amendment protects PCTDDs that contain content. Therefore, under the canon of avoidance, the Pen/Trap Statute should not be interpreted to permit the collection of content, since such an interpretation would bring the statute into conflict with the United States Constitution.

III. AMENDING THE PEN/TRAP STATUTE

Interpreting the Pen/Trap Statute to permit the collection of content will create constitutional problems and may violate the Fourth

233 Smith, 442 U.S. at 742-43 (identifying commonly known reasons that a telephone company monitors dialed digits, including “to aid in the identification of persons making annoying or obscene calls”).

234 See supra note 71 and accompanying text.

235 Smith, 442 U.S. at 742-43.

236 Id. at 745.

237 Id. at 746 (Stewart, J., dissenting) (A “telephone conversation itself must be electronically transmitted by telephone company equipment, and may be recorded or overheard by the use of other company equipment.”). Title III provides an exception for such practices. 18 U.S.C. § 2511(2)(a)(i) (2006); see also In re United States for Orders (1) Authorizing the Use of Pen Registers and Trap and Trace Devices and (2) Authorizing Release of Subscriber Info. (E.D.N.Y. I), 515 F. Supp. 2d 325, 338 (E.D.N.Y. 2007).
Amendment.\textsuperscript{238} Although a preferable approach is to interpret the Pen/Trap Statute to prohibit the collection of content, to some extent this may limit the utility to law enforcement agencies of a valuable investigative tool.\textsuperscript{239} Both options have drawbacks. Therefore, the Pen/Trap Statute requires immediate attention from Congress.

This Part identifies possible methods for amending the Pen/Trap Statute that balance the need to adequately protect privacy expectations with law enforcement’s ability to use pen registers in the course of conducting investigations. In Part A, this Note suggests several courses of action intended to redress the statutory ambiguity created by the 1994 limitation. In Part B, this Note reiterates suggestions made by other commentators that apply to the Pen/Trap Statute more generally.

A. Amending the 1994 Limitation in 18 U.S.C. § 3121(c)

1. Articulate the Consequences of a Lack of Reasonably Available Technology

The interpretive tension in the Pen/Trap Statute results from the interplay between the statutory definition of a pen register in 18 U.S.C. § 3127(3) and the 1994 limitation reflected in 18 U.S.C. § 3121(c).\textsuperscript{240} The definition provides that pen registers shall not collect content. The limitation contains a positive commandment to use reasonably available technology to sort content from non-content, but fails to articulate the consequence of an absence of such technology. This failure allows the statute to be interpreted to permit the collection of content.

If the limitation remains in the statute, then amending the limitation to include language that articulated the effect of an absence of reasonably available technology to sort content from non-content would effectively resolve the ambiguity of the statute. It would also end the divisive speculation into the effect of the limitation and the fruitless debate about Congress’s intention in passing the various amendments to the Pen/Trap Statute over the past several decades.

Congress must articulate the effect of an absence of reasonably available sorting technology. To align the limitation with the considerations discussed in this Note, any additional statutory language should continue to reflect the policies of the PATRIOT Act and prohibit the collection of content. One option would be to provide that in the absence of reasonably available technology, the pen register shall be restricted to collecting the first ten digits of any numbers dialed. This

\textsuperscript{238} See supra Part II.D.
\textsuperscript{240} See generally Part II.B.
would effectively prevent pen registers from collecting PCTDDs.\(^{241}\) The government currently possesses technology that enables it to record a specified number of dialed digits.\(^{242}\) Should the government utilize that technology to record ten digits, it could use those ten digits to identify calls that a telephone user placed to calling card companies. The government could in turn subpoena the calling card provider directly in order to determine the final destination to which the call was routed, rather than the telephone service provider, in order to collect non-content PCTDDs,\(^{243}\) to which it would be entitled under the Pen/Trap Statute.

This solution would impose a greater administrative burden on the government. However, this burden would provide a positive incentive to develop technology to sort PCTDDs. The current statutory regime disincentives such research and development because the government faces no adverse consequences as a result of continuing to collect PCTDDs that contain content. In fact, the government may even have a perverse incentive to avoid developing technology to sort PCTDDs containing content from those that do not, in order to continue obtaining all PCTDDs for as long as possible.\(^{244}\)

2. Modify or Eliminate the Reasonably Available Technology Provision

A second alternative is to modify the limitation by deleting the technology reasonably available exception. One significant benefit of this option is that it would minimize the risk of future constitutional violations by creating an unequivocal prohibition on the collection of content. For instance, the government’s interpretation of the Pen/Trap Statute would be diffused if Congress struck language from the current version of 18 U.S.C. § 3121(c) in the following manner:

\[(c) \text{Limitation.—A government agency authorized to install and use a pen register or trap and trace device under this chapter or under State law shall use technology reasonably available to it that restricts the recording or decoding of electronic or other impulses to the dialing, routing, addressing, and signaling information utilized in the processing and transmitting of wire or electronic communications so as not to include the contents of any wire or electronic communications.}\] \(^{245}\)

\(^{241}\) To date, one law enforcement agency adopted this strategy, agreeing to configure its computers to automatically delete all PCTDDs received from the telephone service provider. This mooted the legal question of whether the pen register could collect all PCTDDs. United States for an Order Authorizing the Use of Two Pen Register and Trap and Trace Devices (E.D.N.Y. II), No. 08-308, 2008 U.S. Dist. LEXIS 97359, at *3-*4 (E.D.N.Y. Nov. 22, 2008).

\(^{242}\) S.D. Tex. I, 441 F. Supp. 2d at 825.

\(^{243}\) Supp. Amicus Brief, July ’07, supra note 170, at *36 n.13.

\(^{244}\) 147 CONG. REC. 10,990, S11,000 (daily ed. Oct. 25, 1001) (statement of Sen. Leahy); see also Supp. Amicus Brief, July ’07, supra note 170, at *36 n.13.

\(^{245}\) 18 U.S.C. § 3121(c) (2006) (alterations to original). The alterations appearing in the block quote are intended to serve an illustrative purpose.
The drawback to this suggestion is that the limitation would be superfluous. Since the definition of a pen register excludes any device that is capable of collecting content, it goes without saying that the government should use technology that prevents it from collecting content when acting under the authority of the Pen/Trap Statute. If the limitation merely reiterated this conclusion, it may as well not be included in the statute.

Therefore, another possibility that would confer the same benefit is to eliminate the limitation in 18 U.S.C. § 3127(c) altogether. The limitation is unnecessary if the definition of a pen register contains a plain prohibition on the collection of content. Further, if no reasonably available technology can sort content from non-content, then the limitation does nothing but muddle the statutory text. The limitation only applies to a set of circumstances that do not exist. Meanwhile, the limitation creates ambiguity by failing to address the circumstances at hand. It appears that the primary function of the limitation is to create confusion.

With the limitation removed from the statutory text, the statutory definition of a pen register would plainly prohibit the collection of content. While this result would temporarily decrease the utility of a pen register for law enforcement agencies, it would not prevent them from obtaining content-based PCTDDs pursuant to other valid methods. For instance, with a showing of probable cause, the government would still be able to obtain a wiretap warrant to intercept PCTDDs.\textsuperscript{246} In addition, the method of restricting the collection of digits dialed to ten would also be available. Further, as soon as the government developed technology to sort content from non-content, it would employ that technology to avoid collecting content, even without the limitation. In other words, the limitation is not an essential component of the Pen/Trap Statute and could be eliminated with no significant negative repercussions.

\textbf{B. Broad Amendments to the Pen/Trap Statute}

\textbf{1. Allow Judicial Review}

Currently, 18 U.S.C. § 3123(a) provides that the court “shall” authorize a pen register upon certification by a government representative of its relevancy to an investigation.\textsuperscript{247} For so long as pen registers can collect content, Congress should amend this section in order to allow for judicial review during the consideration of a pen register

\textsuperscript{246} \textit{S.D. Tex. I}, 441 F. Supp. 2d at 818; \textit{see also} United States for an Order Authorizing the Installation and Use of an Elec. Computerized Data Collection Device Equivalent to a Pen Register and Trap and Trace Device, No. 06:06-mj-1130 at 6 (M.D. Fla. June 20, 2006) (“[T]he government is not without a remedy: if it decides that obtaining post-cut-through digits is sufficiently important to its criminal investigation, it may submit a wiretap application.”).

\textsuperscript{247} 18 U.S.C. §§ 3122(b), 3123(a) (2006).
application. Senator Leahy has advocated that the standard for judicial review should be heightened to provide courts a degree of independent latitude. Instead of relying on a law enforcement agent’s certification that the digits sought to be collected are relevant to an investigation, the court could review the facts for itself to determine whether that was indeed the case. This solution will not minimize the likelihood that the use of a pen register will create a constitutional conflict, since pen registers will still be capable of collecting content. However, granting courts the power of judicial review will at least add oversight to the application process and may prevent the collection of content where the justification for such collection is weak.

2. Heighten the Standard of Proof

Alternatively, the House Judiciary Committee has proposed that Congress modify the Pen/Trap Statute to provide that before a pen register can be ordered and installed, the government must demonstrate “specific and articulable facts [that] reasonably indicate that a crime has been, is being, or will be committed, and [that] information likely to be obtained by such installation and use . . . is relevant to an investigation of that crime.” Another option suggested by one commentator is to raise the relevancy standard so that pen registers can only be authorized pursuant to a greater showing of suspicion, such as the “clear and convincing evidence” standard that applies to requests for disclosure of cable records under the Cable Communications Policy Act. It is clear that either of these options, if adopted, would improve the status quo.

3. Provide a Suppression Remedy

If Congress does not eliminate the limitation, it should amend the Pen/Trap Statute with a provision that provides for the suppression of any PCTDDs collected or decoded by a pen register that represent content. Currently, the government is under no mandate to discard content collected with a pen register and courts routinely admit evidence collected by pen registers, even if that evidence was collected in an unlawful manner. Although the government’s official position is not to

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248 147 CONG. REC. at S11,000 (statement of Sen. Leahy).
249 Id. (citing Report 106-932, 106th Cong. 2d Sess. 13, Oct. 4, 2000). The Bush Administration rejected adding this proposed language to the statute. Id. Another commentator has suggested amending the standard of proof in the context of Internet surveillance using a pen register. See Ditzion, supra note 12, at 1351 (“[A] higher standard for approving Internet pen register orders should be established.”).
251 See Ditzion, supra note 12, at 1348-49 (suggesting ways to clarify and improve pen register laws); see also Bankston, supra note 138, at 631.
252 See supra note 105 and accompanying text.
make affirmative use of content, agents of the DOJ have also received instructions to store records of all content collected indefinitely.\textsuperscript{253} By amending the Pen/Trap Statute to mandate the suppression of content collected with a pen register, Congress would ensure that content collected under a mere relevance standard cannot be used against a telephone user. This would minimize the risk of harm flowing from the constitutional violation of collecting content with a pen register. It would also harmonize the Pen/Trap Statute with Title III, which provides for the suppression of the content of oral or wire communications intercepted unlawfully.\textsuperscript{254}

4. Increased Transparency About the Installation and Use of Pen Registers

Any discussion of pen registers is limited by a lack of information.\textsuperscript{255} There is no meaningful account of the number of applications to install and use a pen register made each year. Likewise, there is no accessible record of the number of applications to install and use a pen register granted or denied by courts.\textsuperscript{256} Although anecdotal evidence indicates that law enforcement agencies install and operate thousands of pen registers each year,\textsuperscript{257} it is impossible to fully appreciate the significance of the government’s ability to collect content under the Pen/Trap Statute without knowing how often this practice occurs. To cure this lack of transparency, the Pen/Trap Statute should be updated to require an annual report about the government’s use of pen registers.\textsuperscript{258}

As with the proposed suppression remedy, Title III provides a fitting model for updating the reporting requirements of the Pen/Trap Statute.\textsuperscript{259} Congress should require the appropriate officials to report annually to the Administrative Office of the United States Courts comprehensive details about pen register applications,\textsuperscript{260} including the percentage of pen register orders that authorize the collection of all digits dialed from a particular telephone number, as distinguished from those orders that restrict the collection of PCTDDs to dialing information.\textsuperscript{261}

\begin{itemize}
  \item \textsuperscript{253} Thompson Memo, \textit{supra} note 141 and accompanying text.
  \item \textsuperscript{254} 18 U.S.C. § 2515 (2006).
  \item \textsuperscript{255} Bankston, \textit{supra} note 138, at 634 (emphasizing that “only the DOJ” knows the extent of electronic surveillance carried out under the authority of the Pen/Trap Statute).
  \item \textsuperscript{256} Id. On the other hand, information about the total number of wiretap applications approved each year is readily accessible. See \url{http://www.uscourts.gov/library/wiretap.html} (last visited Feb. 5, 2009).
  \item \textsuperscript{257} \textit{See supra} notes 13-14.
  \item \textsuperscript{258} Bankston, \textit{supra} note 138, at 633 (suggesting the same solution).
  \item \textsuperscript{259} 18 U.S.C. § 2519 (2006).
  \item \textsuperscript{260} \textit{Id.} § 2519(2) (2006).
  \item \textsuperscript{261} Records reflecting this distinction would show whether a judicial consensus to restrict the collection of PCTDDs was emerging over time. \textit{See}, e.g., United States for an Order Authorizing the Use of Two Pen Register and Trap and Trace Devices (\textit{E.D.N.Y. II}), No. 08-308, 2008 U.S. Dist. LEXIS 97359, at *3-*4 (E.D.N.Y. Nov. 22, 2008).
\end{itemize}
Further, that office should forward a final report to Congress to allow for further consideration of the pen register issue. Knowing that detailed information was being compiled would presumably increase judicial awareness of the questionable uses to which pen registers can be put. In turn, this awareness might encourage meaningful discourse on the subject, as well as prompt Congressional action to more effectively balance the need for vigorous law enforcement with the Fourth Amendment’s protections.

IV. CONCLUSION

Telephone users have a reasonable expectation of privacy in the content of their electronic communications. This expectation includes content that takes the form of a PCTDD. The expectation is also one that society is prepared to recognize as reasonable. As with other forms of communicative content, interception of PCTDDs that contain content is not lawful on a showing of less than probable cause. For these reasons, the collection of content on the mere relevance standard provided by the Pen/Trap Statute should be prohibited.

Nevertheless, until Congress takes steps to do so, the government will continue to solicit and receive court authorization to install and use pen registers in a manner that will result in the collection of content. The time is ripe for Congress to amend the Pen/Trap Statute in order to cure its ambiguities and impose an effective barrier to the continued practice of collecting PCTDDs that contain content using a pen register.

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262 Id. § 2519(3) (2006).
† J.D. Candidate, 2009; A.B. Cornell University, Jan. 2002. Many thanks to Paul Monteleoni and Daniel Bodah, to Professor Brakman Reiser, and to the staff members of the Brooklyn Law Review.
A Compromise Solution to Prevent Fraudulent Claims Under IIRIRA Section 601(a)

A SYSTEM OF CONDITIONAL GRANTS

INTRODUCTION

A young Chinese woman is caught with fake travel documents at John F. Kennedy Airport. Later, she recounts her experience:

I told [the immigration official], as instructed by my snakehead, 1 “I am married. I already have a child, and I am now pregnant. The Chinese government was about to force me to have an abortion,” and so on and so forth. It was really a joke. I was not even married. They took my fingerprints and released me.2

Fraudulent stories regarding China’s coercive population measures, just like the story told above, are all too common at the borders of the United States. Although, in a strange turn of events, it is usually men, rather than women, who are telling them.3 The problem has arisen as a result of legislation intended to provide a solution for an extremely serious human rights concern in China, which has instead often been used as a tool to defraud the United States into granting asylum benefits to undeserving aliens.

In 1996, after facing years of strong social and political pressure to help those persecuted under China’s family planning methods,4

2 Id. at 1306-07.
3 See Paul Sperry, Chinese Aliens Flock to O’Hare: Immigrants with Bogus Asylum Claims Flooding America’s Busiest Airport, WORLDNETDAILY, Feb. 6, 2003, available at http://worldnetdaily.com/news/article.asp?ARTICLE_ID=30903; see also Elisabeth Rosenthal, Chinese Town’s Main Export: Its Young Men, N.Y. TIMES, June 26, 2000 (discussing the fact that since 1990, approximately 80% of the middle-age men in one Chinese town have left for the West, usually for the United States).
4 Kimberly Sicard, Section 601 of IIRIRA: A Long Road to a Resolution of United States Asylum Policy Regarding Coercive Methods of Population Control, 14 GEO. IMMIGR. L.J. 927, 932-36 (2000). Sicard describes the increased social pressure on the United States government arising after pro-democracy rallies in Tiananmen Square were stifled by 150,000 Chinese troops in 1989 and after a freight ship named the Golden Venture ran aground off New York in 1993 carrying 276 Chinese refugees, of which 90% filed for asylum relief based on China’s One-Child Policy. She also discusses the political pressure coming from both human rights advocates and pro-life activists. Id.
Congress enacted the Illegal Immigration Reform and Immigrant Responsibility Act ("IIRIRA" or "Act"). The aim of section 601(a) of the Act, although not explicitly stated, was to provide relief to victims of China’s coercive population control practices. To accomplish this purpose, section 601(a) broadened the definition of "refugee" to include those who have been forced to undergo an abortion and/or sterilization, or who have been persecuted for any other resistance to a country’s population control methods. While it is undisputed that section 601(a) grants per se refugee status to those claimants who are the direct victims of persecution under the population control policies, there is great disagreement among the United States Courts of Appeals over whether the same relief should be given to indirect, physically unharmed, partner victims solely on the basis of their partner’s persecution. This disagreement largely stems from a decision rendered by the Board of Immigration Appeals ("BIA"), the administrative agency charged with implementing section 601(a), one year after section 601(a)’s enactment. In *In re C-Y-Z*, the BIA held that section 601(a) also gives the “spouse”

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6 Sicard, *supra* note 4, at 927 ("Although Congress wrote the statute to apply to any country employing coercive methods of population control, China and the One Child Policy are clearly the statute’s subjects."); see also Thomas L. Hunker, *Generational Genocide: Coercive Population Control as a Basis for Asylum in the United States*, 15 J. TRANSNAT’L L. & POL’Y 131, 140 (2005-2006). In fact, at the time section 601(a) was adopted, “China [was] the only country reported to have mandatory population control policies.” Katherine L. Vaughns, *Retooling the “Refugee” Definition: The New Immigration Reform Law’s Impact on United States Domestic Asylum Policy*, 1 RUTGERS RACE & L. REV. 41, 86 (1998-1999).

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The term “refugee” means (A) any person who is outside any country of such person’s nationality or, in the case of a person having no nationality, is outside any country in which such person last habitually resided, and who is unable or unwilling to return to, and is unable or unwilling to avail himself or herself of the protection of, that country because of persecution or a well-founded fear of persecution on account of race, religion, nationality, membership in a particular social group, or political opinion, or (B) in such special circumstances as the President after appropriate consultation…may specify, any person who is within the country of such person’s nationality or, in the case of a person having no nationality, within the country in which such person is habitually residing, and who is persecuted or who has a well-founded fear of persecution on account of race, religion, nationality, membership in a particular social group, or political opinion.

Id. IIRIRA’s section 601(a)(1) expanded this definition to read:

For purposes of determinations under this Act, a person who has been forced to abort a pregnancy or to undergo involuntary sterilization, or who has been persecuted for failure or refusal to undergo such a procedure or for other resistance to a coercive population control program, shall be deemed to have been persecuted on account of political opinion, and a person who has a well founded fear that he or she will be forced to undergo such a procedure or subject to persecution for such failure, refusal, or resistance shall be deemed to have a well founded fear of persecution on account of political opinion.

of a persecuted person per se qualification for refugee status.\textsuperscript{9} This holding and the subsequent Courts of Appeals decisions interpreting it have paved a path by which indirect male partner victims can easily qualify for asylum relief under section 601(a). In doing so, these decisions have opened the door for widespread abuse by many men who are using false claims based on the alleged persecution of their female partner to qualify as refugees in the United States.

This Note, through exploration of the humanitarian crisis in China and the U.S. government’s response to it, argues that new legislation is required in order to clearly address the seriousness of the Chinese birth control practices and the justifiable U.S. immigration concerns of limiting fraudulent refugee claims, both of which have been muddled by the courts’ inconsistent attempts to balance these somewhat conflicting objectives. Part I of this Note gives a brief history of China’s population control policies. Part II discusses the U.S. refugee system in general, and how section 601(a) of the IIRIRA has changed this general scheme. Part III discusses the Courts of Appeals’ interpretations of the section 601(a). Finally, Part IV begins by explaining how some of these courts’ broad interpretations of the scope of section 601(a) have allowed many men to fraudulently enter into the United States based on the alleged persecution of their female partners. Part IV then goes on to suggest that a legislative amendment that creates a system of conditional grants of refugee status would serve the dual purpose of benefiting the true victims of the coercive family planning methods, as section 601(a) was intended to do, while also deterring these fraudulent claims by indirect male victims.\textsuperscript{10}

I. CHINA’S ONE-CHILD POLICY

The People’s Republic of China (“China”) has a lengthy, and rather contradictory, history of regulating its population growth. From

\textsuperscript{9} In re C-Y-Z, 21 I. & N. Dec. 915, 918-19 (BIA 1997) (“We find that the applicant in this case has established eligibility for asylum by virtue of his wife’s forced sterilization.”).

\textsuperscript{10} See Karen Y. Crabbs, United States Domestic Policies and Chinese Immigrants: Where Should Judges Draw the Line When Granting Political Asylum?, 7 FLA. J. INT’L L. 249, 250 n.3 (1992). Crabbs illustrates the delicacy of deciding whether to grant asylum:

For political reasons, a country which grants foreigners asylum must be careful that such action does not appear too judgmental and thus undermine international relations with the country from which the applicants are fleeing. A country must be careful when granting immigrants asylum for economic reasons as well. Many American economists advocate an extremely selective policy of asylum determination. They view incoming immigrants simply as possible moneymakers or moneytakers. If we take the former, we will enrich our country; but if we choose the latter, we end up a poorer nation because the immigrant will subtract value from our country. Other arguments for limiting immigration into the United States include the effect the additional population would have on the environment or on unemployment and other social problems. At the current rate of birth but without large-scale immigration, the United States could maintain a stable population.

\textit{Id.} (internal citations omitted).
the country’s founding in 1949 and throughout the 1950s, the central government, rather than trying to limit population growth, actively encouraged it. 11 In fact, the Chinese government was convinced that a large population was necessary to meet the production needs of the socialist country. 12 In addition to governmental concerns, Chinese citizens, few of whom benefited from social security or pension plans, had many children to ensure their well-being in old age. 13 Moreover, in rural areas, children were (and still are) often needed for increased labor power on the farms. 14 These factors, combined with the traditional desire to carry on the family name, 15 led to rapid population growth in the country. By 1970, most Chinese women gave birth to six children in their lifetime. 16 In light of this population boom, the central government was suddenly faced with “massive starvation” and “economic and social stagnation.” 17 These concerns led the government to create the “wan, xi, shao” campaign, translated as “later, longer, fewer,” which encouraged couples to marry later, wait longer after marriage to have children, and have fewer children in total. 18 In 1979, the Chinese government determined that more drastic measures were required, and so it adopted a comprehensive family planning policy to help combat population


12 Zhang, supra note 11. Mao Zedong has stated: “It is a very good thing that China has a big population . . . . Of all the things in the world, people are the most precious.” Christie N. Love, Not In Our Country? A Critique of the United States Welfare System Through the Lens of China’s One-Child Law, 14 Colum. J. Gender & L. 142, 149 (2005) (quoting JOHN S. AIRD, SLAUGHTER OF THE INNOCENTS: COERCIVE BIRTH CONTROL IN CHINA 22 (1990)).

13 Sicard, supra note 4, at 928.

14 Id.; see also Grey Areas in China’s One-Child Policy, BBC News, Sept. 21, 2007 [hereinafter Grey Areas], available at http://news.bbc.co.uk/2/hi/asia-pacific/7002201.stm (“Rural families also want boys so they can help with farm work.”).

15 Sicard, supra note 4 (“In addition, sons continue the family line.”); see also, Grey Areas, supra note 14 (Mrs. Wu, a Chinese citizen states, “When I got married I only wanted one child. But because it was a girl, my parents-in-law wanted me to try for a boy to carry on the family name.”).


17 Charles E. Schulman, The Grant of Asylum to Chinese Citizens Who Oppose China’s One-Child Policy: A Policy of Persecution or Population Control?, 16 B.C. Third World L.J. 313, 317 (1996). China felt the consequences of its unimpeded population growth when, by 1979, the country was trying to sustain over 20% of the world’s entire population with less than 8% of the world’s arable land. Id. at 316-17; see also Kung, supra note 1, at 1303 (noting that even as early as 1958, famine ensued and that “[b]etween 1958 and 1962, a nationwide famine killed at least 20 million people”).

18 Stewart, supra note 11. The goal of the campaign was to have a growth rate of zero by 2000. Schulman, supra note 17.
growth.\textsuperscript{19} Of central importance to this plan was the implementation of the “one couple, one child” policy\textsuperscript{20}—popularly known today as the “One-Child Policy” (“OCP”).\textsuperscript{21} The OCP generally restricts married Chinese couples to having one child, although there are some notable exceptions to the rule.\textsuperscript{22}

In 1981, the government created the State Family Planning Commission (“SFPC”) to set target population goals.\textsuperscript{23} The SFPC, in turn, delegates the task of monitoring and enforcing OCP targets to officials at the provincial and local levels.\textsuperscript{24} While this decentralized system has led to varying enforcement techniques throughout China’s provinces, local officials have generally put into place a stick-and-carrot system of economic and social rewards and penalties to encourage couples to comply with the OCP rules.\textsuperscript{25} Couples that abide by the OCP, for example, may be rewarded with cash stipends for their child’s medical and educational purposes, a larger residence for their family, and extended time off from work for the mother after giving birth.\textsuperscript{26} On the other hand, punishments for disobeying the OCP range from monetary penalties, to job demotions or firings, to imprisonment and the seizure or destruction of the couple’s property.\textsuperscript{27} The most extreme enforcement techniques include forced Intrauterine Device (“IUD”) insertions, late-term abortions, and sterilizations.\textsuperscript{28} Although the central government has officially condemned all such coercive methods since 1984,\textsuperscript{29} local


\textsuperscript{20} Zhang, supra note 11, at 561.


\textsuperscript{22} The term “One Child Policy” is a bit of a misnomer, as there are a number of exceptions to the one couple, one child rule. For example, in some cases ethnic minorities are allowed to have more than one child. Likewise, couples in rural areas who have a daughter as their first child may be permitted a second after a certain amount of time. Zhang, supra note 11, at 561-62 (1996); see also Grey Areas, supra note 14 (A “significant number of people” have more than one child either because they fall under one of the exceptions, or because they ignore the rules, no matter what the consequences. In fact, “[i]n July [of 2007], it was revealed that nearly 2,000 officials and celebrities in Hunan Province breached the nation’s family planning regulations between 2000 and 2005.”).

\textsuperscript{23} Schulman, supra note 17.

\textsuperscript{24} Id. at 317-18. Thirteen million volunteers also partake in enforcing the OCP. Id. at 318.

\textsuperscript{25} Zhang, supra note 11, at 562. In addition, education is used to teach people about the dangers of continued population growth. Id.

\textsuperscript{26} Id. at 563.


\textsuperscript{28} Id. at 1025-26.

officials routinely turn to such practices in fear of punishment for failure to meet the quotas set in place by the SFPC. In fact, by the mid-1980s, forced birth control practices, including abortions, sterilizations, and IUD insertions, averaged nearly thirty million per year.

Another integral tool in China’s family planning policy is its Marriage Law of 1980, which sets forth minimum marriage ages—twenty for females and twenty-two for males. However, these ages are only a floor and in many provinces the local governments have set the actual minimum age for marriage a number of years higher. The Marriage Law also requires every couple to register their marriage with the government. If a couple fails to get this registration or their registration is denied, i.e., because one of the partners is below the minimum age, the government will not legally recognize the marriage, and the couple will not be legally permitted to have a child. Marriage without this official government authorization is termed a “traditional” marriage. If a woman gets pregnant while in a traditional, rather than a “legal,” marriage, local officials once again have wide discretion in punishing the couple and aborting the child, even where that child would only be the couple’s first child.

Through the combination of such laws and enforcement techniques, Chinese officials have recently reported that since its implementation the OCP has been responsible for preventing

30 Id.; see also, Hannah Beech, Enemies of the State?, TIME, Sept. 12, 2005 (“One set of bad population figures can stop an official from getting promoted.”). Beech also explains that local officials in Linyi started mass sterilizations and abortions after getting castigated for having the highest rate of extra births in Shandong. Id.; Rivera, supra note 21, at 235 n.40 (noting that “[t]he Chinese government rewards local officials who achieve the birth quotas for their province... [b]ut it also punishes them with sanctions, demotions, and salary reductions if they fail to achieve the quotas”). Since “the goal is to achieve the targeted birth quota, family-planning officials are obligated and motivated to track down women with ‘out-of-plan’ pregnancies and make sure that they have abortions, regardless of how far their pregnancies have advanced.” Xiaorong Li, License to Coerce: Violence Against Women, State Responsibility, and Legal Failures in China’s Family Planning Program, 8 Yale J.L. & Feminism 145, 163 (1996).

31 Hunker, supra note 6, at 134.


33 Id. art. 5. These age minimums are “easily the highest in the world.” See Rabkin, supra note 16, at 971; see also Chen v. Ashcroft, 381 F.3d 221, 230 (3d Cir. 2004) (noting that “it appears probable that no other country sets the minimum as high as does China”). Article 5 of the Marriage Law says that “late marriage and late childbirth” shall be encouraged. Marriage Law art. 5.

34 Rabkin, supra note 16, at 971.

35 Rivera, supra note 21, at 236.

36 Id. In fact, “[l]ocal officials require unmarried women to undergo frequent gynecological exams to ensure that they are not pregnant; if they are, they are required to have abortions.” Rabkin, supra note 16, at 972.

37 See Ma v. Ashcroft, 361 F.3d 553, 555 (9th Cir. 2004).

38 Rivera, supra note 21, at 237; see also Ma v. Ashcroft, 361 F.3d 553, 555 (9th Cir. 2004) (an example of a woman being forced to abort her child because she wasn’t in a legal marriage, even though the couple had no other children yet).
approximately 400 million births.\textsuperscript{39} Despite calls for change to stop this “ongoing genocide,”\textsuperscript{40} coercive enforcement methods are still widely used in China today.\textsuperscript{41} In fact, a recent congressional hearing reported that “China’s drive to control its population growth at any cost to the Chinese people is as strong and dangerous as ever.”\textsuperscript{42} While the OCP, when originally enacted, was supposed to be terminated by 2000,\textsuperscript{43} in 2008 Chinese population officials said that the Policy will persist for at least another decade.\textsuperscript{44}

II. UNITED STATES REFUGEE POLICY AND THE EFFECT OF SECTION 601(A) ON THE DEFINITION OF “REFUGEE”

A. United States Refugee Policy

Before specifically examining the U.S. government’s response to the extreme humanitarian crisis that has resulted from China’s OCP and other related population planning policies, it is useful to have a basic understanding of how a claimant can generally gain refugee status in the United States. This background information explains how the various broad or narrow interpretations of who falls under section 601(a) can have a major impact on how easily a claimant can gain refugee status. It


\textsuperscript{40} Stephen Moore, Don’t Fund UNFPA Population Control, WASH. TIMES, May 9, 1999 (also referring to the OCP as a “fanatical crusade”), available at http://www.cato.org/pub_display.php?pub_id=5457; see also A Brother for Her, supra note 39 (discussing how some Chinese scholars believe that the costs of dealing with an aging population and the increasingly worrisome male to female sex ratio may outweigh the benefits of keeping the OCP in place and stating that “officials have hinted in the past that the policy could be eased after 2010”); James Reynolds, Chinese Challenge One-Child Policy, BBC NEWS, May 25, 2007, http://news.bbc.co.uk/2/hi/asia-pacific/6094135.stm (discussing how one Chinese province recently burned cars and destroyed official buildings when officials tried to collect fines from those who had more than one child, and how many people take fertility drugs because, if you have more than one child at the same time, there are no penalties).

\textsuperscript{41} Although there is no hard data about how often coercive population control policies are really used, there are many undocumented stories of coercive techniques that are still widely practiced as part of enforcing the OCP. GREENHALGH & WINKLER, supra note 29.

\textsuperscript{42} China: Human Rights Violations and Coercion in One-Child Policy Enforcement: Hearing Before the H. Comm. On Int’l Relations, 108th Cong. at 1 (2004), available at http://www.internationalrelations.house.gov/archives/108/97563.pdf; see also Has China’s One-Child Policy Worked?, supra note 39 (“And it looks likely that, nearly 30 years after the policy was first introduced, it will not be relaxed to allow couples to have more children. . . . At [a] press conference earlier this year, Minister Zhang said there was not the ‘slightest doubt’ about the need to continue with the policy.”).

\textsuperscript{43} Zhang, supra note 11, at 562 (“The one-child policy will be officially withdrawn in the year 2000.”).

\textsuperscript{44} Jim Yardley, China Says One-Child Policy Will Stay for at Least Another Decade, N.Y. TIMES, Mar. 11, 2008, at A10 (“China’s top population official said the country’s one-child-per-couple family planning policy would not change for at least another decade.”).
also highlights how broad interpretations of section 601(a) have made it much easier for Chinese men, with only a false claim of persecution, to gain refugee status, and why new legislation should be enacted to curb this problem. New legislation can help prevent the further diversion of resources away from those with genuine claims of persecution—those who section 601(a), and the refugee laws in general, are truly designed to protect.

There are two main routes a migrant may take when seeking to gain asylum. First, a migrant may affirmatively seek asylum through a request to a U.S. Citizen and Immigration Services (“USCIS”) asylum officer, who will conduct an interview with the applicant and determine whether to grant asylum. If the USCIS officer denies the application, the applicant will then be able to go to immigration court where an immigration judge (“IJ”) will review his or her claim. Second, a migrant can seek asylum defensively through a ruling of an IJ once a removal proceeding has been brought against him or her. U.S. immigration law requires that aliens who arrive at a U.S. port of entry without, or with fraudulent, travel papers, must be detained and placed in expedited removal proceedings. At this point, the migrant can express a fear of persecution, and an IJ will review the case. Under either route to asylum, the BIA is responsible for hearing appeals from decisions of the IJs. All BIA decisions are then subject to review by the federal courts.

An asylum officer or IJ has discretion to grant the migrants application upon an affirmative finding that the alien meets the definition of a “refugee.” A “refugee,” in turn, is defined by 8 U.S.C. § 1101(a)(42) as a person who “is unable or unwilling to return to, and is unable or unwilling to avail himself or herself of the protection of [the applicant’s native country] because of persecution or a well-founded fear or persecution on account of race, religion, nationality, membership in a particular social group, or political opinion.” What qualifies as

45 U.S. Citizenship and Immigration Servs., Obtaining Asylum in the United States: Two Paths, available at www.uscis.gov (search “obtaining asylum in the United States”; then follow “Obtaining Asylum in the United States: Two Paths” hyperlink) (last visited Mar. 27, 2009). If an application under the Refugee Act is made within the United States and granted, this person is said to have been granted “asylum.” If the application under the Refugee Act is made from outside the United States and granted, this person is said to have been granted “refugee status.” The terms are used interchangeably in this Note. See RapidImmigration.com, Political Asylum & Refugee Status, http://www.rapidimmigration.com/usa/1_eng_kit_asylum.html (last visited Jan. 22, 2009).
46 Obtaining Asylum in the United States: Two Paths, supra note 45.
47 Id.
48 Id.
49 Id.
51 Id.
52 Approval, Denial, or Referral of Application, 8 C.F.R. § 208.14 (2005).
persecution on account of “political opinion” is where section 601(a), and the court interpretations of it, becomes so important.

B. IIRIRA Section 601(a) and Its Effect on the U.S. Refugee Qualifications

Throughout the 1980s, reports of China’s coercive family planning enforcement practices spread worldwide, leading to international outrage and United States action. After years of unsuccessful proposed legislation by human rights activists to provide enhanced protection for victims of these “undeniable and grotesque violations of fundamental human rights,” efforts finally culminated with Congress’s 1996 enactment of section 601(a) of the IIRIRA. The specific language of section 601(a)(1) provides that:

For purposes of determinations under this chapter, a person who has been forced to abort a pregnancy or to undergo involuntary sterilization, or who has been persecuted for failure or refusal to undergo such a procedure or for other resistance to a coercive population control program, shall be deemed to have been persecuted on account of political opinion, and a person who has a well-founded fear that he or she will be forced to undergo such a procedure or subject to persecution for such failure, refusal, or resistance shall be deemed to have a well-founded fear of persecution on account of political opinion.

The statute effectively eradicated the highly criticized prior practice of the BIA, by which the Board required Chinese asylum claimants to show that the coercive family planning practice was being selectively applied against them on account of one of the five enumerated protected classes in the “refugee” definition—race, religion, national origin, social group, or political opinion.” In other words,

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54 Zhang, supra note 11, at 572 (discussing the U.S. withdrawal of financial support for the UN Fund for Population Activities (UNFPA) that provided assistance to China’s government in implementing the OCP).
58 8 U.S.C § 1101(a)(42)(B).
60 Matter of G-, 20 I. & N. Dec. 764, 779 (1993) (“Coerced abortions and sterilization are certainly horrible acts. However, . . . the applicant has failed to show that the one couple, one
section 601(a) eliminated the burden on OCP applicants of proving a “nexus” between their persecution under the OCP and one of these protected statuses. For example, before section 601(a) was enacted, an applicant would only meet the requirements of the refugee statute by showing that the OCP practices were being enforced against him or her because of his or her race or because of a specific political opinion he or she had. However, it was very difficult for an applicant to show that the OCP was being selectively enforced against him or her, since enforcement of the OCP is so widespread throughout China. Further, enforcement is done with the goal of population control in mind rather than with the goal of harming those of a particular religion, race, or political opinion. Thus, in Matter of Chang, decided seven years before section 601(a) was passed, the BIA held that a man who had alleged that his family was persecuted under the OCP did not qualify as a refugee under the Refugee Act because the OCP was not, in and of itself, “persecutive.”

By coming to this conclusion, the BIA made it clear that in order to qualify under the pre-section 601(a) refugee definition based on OCP practices, an alien would not only have to show that he or she was the victim of a coercive birth control method, but also that enforcement of the OCP was selectively applied against him or her based on his or her race, religion, national origin, social group or political opinion. With the enactment of section 601(a), however, this all changed. Under section 601(a), any direct victim, whether male or female, who has been “forced to abort a pregnancy or to undergo involuntary sterilization, or who has been persecuted for failure or refusal to undergo such a procedure or for other resistance to a coercive population control program,” is automatically deemed to have a well-founded fear of...
persecution on account of his or her “political opinion.”63 By lifting the burden on the applicant of proving a nexus between his or her persecution and one of the protected categories in the refugee definition, section 601(a) is unambiguously intended to provide per se refugee status to the direct victims of persecution, or those who have a well-founded fear of direct persecution.64 The plain language of the statute, however, is seemingly silent as to its intended effect on husbands, fiancés, or boyfriends of such persecuted women.65 If the woman who has been forced to abort a child can be granted political asylum in the United States, then should the man whose child was also aborted, but who did not himself have to physically endure the pain of the forced abortion, also meet the refugee definition based on this abortion? What about where the physically unharmed man comes to the United States while his allegedly persecuted partner remains in China? And if this is the case, how will an IJ be able to distinguish between genuine and fraudulent claims by physically unharmed males who have no evidence at all of the persecution allegedly done against their female partners? The series of cases discussed below illustrate how the BIA has addressed some of these issues and how the different Courts of Appeals have expanded or narrowed the BIA’s determinations.

III. THE BIA’S DECISION AND THE DIFFERING CIRCUIT COURT INTERPRETATIONS OF THAT DECISION

Before either the BIA or a federal court reviewing the BIA’s decision can expand or narrow the plain-meaning of the statute, which seemingly only grants relief to the direct victims of persecution, it must determine that the statute is silent or ambiguous with respect to the issue at hand—i.e., whether section 601(a) explicitly provides protections for indirect partners of the direct persecution victim. This determination of silence or ambiguity is required under the Supreme Court’s decision in Chevron v. NRDC, which mandates that “[i]f the intent of Congress is clear, that is the end of the matter, for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.”66 However, if the court finds the statute is silent or ambiguous, then the...
federal court, under the second step of *Chevron*, must defer to the agency’s interpretation of the statute, here the BIA’s, “unless [such interpretation is] arbitrary, capricious, or manifestly contrary to the statute.” In other words, a court should only follow the BIA’s interpretation if it finds that such an interpretation constitutes “a permissible construction of the statute.” Different applications of these two *Chevron* steps have led to the numerous competing interpretations of section 601(a) amongst the circuit courts.

A. **In re C-Y-Z**

*In re C-Y-Z* is the seminal BIA case with respect to asylum relief under section 601(a), and it is the application of this holding that has spawned the conflicting Courts of Appeals’ interpretations of section 601(a). The asylum applicant in *C-Y-Z* was a male Chinese citizen, who was legally married in China and who had three children. In his application he stated that after the birth of his first child government officials in China forced his wife to get an IUD insertion. After the IUD was removed, his wife became pregnant a second time, and this time she was ordered to have an abortion. She was able to escape the abortion only by hiding in a relative’s home. When his wife became pregnant a third time, she again hid with relatives, but after she gave birth, she was sterilized against her will. Eighteen months later, the applicant left China for the United States. When the case was originally brought before the Immigration Judge, section 601(a) had not yet been enacted. Therefore, the IJ denied the applicant’s claim relying on *Matter of Chang*’s not-yet-overruled holding that applicants have a burden of proving a “nexus” between their persecution under the OCP and one of the protected statuses listed in the Refugee Act. The IJ noted that “if indeed [the applicant’s wife] was forced to undergo an involuntary sterilization, [she] did not gain anything from having the applicant abandon her and the children for the United States. . . . In effect, the applicant seeks to ride on his wife’s coattails.” The applicant then appealed to the BIA and before the BIA decided the case, section 601(a)

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67 *Id.* at 844.
68 *Id.* at 843.
70 *Id.* at 915.
71 *Id.* at 916.
72 *Id.*
73 *Id.*
74 *Id.*
75 *Id.* To support his claim, the applicant presented copies of his marriage certificate, a copy of his wife’s sterilization certificate, his children’s birth certificates, etc. *Id.*
76 *Id.* at 917.
77 *Id.* at 916-17.
78 *Id.* at 916.
was enacted, abolishing the nexus requirement of the Refugee definition for those persecuted under coercive population policies. 79

Once the case reached the BIA, the Immigration and Naturalization Service (‘INS’) conceded in its appeal brief that, as argued by the applicant, the husband of a persecuted wife could “stand in [his wife’s] shoes.”80 Nevertheless, the INS argued that any persecution that may have occurred to the applicant was over81 and that any possible harm did not directly impact the applicant. In rebuttal, the applicant argued that because he could stand in this wife’s shoes, he has established past persecution.82 Furthermore, because the conditions in China with respect to its OCP had remained unchanged, he alleged that he continued to have a well-founded fear of future persecution.83 The BIA, largely relying on the INS’s concession, agreed with the applicant, and ruled that “the applicant has established eligibility for asylum by virtue of his wife’s forced sterilization.”84

A major problem with C-Y-Z-’s holding was the BIA’s lack of clarity in explaining its rationale for accepting the INS’s concession and the applicant’s argument that a husband can stand in his wife’s shoes for purposes of establishing past persecution under section 601(a).85 For example, the BIA did not point to any specific language in section 601(a)

79 Id. at 917.
80 Id. at 918 (“The [INS] is aware that its legal perspective as directed by the General Counsel is that the husband of a sterilized wife can essentially stand in her shoes and make a bona fide and non-frivolous application for asylum based on problems impacting more intimately on her than on him.”).
81 Id. at 928 (Board Member Filippu’s concurring and dissenting opinion notes that the applicant had testified that in the time between his wife’s sterilization and his arrival in the United States, which was over 17 months, he had absolutely no problems with the Chinese government).
82 Id. at 918.
83 Id.
84 Id.; see also id. at 919 (“In view of the enactment of section 601(a) of the IIRIRA and the agreement of the parties that forced sterilization of one spouse . . . is an act of persecution against the other spouse, the applicant has established past persecution.”).
85 Board Member Filippu recognized this in his separate opinion. He notes that the INS brief, which concedes that a wife’s persecution can establish persecution for a husband, fails to set forth “the reasoning behind this position on ‘joint spousal persecution.’” Id. at 928. He further concludes that husbands should not be granted *per se* refugee status based on their wife’s persecution:

It seems to me that the infliction of an abortion or sterilization procedure on one spouse may or may not lead to the conclusion that the other spouse has been persecuted. For example, a couple may jointly want more children and oppose their government’s efforts to restrict family size. In these circumstances, the sterilization of one spouse adversely affects both . . . . On the other hand, a particular husband might believe the family has enough children. He then might not oppose the family’s compliance with a country’s population control laws through his wife’s sterilization, even though she may vigorously disagree . . . . But it is not self-evident to me why the wife’s sterilization would necessarily amount to past persecution of the consenting husband.

In re C-Y-Z, 21 I. & N. Dec. at 928-29. Additionally, dissenting board member Villageliu stated that “my reluctance to join the majority is that I find it implausible that the natural reaction of a husband whose wife has been sterilized, and who deems it persecutive, would be to then proceed to the United States seeking asylum, leaving her behind.” Id. at 935.
that supports this theory. Nor did it explain the scope of its holding. It leaves open the question as to whether its holding should apply only to legally married husbands, or extend to traditionally married husbands as well. Nor does the court speak to whether unmarried partners, such as fiancés or boyfriends, can also stand in their female partner’s shoes. Thus, while the BIA has the power to interpret section 601(a), its bare bones reasoning of this case left the door open for the federal circuit courts, facing appeals from the BIA, to develop their own interpretations of section 601(a) based on their own policy ideas. And indeed, there is a big split among the Courts of Appeals as to how broadly the BIA’s decision should extend.

B. The Ninth Circuit Construes the Holding of C-Y-Z Broadly

In Ma v. Ashcroft the Ninth Circuit interpreted the BIA’s C-Y-Z holding broadly. Ma, a Chinese citizen, married his wife, Chiu, at age nineteen. Since Ma was not of legal age to get married under China’s Marriage Law, the government refused to legally recognize the marriage. Thus, even though Ma and Chiu were wed in a traditional marriage, Chiu could not legally have a child and any resulting pregnancy could be subject to a forced abortion. Chiu soon got pregnant, and in the third trimester of the pregnancy, she was detained by birth control officials and was forced to abort the pregnancy. Soon

86 8 C.F.R. § 1003.1(g) (2000). Section 1003.1(g) provides:

Except as Board [i.e., BIA] decisions may be modified or overruled by the Board or the Attorney General, decisions of the Board, and decisions of the Attorney General, shall be binding on all officers and employees of the Department of Homeland Security or immigration judges in the administration of the immigration laws of the United States. By majority vote of the permanent Board members, selected decisions of the Board rendered by a three-member panel or by the Board en banc may be designated to serve as precedents in all proceedings involving the same issue or issues. Selected decisions designated by the Board, decisions of the Attorney General, and decisions of the Secretary of Homeland Security to the extent authorized in paragraph (i) of this section, shall serve as precedents in all proceedings involving the same issue or issues.

Id.

87 361 F.3d 553 (9th Cir. 2004).

88 Id. at 554-55.

89 Id. at 555.

90 Id.

91 Id.

92 Id. at 555-56. A more detailed version of the facts is as follows: Ma, no longer wanting to live in fear, attempted to register his marriage to Chiu with local authorities. This attempt, however, put local officials on notice that Ma and Chiu had violated the OCP, and later word spread to officials that Chiu was pregnant. Soon thereafter, five officials came to Ma’s home, wanting to do a physical examination on Chiu. However, Chiu, fearing that this would happen, was already hiding with relatives in a nearby village. Since the officials could not find Chiu, they instead beat Ma and seized Ma’s father, threatening that they would hold the father until Chiu came forward for an abortion. When word spread to Chiu that officials were holding Ma’s father, she went to the Family Planning Office, begging that he be released. There, Chiu was detained and forced to abort her child. After the abortion, Ma and Chiu decided to leave China. Chiu encouraged Ma to go first and send for her as soon as possible. Ma thus left China, smuggled in a boat. Id.
thereafter, Ma left for the United States with the hope of sending for his wife once he got settled.93 Once in the United States, Ma applied for asylum,94 specifically alleging persecution on the basis of China’s refusal to recognize his marriage and the OCP regulation that forced his wife to abort their child.95 The immigration judge granted Ma’s claim, and the INS appealed to the BIA.96

The BIA held that Ma, because of his lack of a legally recognized marriage, did not qualify as a “spouse” under its previous holding in C-Y-Z-.97 The BIA thus somewhat clarified that its holding from C-Y-Z- was a narrow one, something that they had not made clear in C-Y-Z- itself. Ma petitioned the BIA to reconsider his case, but the Board denied his request,98 determining that its C-Y-Z- holding was limited to spouses in legally registered marriages only.99 Ma then appealed to the Ninth Circuit where he argued that the BIA’s decision denying him asylum was based on an erroneous bright-line distinction between legally married couples and traditionally married couples.100 He further argued that such a distinction was senseless because only those who are too young to marry under China’s Marriage Law, which is itself an integral part of the OCP, are in traditional marriages.101

The Ninth Circuit agreed with Ma.102 It noted:

The BIA’s refusal to grant asylum to an individual who cannot register his marriage with the Chinese government on account of a law promulgated as part of its coercive population control policy, a policy deemed by Congress to be oppressive and persecutory, contravenes the statute and leads to absurd and wholly unacceptable results. Accordingly, we need not defer to the BIA’s decision.103

In other words, the Ninth Circuit did not defer to the BIA’s decision because, under the second step of Chevron, it believed that the BIA’s limitation of granting relief to “legal,” but not “traditional,” spouses was an unreasonable interpretation of section 601(a). The court further noted that granting relief only to legal spouses could lead to the absurd result of breaking up the family, which would not only be “at odds” with the purpose of section 601(a), but also with U.S. immigration policy as a

93 Id. at 556.
94 Id. When the boat in which Ma was being smuggled was intercepted, Ma was put in a detention center for a number of years, but eventually applied for asylum. Id.
95 Id.
96 Id. at 556-57.
97 Id. at 557.
98 Id.
99 Id.
100 Id. at 555.
101 Id.
102 Id.
103 Id. at 559. The Seventh Circuit has followed the Ninth Circuit’s lead in extending relief to traditional spouses. Zhang v. Gonzales, 434 F.3d 993, 999 (7th Cir. 2006) (describing the BIA’s bright-line rule between legal spouses and traditional spouses as a “Catch-22”).
whole.\textsuperscript{104} This absurd result could occur, for example, if Chiu was granted refugee status based on her forced abortion, while Ma, not legally recognized as her husband, would be unable to derivatively achieve the same status.\textsuperscript{105} Finally, the court noted that while in most instances it defers to other nations’ minimum marriage ages, it would not do so here.\textsuperscript{106} It reasoned that in light of the enactment of section 601(a) to provide relief to OCP victims, and in light of the fact that the minimum marriage ages in China are an essential part of the OCP, it would avoid such deference because giving it “would contravene the fundamental purpose of the statute.”\textsuperscript{107}

Thus, under the Ninth Circuit’s decision in \textit{Ma}, any spouse, whether traditional or legal, qualifies for relief under section 601(a) based solely on the persecution of their wife. Note, however, that while this holding does not appear to be exceedingly broad, it has left the door wide open to the possibility for manipulation and fraudulent claims under section 601(a). This is because those who are married in a traditional marriage rather than a legal marriage will have no proof of their marriage from the Chinese government because the Chinese government has rejected the couple’s marriage application.\textsuperscript{108} It can therefore be quite easy for both fiancés and boyfriends of persecuted females to allege that they were actually in a traditional marriage with their partner. Even beyond fiancés and boyfriends, however, the Ninth Circuit’s holding opens the door to the possibility of fraudulent claims. While a “legal” spouse should at the least be able to prove that he was legally married (by presenting official government documents such as the marriage certificate, joint tax returns, joint bank account statements, property titles, etc.), and will hopefully have documented evidence of his wife’s persecution (medical records showing that she was pregnant at one time, etc.), a person claiming to be in a mere traditional marriage is unlikely to have many of these documents. Thus, nearly anyone, even males who do not even have a partner \textit{at all}, can, under the Ninth Circuit’s broad holding, easily make a fraudulent claim that they now meet the requirements of section 601(a). Indeed, as will be discussed below, fraudulent asylum claims by Chinese males under section 601(a) have recently become quite common.

\textsuperscript{104} \textit{Ma}, 361 F.3d at 561 (“Application of the BIA’s rule would result in the separation of a husband and wife, the break-up of a family, a result that is at odds not only with the provision at issue here, but also with significant parts of our overall immigration policy.”).
\textsuperscript{105} \textit{Id.}
\textsuperscript{106} \textit{Id.}
\textsuperscript{107} \textit{Id.}
\textsuperscript{108} Note, however, that the couple, in trying to prove that they were wed in a traditional marriage ceremony, may actually have proof of the denial of a legal marriage from the Chinese government. \textit{See} Meredith M. Snyder, \textit{Note, For Better or Worse: A Discussion of the BIA’s Ambiguous C-Y-Z Decision and its Legacy for Refugees of China’s One Child Policy}, 84 WASH. U. L. REV. 1541, 1543 (2006).
C. The Third Circuit Construes the Holding of C-Y-Z- Narrowly

Shortly after Ma was decided, the Court of Appeals for the Third Circuit, unlike the Ninth Circuit, held that it must accord Chevron deference to the BIA’s C-Y-Z- holding that per se relief will only be granted to those husbands who are legally married to their wives. In Chen v. Ashcroft, Chen and his girlfriend, Chen Gui, started living together when Chen was nineteen years old and Chen Gui was eighteen. When the couple discovered that Chen Gui was pregnant, they applied for a marriage license. However, since neither Chen nor Chen Gui had reached the minimum age for marriage, the application was denied by the Chinese government. OCP Officials, receiving word of the pregnancy, went to look for Chen Gui. Chen Gui was not home, and Chen, after getting into a minor physical fight with the officials, was told that he had a few days to inform them of her whereabouts, or he would be arrested. The couple then went into hiding, and Chen soon thereafter left for the United States. After Chen left, he learned that the OCP officials ultimately had found Chen Gui and had forced her to abort their baby in the eighth month of the pregnancy. When the INS initiated removal proceedings against Chen, he sought asylum relief under section 601(a). Similarly to Ma, Chen argued that although he was not legally married, the BIA’s distinction between the status of legally married couples and the status of other couples “evinces such a lack of rationality as to be [an] arbitrary and capricious” interpretation of section 601(a). He also claimed that, if not for China’s refusal, he and Chen Gui would have been legally married. The BIA, however, summarily reaffirmed that its C-Y-Z- holding had “not been extended to include [legally] unmarried partners.” Chen appealed to the Third Circuit.

The Third Circuit assumed for the sake of argument that C-Y-Z-’s interpretation of section 601(a) was permissible under step one of Chevron—i.e., that the statute was ambiguous as to its intended relief.

109 381 F.3d 221 (3d Cir. 2004).
110 Id. at 223.
111 Id.
112 Id.
113 Id.
114 Id.
115 Id.
116 Id.
117 Id.
118 Id. at 227.
119 Id. at 222.
120 Id. at 223. In this case, the IJ who initially heard Chen’s case granted his asylum petition. The IJ reasoned that since Chen and Chen Gui would have married if they had been legally allowed to, they fell under C-Y-Z-’s holding “by analogy . . . if not by the letter.” The INS then appealed to the BIA. Id.
121 Id.
for physically unharmed partners of persecuted women.  

The court then concluded that under the second step of *Chevron*, it must accord deference to the BIA’s limitation because expanding relief to only legal spouses of persecuted victims was within the range of permissible interpretations of section 601(a).  

The court first reasoned that using legal marital status to distinguish those who deserve per se relief from those who still must prove the nexus requirement of the refugee definition was a simple way to identify those whose opportunities to reproduce and raise children were seriously impaired by the wife’s forced abortion or sterilization and those who would likely suffer the most emotional pain by such persecution.  

Second, the court noted that, in light of the BIA’s heavy caseload, it was entirely reasonable for it to adopt a position requiring a legal marriage because only legal marriages can be proven by documentation.  

The court further noted that the BIA might have wanted to avoid the practical difficulties that would arise if unmarried males had to prove paternity of a child that was forcibly aborted and the great potential for false claims that would come along with such a difficulty.  

It specifically pointed to legislative history of section 601(a) in which some legislators appeared concerned “about the ease with which ‘young Chinese single-unmarried-males’ might falsely claim eligibility for asylum under the proposed amendment, resulting in a flood of meritless applications.”  

Finally, the court expressly disagreed with the Ninth Circuit’s *Ma* rationale. It stated: “[W]e see no basis for concluding that Congress’s intent in amending [the original refugee definition] was to afford relief to every person who is a victim of any rule or practice that

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122 Id. at 227.
123 Id.
124 Id. at 227-28. Chen argued that even if it was rational not to extend the C-Y-Z- holding to include all unmarried indirect male partners, the holding should at the very least be extended to cover those who wanted to marry but were denied a marriage certificate because they did not meet the minimum age requirements. However, the Third Circuit rejected this argument as well, noting that they must respect the minimum age requirements put in place. The court conceded, however, that, “Chen’s situation simply shows that C-Y-Z- is underinclusive with respect to a narrow but sympathetic class,” but went on to say that this underinclusiveness is not enough to deem the BIA’s interpretation as unreasonable. Id. at 229-30.
125 Id. at 229. The court, in further determining that C-Y-Z- was not arbitrary and capricious, also pointed to the fact that marital status is used as a proxy in many areas of law—i.e., “income tax, welfare benefits, property, inheritance, testimonial privilege, etc.” Id. at 227 n.6.
126 Id. at 229 (“The BIA might also have been concerned that unmarried asylum-seekers would falsely claim to have had an intimate relationship with a person who suffered a forced abortion or sterilization, and the BIA might have felt that it would be too difficult to distinguish between those unmarried persons who had a truly close relationship with the person who underwent the medical procedure and those unmarried asylum seekers who did not.”).
127 Id. at 233 (quoting 142 CONG. REC. S4592 (daily ed. May 2, 1996) (statement of Sen. Simpson)). While the *Ma* court had pointed to legislative intent to show that section 601(a) was adopted to provide relief to persecuted “couples” and to prevent the break up of families, *Ma v. Ashcroft*, 361 F.3d 553, 559 (9th Cir. 2004) (quoting H. R. REP. NO. 104-469(I), at 174 (1996)), the *Chen* court points to legislative history of fraudulent claims under section 601(a). *Chen v. Ashcroft*, 381 F.3d 221, 233 (3d Cir. 2004).
forms a part of the Chinese population control program.” The court therefore concluded that “the BIA’s interest in promoting administrability and verifiability” was sufficient to meet the low burden of reasonableness under the second step of Chevron, and that it was therefore compelled to rule in line with C-Y-Z.

D. The Second Circuit Disagrees with C-Y-Z’s Holding

With this circuit split firmly in place, in July 2007 the Court of Appeals for the Second Circuit took an entirely different approach to the interpretation question, further adding to the confusion of the scope of section 601(a). The Second Circuit was faced with the three appeals of Lin, Dong, and Zou. Each of these refugee applicants was a legally unmarried male Chinese citizen who alleged that he should qualify as a refugee under section 601(a) on account of his partner’s persecution. As expected, the BIA denied each of their asylum claims, finding that its holding in C-Y-Z did not extend to non-legally married spouses. On appeal, the Second Circuit, rather than assuming that section 601(a) was silent or ambiguous with respect to indirect victims of persecution (as the Third Circuit had done in Chen)—an interpretation that would permit the BIA to “fill in the gap” under step two of Chevron—remanded the case to the BIA. The purpose of the remand was to give the BIA an opportunity to explain how it read section 601(a) to grant per se relief to indirect partners of direct victims at all, and further, to clarify its reasoning for extending such relief to legal spouses only. On remand,

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128 Chen v. Ashcroft, 381 F.3d 221, 232 (3d Cir. 2004). The court discussed that since the asylum statute clearly limits relief only if the harm amounts to a level of “persecution” (with only abortions and sterilizations automatically meeting that requirement), then it necessarily excludes lesser harms (i.e., being in a minor fight, getting a fine, or losing your job) even if those harms implicate humanitarian interests for which the statute was passed. Id. at 231-33.

129 Id. at 229.

130 Lin v. U.S. Dep’t of Justice, 494 F.3d 296, 296 (2d Cir. 2007).

131 Id. at 299. Specifically, Lin alleged that he and his girlfriend were denied governmental permission to marry and have a child because his girlfriend was below the minimum marriage age. Id. at 301. When his girlfriend got pregnant and was forced to have an abortion, Lin left for the United States. His girlfriend was not well enough to travel so she stayed behind in China. Petitioner Dong, when detained in the United States, claimed that his fiancée (who was still in China) had been forced to have two abortions. Petitioner Zou, who was too young to marry his girlfriend, claimed that his girlfriend had been forced to undergo an abortion. Id.

132 Id. at 299.

133 Lin v. U.S. Dep’t of Justice, 416 F.3d 184, 187 (2d Cir. 2005).

134 Id. The Second Circuit stated that the because the BIA had failed to articulate a reasoned basis for making [legal] spouses eligible for asylum under IIRIRA § 601(a), IJs cannot possibly advance principled—let alone persuasive—reasons to distinguish between, on the one hand, the BIA’s decision to create spousal eligibility under IIRIRA § 601(a), and, on the other hand, the eligibility of boyfriends and fiancés under that same statutory provision.

Id. at 191. Indeed, “a fresh look at C-Y-Z reveals that the BIA never adequately explained how or why, in the first instance, it construed IIRIRA § 601(a) to permit spouses of those directly victimized by coercive family planning policies to become eligible for asylum themselves.” Id. With no basis
the BIA affirmed its C-Y-Z- position.\textsuperscript{135} It also clarified that only those legal spouses who actually opposed their wife’s persecution should qualify under the statute.\textsuperscript{136} However, it once again failed to specifically point to any text of section 601(a) to support this reading, and instead pointed merely to the “overall purpose of the amendment” for its conclusion that both partners of a legal marriage deserved protection under section 601(a) rather than only the direct victims of the persecution.\textsuperscript{137}

The Second Circuit then ordered a rehearing of the petitioners cases to consider two particular issues: (1) whether section 601(a)’s language is ambiguous so as to allow the BIA to determine its effect on partners of direct victims, and (2) if section 601(a) is ambiguous, was C-Y-Z-’s bright-line rule between legal marriages and traditional marriages or other relationships a reasonable construction of the statute.\textsuperscript{138} With respect to the first issue, the Second Circuit examined the language of section 601(a) itself to determine whether Congress, through the statute, had directly and unambiguously spoken as to its intended effect on indirect victims.\textsuperscript{139} The court determined the language to be unambiguous in \textit{not} extending \textit{per se} refugee status to anyone beyond the direct victim.\textsuperscript{140} Since section 601(a) refers to “\textit{a person} who has been forced to abort a pregnancy,” \textsuperscript{141} “\textit{a person} who had been forced . . . to undergo an involuntary sterilization,” \textsuperscript{142} “\textit{a person}” who “has been persecuted for

given by the BIA, the Second Circuit stated that it would be “impossible” to make a reasoned decision as to whether it should affirm or reverse the petitioners’ cases. \textit{Id.} \textsuperscript{135} \textit{In re S-L-L-}, 24 I. & N. Dec. 1., Interim Decision (BIA) 2006 WL 3337624 (BIA), at *4. In order to come to such a conclusion, the BIA necessarily had to first determine that section 601(a) was unclear as to the scope of its protections for indirect victims and thus the BIA had the power to fill this gap, as it did in fact conclude. \textit{Id.} Having concluded that the statute was silent, the BIA looked at “the focus of the amendment and the legislative history” in order to justify its C-Y-Z-holding. \textit{Id.} Focusing on policy considerations, the BIA noted the responsibilities with respect to family planning that legally married couples share. \textit{Id.} at *6. Once again, it stopped short of extending automatic relief to non-legally married partners because “the sanctity of marriage and the long term commitment reflected by marriage place the husband in a distinctly different position from that of an unmarried father.” \textit{Id.} at *9. The BIA also noted that C-Y-Z- was already a ten-year-old precedent. \textit{Id.} at *4. Board Member Pauley concurred, but stated that had the BIA been “writing on a clean slate,” he would have opted for a case-by-case approach of whether the indirect partner had been persecuted for other resistance to a coercive OCP practice rather than granting legally married spouses \textit{per se} relief. \textit{Id.} at *13. Board Member’s Filppu and Cole dissented, reasoning that section 601(a) was unambiguous in that is used the words “\textit{a person}” rather than “\textit{a couple}.” \textit{Id.} at *16.

\textsuperscript{135} \textit{Id.} at *4.
\textsuperscript{136} \textit{Id.} at *8.
\textsuperscript{137} \textit{Lin v. U.S. Dep’t of Justice, 494 F.3d 296, 299-300 (2d Cir. 2007).
\textsuperscript{138} \textit{Id.} at 305-06.
\textsuperscript{139} \textit{Id.} at 304-07 (“We conclude that Congress has spoken to this issue and that it has done so unambiguously.”). The Second Circuit noted that in previous cases it had deferred to the BIA’s holding without ever doing a \textit{Chevron} analysis. \textit{Id.} at 305. For example, in \textit{Yuan v. U.S. Department of Justice}, although the court noted that “[b]y its plain language, the law would seem to extend refugee status only to actual victims of persecution—for example, a woman who was ‘forced to abort a pregnancy,’ but not her husband,” it nevertheless “followed the lead of the BIA.” 416 F.3d 192, 196 (2d Cir. 2005).
\textsuperscript{141} \textit{Id.} (emphasis added).
failure or refusal to undergo such a procedure,”143 and “a person who has a well founded fear that he or she will be forced to undergo [such a procedure],”144 rather than stating “a married couple who has been subjected to a forced abortion or involuntary sterilization”143 or something analogous, the Second Circuit concluded that Congress did not intend to extend per se relief beyond the direct victim.146 Consistent with the interpretive principle that “the inclusion of some obviously results in the exclusion of others,” the court also reasoned that, because section 601(a) specifically mentioned some people (e.g. those who directly undergo, fear, or resist abortions or sterilizations), it would be unreasonable to read it so as to apply to others.147 Because it concluded that the statute was unambiguous with respect to indirect victims in its application, the court did not need to reach the second issue of whether or not the BIA’s bright-line rule was a reasonable interpretation of the statute.148

Under the Second Circuit’s approach, a male can only qualify for asylum relief under section 601(a) if he demonstrates that he himself has been sterilized or can show “other resistance”149 to a coercive population control program” or “a well founded fear that he . . . will be . . . subject

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143 Id. (emphasis added). The court noted that the natural meaning of “undergo” means submitting to a procedure that affects your own body, not anyone else’s. Lin v. U.S. Dep’t of Justice, 494 F.3d 296, 305 (2d Cir. 2007) (emphasis added).
144 8 U.S.C § 1101 (a)(42)(B) (emphasis added).
145 Lin v. U.S. Dep’t of Justice, 494 F.3d 296, 305 (2d Cir. 2007) (“Had Congress intended this clause to refer to a spouse or partner of someone who has been physically subjected to a forced procedure, it could simple have said so.”) (internal quotation marks omitted).
146 Id. at 304.
147 Id. at 307. The court noted that the “critical defect in the BIA’s policy of according per se refugee status to spouses of individuals explicitly protected by § 601(a) is its creation of an irrebuttable presumption of refugee status for a new class of persons.” Id. at 308. The court further noted that if its conclusion is contrary to Congress’s intentions, Congress could, of course, amend the statute. Id. at 309 n.10.
148 Id. at 309. Nevertheless, some would argue that the mere existence of the previous circuit split, and the numerous circuit courts who concluded that section 601(a) was ambiguous, is proof enough to contradict the Second Circuit’s finding that section 601(a) is unambiguous as to its treatment of indirect partners of physically harmed victims. See Katherine F. Riordan, Comment, Withholding Automatic Asylum for Spouses or Partners of Victims of China’s Coercive Family-Planning Policies: Shi Liang Lin v. U.S. Dep’t of Justice, 494 F.3d 296 (2d. Cir. 2007), 41 SUFFOLK U. L. REV. 983, 989-90 (2008).
149 The Second Circuit admits that what is required under the phrase “other resistance” is ambiguous and thus subject to a reasonable BIA interpretation. Lin, 494 F.3d at 312. In In re S-L-L-, the BIA held that to show “other resistance,” an applicant must demonstrate both resistance to coercive OCP practices and that he or she has suffered based on such resistance. In re S-L-L-, 24 I. & N. Dec. 1, at 10, Interim Decision (BIA) 2006 WL 3337624 (BIA). The fact that the person’s spouse has been the victim of a coercive OCP practice could play into this analysis, but, standing alone, would not be enough to let the person automatically satisfy the “other resistance” language. Lin, 494 F.3d at 313. An example of “other resistance” besides a forced abortion or sterilization that might rise to the level of persecution so as to fall under section 601(a) would be extreme economic sanctions or penalties imposed based on the female’s refusal to abort a child. Karen Y. Crabbs, United States Domestic Policies and Chinese Immigrants: Where Should Judges Draw the Line When Granting Political Asylum?, 7 FLA. J. INT’L L. 249, 271-72 (1992).
to persecution for such . . . resistance.” Alternatively, an indirect claimant can gain derivative asylum if his spouse has already applied and qualified for asylum based on her direct persecution. And, of course, the alien can always try to meet the traditional nexus requirement of the refugee definition. The Supreme Court denied certiorari of the claimants in this case, thus leaving the three contrasting approaches of the Courts of Appeals in place.

IV. DECRYPTING THE FUTURE

A. The Problem: The Effect of the Case Law on Section 601(a) Usage

The inconsistent application of the statute among the circuits and specifically the broad interpretation followed by the Ninth Circuit has raised serious doubt as to whether section 601(a) sufficiently serves those for whom it was primarily implemented to protect and who most urgently and deservingly need its protections—direct female victims of OCP policies and the victims’ families. When section 601(a) was written in 1996, there were two major concerns raised regarding its enactment. The first was a serious fear that it would open the floodgates to meritless claims by large numbers of Chinese citizens in general. This concern stemmed from the fact that coercive OCP enforcement techniques are used throughout the vast majority of China’s provinces, with millions

150 Lin, 494 F.3d at 314 (quoting 8 U.S.C. § 1101(a)(42)). The court did not find stare decisis to be a valid reason to continue to follow an interpretation of the statute that was inconsistent with its plain language. Id. at 310. Nor would the court, given the clarity of the statute, use legislative history to help determine its correct interpretation. Id. However, the court noted that there was legislative history to support its holding. For example, it pointed to a House Report that stated:

The Committee is aware that asylum claims based on coercive family planning are often made by entire groups of smuggled aliens, thus suggested that at least some of these claims, if not the majority, have been ‘coached.’ Section [601(a)] is not intended to protect persons who have not actually been subjected to coercive measures or specifically threatened with such measures.

Id. at 310-11 (quoting H.R. REP. 104-469, pt. 1, at 174 (1996) (alterations and emphasis by the Second Circuit)).

151 Id. at 312. Under 8 U.S.C § 1158(b)(3)(A), “a spouse . . . of an alien who is granted asylum . . . may, if not otherwise eligible for asylum, . . . be [automatically] granted the same status as the alien if accompanying, or following to join, such alien.” 8 U.S.C. § 1158(b)(3)(A). The court noted that such a policy of granting the direct victim asylum first, and then derivatively allowing a spouse to do so, not only encourages the preservation of the family unit, but also eliminates the perverse incentive of encouraging husbands to leave their wives. Lin, 494 F.3d at 312.

152 Zhen Hua Dong v. Dep’t of Justice, 128 S. Ct. 2472 (2008).

153 The Fifth Circuit has followed the Ninth’s Circuit broad approach. Chen v. Gonzales, 457 F.3d 670, 674 (“[W]e have joined the Ninth Circuit in extending protections to spouses in cases ‘[w]here a traditional marriage ceremony has taken place . . . .’” (quoting Zhang v. Gonzales, 434 F.3d 993, 999 (7th Cir. 2006) (alteration in original))).

154 Hunker, supra note 6, at 146 (“Arguably, every alien fleeing China could claim refugee status under section 601 because the practice of coercive population control permeates most areas of the country.”).
of people being exposed to the practices in their lifetimes.\textsuperscript{155} To alleviate this concern, Congress initially enacted a one-thousand-per-fiscal-year cap on the number of people who could qualify for asylum under the statute.\textsuperscript{156} Even though the one-thousand-per-year cap was repealed in 2005,\textsuperscript{157} the United States has not experienced the feared “flood” of Chinese refugees,\textsuperscript{158} which has alleviated the initial fear that this would occur.\textsuperscript{159} The second concern was that section 601(a) was gender-biased in that males would have a harder time than females claiming asylum under the statute.\textsuperscript{160} However, this concern does not logically recognize that the statute should more readily apply to women than men because state population policies, including China’s, most frequently target women.\textsuperscript{161} For example, women in China are subjected to forced sterilizations more often than men, despite the fact that both genders are potentially subject to such a procedure capable of having such a procedure.\textsuperscript{162} As a result, between 1979 and 1984, thirty-one million women received forced sterilizations while only\textsuperscript{163} 9.3 million men did.\textsuperscript{164} This large differential in treatment can be explained in part because some people in China believe that vasectomies make men weak.\textsuperscript{165} In addition,

\begin{itemize}
  \item Id. at 134; see also Rivera, supra note 21, at 259 (“One hundred million—that is the number of couples that the Chinese government had prevented from having a child as of 1993.”); Patricia Wen, Law Offers Chinese a Path to US, BOSTON GLOBE, Aug. 18, 2002, at B1 (“If these asylum cases work so easily, millions of Chinese would qualify [for asylum] based on the one-child policy.” (quoting Chinese immigrant Dong-Sheng Zang)).
  \item The statute read, “For any fiscal year, not more than a total of 1,000 refugees may be . . . granted asylum . . . pursuant to a determination under the third sentence of section 101(a)(42),” which discusses persecution under China’s OCP. 8 U.S.C. § 1157(a)(5); see Chen v. Ashcroft, 381 F. 3d 221, 225 n.2 (3d Cir. 2004). Once the 1000 limit was surpassed in any given year, the INS would begin to issue asylum claimants conditional grants. In practice, it would usually take up to seven years before the receiver of such a conditional grant would get the full benefits of asylum. Furthermore, it usually took another sixteen years before the claimant would be able to receive the status of a legal permanent resident. Jordan, supra note 59, at 230-31.
  \item The number of asylum claimants from China has slowly increased from 4913 new claims a year for fiscal year 1998 to 7934 new claims a year for fiscal year 2007, with Chinese applicants making up only 6.9% of all asylee applicants that year. United States Dep’t of Justice, Electronic Reading Room Information, available at http://www.usdoj.gov/ceoi/efoia/foiafreq.htm (follow 1998 and 2007 hyperlinks under “Statistics, Publications, and Manuals”). Additionally, although there are no statistics, it is clear that not every Chinese alien who applies for asylum in the United States is doing so based on persecution under the OCP.
  \item I do not use the word “only” here to intend that 9.3 million is a small number. I use the word merely to demonstrate that 9.3 million is comparatively smaller than 31 million.
\end{itemize}
only women are subject to other coercive techniques such as forced abortions and IUD insertions. Therefore, the statute logically should be written with broader protection for women than for men. In spite of the greater necessity for women to be protected under the statute, the perceived gender-bias concern was partially removed in 1989 by the BIA’s decision in C-Y-Z- making it much easier for legally married male partners to come within the protections of the statute.166 This perceived concern was further alleviated with the decision from the Ninth Circuit in Ma, which extended relief to the male spouses of persecuted women in traditional marriages.167

With the implementation of such decisions, however, a new problem has arisen that is in striking contrast to the initial concern of male-gender bias. This new problem is that, while most OCP victims are women, section 601(a) is being overwhelmingly used by men to gain asylum in the United States.168 In fact, those in the field of immigration have commented that “the little-known provision of US immigration law . . . has become a quick way into the country for thousands of Chinese citizens—three-quarters of them men.”169 The concern has shifted from a general fear of “floodgates” and male gender-bias, into a fear of specificity that section 601(a) has, in particular, opened the floodgates for Chinese males seeking asylum in the United States by way of false coercive population control claims.170

The fact that three-fourths of those using section 601(a) are male is not a problem in and of itself. Indeed, there are a number of completely reasonable explanations for such a phenomenon. One explanation is that men who have been directly persecuted through forced sterilizations might be more likely to leave their families and homeland than females who have been directly persecuted. This can be explained in part by the harsh travel conditions that most migrants have to endure to get to the U.S.—a journey a male might be more willing to face.171 Additionally, women will often remain in China, despite

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167 Wen, supra note 155 (“But the law intended to shelter Chinese women has largely benefited Chinese men.”); Nancy Kelly, Gender-Related Persecution: Assessing the Asylum Claims of Women, 26 CORNELL INT’L L.J. 625, 629 n.16 (1993).
168 Wen, supra note 155 (“Of the 10,000 Chinese people who have obtained political asylum based on China’s one-child policy, federal statistics show, three out of four are men.”).
169 Moshe S. Berman, Note, The Appropriate Response of the United States to Forced Abortion in China: Should Section 601(a) of the IIRIRA be Extended to Allow Asylum for Unmarried Couples?, 41 NEW ENG. L. REV. 339, 352 n.104 (2006-2007) (“[I]f this amendment . . . were to come to pass . . . I suggest that there will be millions of people who, under this language, will qualify.” (quoting Senator Simpson)); see also Rabkin, supra note 16, at 975.
170 Rosenthal, supra note 3 reporting that the traveling "at best involve[s] flying through a series of countries with forged travel documents and at worst mean[s] crossing borders on foot or packed in airless trucks, disguised as tomatoes"; see also Kung, supra note 1, at 1275 (“Lured by the prospect of a richer life in the United States, Chinese emigrants may endure treacherous journeys by air, sea and land in abhorrent conditions . . . .”).
persecution, because they feel obligated to tend to their familial duties. A second possibility is that, where the male has not been directly persecuted but his female partner has been, it is common for the man to come to the United States prior to the female spouse or partner in order to secure a job. Once settled, the males will then, theoretically, seek to have their partners and children join them. Indeed, such a practice has been in place for decades and is reflected in the Ma case above where Ma left China before his wife and alleged that he hoped to send for her shortly thereafter.

While these explanations are plausible and help justify the discrepancy in section 601(a)’s gender usage to some extent, fraud undeniably also plays a major part in the equation. Some Chinese men are undoubtedly using stories of partner persecution as mere pretext to gain refugee status in the United States. While a male migrant may be hesitant to falsely claim that the Chinese government forced him to be sterilized for fear that a medical examination could reveal the truth, he would likely be more willing to falsely claim persecution based on the persecution of his legal or traditional wife. While a claim of indirect persecution might be enough to qualify the man under the “other resistance” clause of section 601(a), the applicant faces a greater probability of denial using that route instead of the stand-in-the-shoes-of-his-partner route.

This is true because the BIA continues to hold that “generally harsh conditions shared by many others do not [rise to a level of other resistance] persecution, even where a policy may be repugnant to our concepts of freedom.” Thus, it appears that a male applicant’s best chance of qualifying as a refugee where he has not been directly persecuted (sterilized) under OCP practices is to claim that his female partner has been directly persecuted.

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172 Abrams, supra note 55, at 904 (“The husbands and fathers escape persecution, while women often remain to tend to family responsibilities.”).

173 Wen, supra note 155 (reporting that Nancy Kelly, an immigration specialist, argues that “families send the men out first so they can get a job, then try to get the rest of the family over”); see also Ma v. Ashcroft, 361 F.3d 553, 556 (9th Cir. 2004) (“Chiu encouraged Ma to leave for America first and then to send for her as soon as possible.”); Abrams, supra note 55, at 904 (“[W]omen often lack the economic independence to escape oppressive conditions.”).

174 Wen, supra note 155; see also Ma, 361 F.3d at 556; In re C-Y-Z-, 21 I. & N. Dec. 915, 927 (BIA 1997) (Rosenberg, concurring) (“The fact that the respondent preceded his family is no different from the cultural practice followed by hundreds of thousands of immigrants and refugees who fled anti-Semitic pogroms in czarist Russia, famine in Ireland, fascism in Germany, political or religious upheaval in other European countries, and civil war and death squads in Central America.”); Rabkin, supra note 16, at 993 (noting that families escaping civil wars, famine, and religious persecution have for many years sent the male over first to get established before bringing over the rest of their family); Rosenthal, supra note 3 (where a woman living in a town known as “widow’s village” because most of the husbands left for the United States, says, “Of course I plan to go join my husband”).

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176 See supra note 149 and accompanying text.

177 Abrams, supra note 55, at 901 & n.123 (referring to the BIA’s decision in In re Acosta, 19 I. & N. Dec. 211, 222 (BIA 1985)).
The case law interpreting the statute, with the exception of the recent Second Circuit holding in Lin, affords men who would otherwise have to meet the nexus requirement of the traditional refugee definition a less complicated path to asylum. So long as the claimant appears credible, his own testimony may well be enough for him to gain asylum. 178 With documentation being scarce in even legitimate refugee cases, a lack of a marriage certificate from the Chinese government will not necessarily be enough to dispose of the claim. 179 Furthermore, since even in legitimate cases it is common for a male to come to the United States before his female partner, oftentimes the female will not be available to undergo a medical examination or to test her credibility. Thus, the IJ will likely have nothing to help guide his asylum decision except for a credibility determination of the physically unharmed male applicant’s story. It is for these reasons that Merle Goodman, a professor of Chinese history, has noted that “[t]he potential for abuse [under Section 601(a)] is huge.” 180

Unfortunately, this cynical view of fraudulent claims as the explanation for why so many men are using section 601(a) is not without merit. In fact, while there is no way to know exact numbers, there are many documented cases of Chinese asylum seekers presenting claims that are later found to be fraudulent. 181 The easier it is to make a claim under section 601(a), the higher the likelihood is that an alien wanting to

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178 See In re S-M-J-, 21 I. & N. Dec. 722, 723 (BIA 1997) (“[A]n alien’s own testimony may in some cases be the only evidence available, and it can suffice where the testimony is believable, consistent, and sufficiently detailed to provide a plausible and coherent account of the basis of the alien’s alleged fear.”); see also John R.B. Palmer, The Second Circuit’s “New Asylum Seekers”: Responses to an Expanded Immigration Docket, 55 CATHOLIC U. L. REV. 965, 984 (2006) (discussing the fact that, if a person is deemed credible, a lack of corroborating evidence will not be a valid reason to deny an asylum claim unless the Immigration Judge can explain why there should be corroborating evidence, and that the applicant’s explanation as to why he does not have such evidence is insufficient); Rabkin, supra note 16, at 975 (“For the same reason, the House Committee emphasized that the success of a claim under section 601(a) would continue to depend on the credibility of the asylum-seeker.”). Such a situation (where an IJ would deny a credible Chinese person asylum based on his lack of corroborative evidence), however, would likely be rare, because oftentimes even legitimate asylum-seekers lack any type of documentation of persecution.

179 See Palmer, supra note 178, at 983 (“[A] genuine refugee does not flee her native country armed with affidavits, expert witnesses, and extensive documentation.” (quoting Abankwah v. INS, 185 F.3d 18, 26 (2d Cir. 1999) (internal quotation marks omitted)).

180 Wen, supra note 155. Merle Goodman is a professor and a researcher for Harvard University’s Fairbank Center for East Asian Research. Id. But note that later in the article, Shen-Shin Lu, a Boston lawyer, says that “[w]hile there’s room for abuse in these asylum cases, . . . many Chinese men are forced to be sterilized after having one child, so it’s not unreasonable for men to directly appeal for asylum based on the one-child policy.” Id. (internal quotation marks omitted). Dong-Shen Zang, a Harvard student and Chinese immigrant, noted that he thinks many Chinese citizens would be embarrassed to seek asylum relief based upon a fabrication of persecution, knowing that such a claim would be a manipulation of the statute and the U.S. immigration system. Rather, he states that most Chinese immigrants will either enroll in school, get a job, or get sponsored by other relatives already living in the United States, and only then will they seek permanent residency. Id.

181 Palmer, supra note 178, at 992 (“It is not that the administrators have no grounds to be skeptical. Many of today’s asylum seekers do present fraudulent claims.”).
come to the United States might take advantage of the “loophole.” This fear of fraudulent claims is exacerbated “when high-volume law offices and ‘travel agencies’ end up standardizing peoples’ stories so that they can churn out large quantities of cookie-cutter filings.” Thus, when a Chinese applicant is defending against a removal proceeding, there are known places where he can go to quickly and cheaply obtain help. These agencies are able to provide these quick and inexpensive services to the applicant, however, only by using a somewhat standardized story for all section 601(a) applicants, with many stories based on the female partner’s persecution under China’s OCP. Similarly, “snakeheads,” who are in charge of human trafficking rings in China, are known for frequently coaching males they smuggle into the United States to memorize tales of the persecution that their partners faced under the...

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183 Palmer, supra note 178, at 980; see also Susan Sachs, Cracks in Façade of Refuge; Documentary Shows Pitfalls in Process of Seeking Asylum, N.Y. TIMES, Dec. 19, 1999, at A53 (discussing a documentary called Well-Founded Fear that gives a behind-the-scenes look at the asylum process in New York). The documentary in Sachs’s article tells the story of “[a] Chinese man follow[ing] the instructions of the smuggler who brought him to the United States and concocts an improbable story of fleeing his country’s one-child policy.” It also reports that in the view of some long-time asylum interviewers, most of the stories told by applicants are contrived and thus the interviewers oftentimes have to rely on nothing more than their “gut feelings” in determining whether to approve the application. The documentary further tells of many interviewers resentment over being lied to and shows one interviewer, Jim, who mutters, “Oh, another Chinese” and who later rolls his eyes when the person cannot get his story straight.

184 See supra note 2, and accompanying text; see also Matt Hayes, Corrupt Lawyers Aid Immigration Woes, FOXNEWS.COM, Apr. 29, 2002, http://www.foxnews.com/story/0,2933,72149,00.html. Hayes writes,

For most lawyers, the practice of immigration law is attractive simply because there are so many immigrants. There are over 100,000 new political asylum cases each year alone. But this volume also drives down rates and makes the lawyer less than diligent in assessing the credibility of his client’s asylum claims. To be too diligent could mean one less fee.

185 Those who are in charge of Chinese human smuggling are called snakeheads. The snakehead system is quite a complex one: “Big snakeheads” control networks of “small snakeheads,” debt collectors, and enforcers. The small snakeheads are generally local Chinese people and are in charge of recruiting people to be smuggled and for collecting down payments from them. Once the down-payment is paid, middlemen guide the migrants from one point to the next and enforcers are in charge of controlling the people as they are en route to the United States. Once arrived, the migrants are locked in safe-houses until their fees are paid. Kung, supra note 1, at 1274. Lured by the American dream, experts have estimated that each year snakeheads smuggle approximately 50,000 Chinese citizens into the United States. Id. at 1273 & n.12, 1275 (noting that estimates range from 10,000 a year and that such human trade is big business, yielding an estimated $3 billion a year, with each migrant usually paying between $30,000 and $60,000 for his trip). The reason so many Chinese turn to this path is that it is very difficult for the average Chinese citizen to get a passport (which they must apply for), a visa from the U.S. embassy in Beijing, and an exit permit, all of which are required to travel abroad. Snakeheads, for a hefty price, will procure fake copies of these needed documents. Documents in hand, the migrants will travel by land, sea, or air, often in horrible conditions, on journeys that can be months long. Id. at 1278-81. “[M]any don’t survive the journey.” Hayes, supra note 184.
OCP, even when no such persecution ever took place. 186 Thus, these aliens will be prepared with their story of persecution if they are ever caught. In addition to verbal fabrication of persecution stories, human smuggling by snakeheads oftentimes involves false documents. 187 A 1998 State Department Report found that in certain areas of China, documentation “is subject to widespread fabrication and fraud.” 188 Authentic-looking marriage certificates can easily be printed to add credibility to a male’s claim that his “legal” spouse has been persecuted. And, even if an immigration officer discovers the documents as false, the applicant can then simply tell his coached story of his partner’s persecution and hope that his credibility has not been too damaged by way of the false documents to warrant an adverse asylum determination by the official. 189 Section 601(a) thus acts as a safety net—if the migrant is not caught, he will be safe, and, if he is caught, he can simply give his false documents or tell his oftentimes-false memorized story to be granted asylum relief.

Despite the fact that asylum officers know such fraud is taking place, and perhaps even frequently so, the “overwhelming majority” of asylum claims under section 601(a), most of which are made by males, are granted. 190 Asylum officers are required to determine credibility by “elicit[ing] detailed testimony about the applicant’s past experiences, comparing the applicant’s live testimony with prior statements, examining any documentary evidence provided by the applicant, and considering any other relevant information [about] conditions in the applicant’s home country, region, or town.” 191 Asylum officers who have no access to information, especially at the point of entry, are sympathetic to plausible stories of Chinese men who claim their Government persecuted their wives, for there is nothing to possibly contradict their stories. For example, one supervisor at O’Hare airport in Chicago stated,

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186 Rabkin, supra note 16, at 992 (discussing how opponents of broadening section 601(a) often cite “the frequency with which snakeheads coach the people they smuggle into the United States to say they are victims of coercive family planning”); see also Kung, supra note 1, at 1273 (noting that China “is a major source of smuggled migrants”).
187 Palmer, supra note 178, at 995 (noting that “[t]o the extent that [State Department] reports are accurate, it would not be illogical to conclude that any given group of Chinese asylum seekers may be carrying a higher than average proportion of fraudulent documents”).
188 Xiu Ling Zhang v. Gonzales, 405 F.3d 150, 157 (3d Cir. 2005) (discussing the judge’s possible reliance on this report); see also Palmer, supra note 178, at 995 n.208.
189 Kung, supra note 1, at 1289 (noting that INS officials are trained to detect such fake passports and visas).
190 Sperry, supra note 3 (discussing how, after LAX starting cracking down on undocumented Chinese nationals, O’Hare had a huge influx, where they know the longest they will be held is two weeks); see also Wen, supra note 155. But Wen notes that immigration officials may well have started cracking down—while only 52 asylum requests under section 601(a) were denied in 1998, 324 were denied in 2000. Id.
“We’re letting these people in even though we really have no idea who they are . . . . It’s almost impossible to get any information or any kind of background checks from our embassy in Beijing.” And later the supervisor said, “We’re getting a lot of men who say their wife is pregnant with their second child, . . . [b]ut when we ask where their wife is, they say she’s back in China.” Relying on asylum officers as a means of separating honest and fraudulent cases, circuit courts that have granted per se relief to spouses under section 601(a) have opened the door to new issues of fraud. In fact, the sheer number of false claims can hurt asylum-seekers with legitimate claims as immigration officials start to become more and more skeptical of anyone claiming asylum under section 601(a). With snakeheads and “travel agents” coaching Chinese male migrants to exploit the ease with which males are granted political asylum under section 601(a), and with courts struggling to find the proper balance for letting in those with legitimate claims while keeping undeserving aliens out, there is a clearly a need for change.

B. Suggestions to Deter Fraudulent Claims under Section 601(a)

With respect to the circuit court decisions discussed above, none of these holdings are without serious flaws. The Ninth Circuit’s expansive approach from Ma, which grants both legal and traditional spouses per se relief, does nothing to solve the fraud problem. Rather, it is these expansive applications of section 601(a) that have been a cause of the problem. Additionally, from a policy perspective, in order to

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192 Sperry, supra note 3 (quoting an INS inspections supervisor) (internal quotation marks omitted).

193 Id.

194 Kung, supra note 1, at 1305.

195 Id. at 1307.

196 Cleo Kung’s Comment about Snakeheads suggests that section 601(a), having subjected the already over-burdened U.S. asylum system to the abuses of Chinese smugglers, should be completely repealed. He says the statute is redundant in that anyone who is actually persecuted under China’s coercive OCP practices would qualify for refugee status under the pre-section 601(a) definition of a refugee. However, I believe that such a step is unwise and that there are other possible solutions to help limit abuse without going so far as completely repealing the statute. While Kung states that anyone who has actually been persecuted under the OCP would qualify as a refugee on account of his or her political opinion, he does not explain why, if this is true, the BIA, prior to the adoption of section 601(a), had not granted refugee status solely on the basis of OCP persecution. Id. at 1306, 1312. In fact, the BIA’s previous failure to grant refugee relief to those persecuted based on OCP policies was one of the major motivations for the enactment of section 601(a). See supra notes 60-62 and accompanying text. Many other commentators on the subject of section 601(a) simply argue that the Ninth Circuit’s broad approach to section 601(a) should be more widely adopted, pointing to the serious human rights abuses in China and the fact that unmarried male partners whose children have been aborted are just as harmed by the coercive act as are legally married male spouses. See, e.g., Berman, supra note 170, at 3367-68; Raina Nortick, Note, Singled Out: A Proposal to Extend Asylum to the Unmarried Partners of Chinese Nationals Fleeing the One-Child Policy, 75 FORDHAM L. REV. 2153, 2183 (2007); Rabkin, supra note 16, at 986. However, these suggestions to follow the Ma approach seem to discount the serious U.S. immigration concerns of limiting fraudulent claims under section 601(a). See infra Part IV.B.

197 Ma v. Ashcroft, 361 F.3d 553, 559 (9th Cir. 2004).
follow this approach the United States has to disrespect China’s marriage law. While these laws are unquestionably tied to the OCP, they may also be necessary to help to diminish China’s population growth—a goal that many people agree to be a valid one. While the coercive enforcement techniques of the OCP are criticized, the OCP, in general, when done with appropriate incentives to follow the OCP rules, may be the only way to ensure China’s long-term success.198 The OCP can help to prevent serious food shortages, environmental problems, and health problems for Chinese citizens. Thus, despite the marriage law being tied to the OCP, this alone might not be a legitimate reason for the United States to disrespect it, when the law by itself is not physically harmful to the Chinese citizens.

While the Third Circuit’s narrower approach in Chen is a step in the right direction, there is still nothing to prevent males in a traditional marriage from simply lying and saying they are in a legal marriage.199 Immigration officials may have a difficult time making an adverse credibility determination when most legitimately legally married spouses lack documentation of their marriage.200 Additionally, such a system does little to help ensure the benefits of U.S. law to those directly persecuted under the OCP.

Thus, from the perspective of trying to reduce fraudulent use of section 601(a), if any of the above circuit decisions should be followed at all, it should be the Second Circuit’s case-by-case approach from Lin. The Lin court has been the only court, to date, to adequately analyze section 601(a)’s language prior to ruling. This analysis is in contrast to the Third and Ninth Circuits’ analysis, which simply assumed that section 601(a) was silent or ambiguous as to its protections for indirect, physically unharmed partners. Given the Second Circuit’s detailed analysis of the statute’s language, it is the most likely to represent Congress’s intended treatment of such partners. For example, Congress’s repeated use of the phrase “a person,” rather than “a couple” should not be ignored. Additionally, this restrictive interpretation, which denies personal relief to any and all indirect victims solely on the basis of their partner’s persecution, eliminates the low hurdle that males have faced since C-Y-Z. Reimplementation of the nexus requirement of the Refugee Act will raise the burden of proof on the applicant and will thereby reduce the number of fraudulent claims attempted and reduce those that go undetected. However, a case-by-case approach toward indirect

199 Berman, supra note 170, at 374 (“[P]eople who are willing to lie in order to receive asylum would change their story to fit whatever laws are in place to regulate asylum.”).
200 Sperry, supra note 3.
victims would be time consuming and costly for the BIA. Without a bright-line rule, all appeals from IJs to the BIA would have to be carefully considered on the merits rather than being summarily decided based on the marriage status of the male. The BIA’s caseload has already been described as “crushing,” and such a detailed analysis of all indirect victims’ claims would only add to this heavy burden.201

There are a number of other possible strategies that could be followed, which are also unlikely to be effective at preventing fraud. One such strategy might be to re-implement an annual cap on the number of people who can use section 601(a) every year, as existed when section 601(a) was originally implemented. The number should be set higher than the previous one-thousand-per-year cap to reflect the reality that today far more than one thousand claimants a year are likely to have valid claims under section 601(a). However, the number should also be lower than the number of people currently using section 601(a) to limit some of the fraudulent claimants from gaining refugee relief. While such a strategy would certainly achieve a desired effect of closing the floodgates to some extent, there would still be no guarantee at all that those being closed out will be the ones with the fraudulent claims. In fact, such a cap may serve to deny asylum to people who have legitimate claims, which is why the cap was abandoned in the first place.

A second possible solution would be to require documentation of medical examinations and/or marriage certificates so that fraud-perpetrating males could not simply rely on their coached story, without more, to gain refugee status. However, as noted above, documentation fraud in China is already widespread.202 Having such a requirement may have the perverse effect of encouraging greater documentation fraud. Indeed, unscrupulous snakeheads and lawyers may, knowing of such a requirement, try to turn a larger profit than they already do by charging more for such documents. Moreover, because many refugees quickly flee their home country without time to seek out such documents,203 such a strategy might also have the unintended consequence of denying legitimate section 601(a) claimants refugee status.

Given the above stated concerns, the best possible solution may be to enact a legislative amendment to section 601(a) that implements a system of conditional refugee grants to indirect male victims. Such a system should be modeled after the regulations put in place by Congress to deter immigration based on fraudulent marriages—i.e., marriages between aliens and U.S. citizens that are entered into solely for the immigration benefits available to the alien based on such a marriage. In

201 Chen v. Ashcroft, 381 F.3d 221, 228 (3d Cir. 2004).
202 Palmer, supra note 178, at 995 (noting that “[t]o the extent that [State Department] reports are accurate, it would not be illogical to conclude that any given group of Chinese asylum seekers may be carrying a higher than average proportion of fraudulent documents”).
203 Id. at 980.
1986 Congress passed the Immigration Marriage Fraud Amendments (IMFA) to directly help combat such marriage fraud. Although marriage fraud undoubtedly occurs on a much grander scale than section 601(a) fraud, the same principles that are used to deter fraud in the former can likewise be used to deter the lesser volume, but no less important, fraud under the latter.

The most important tool put in place by the IMFA amendments was its system of conditional grants of lawful permanent residency for any alien who obtains lawful permanent resident status based on a marriage that is less than two years old. This conditional period lasts for two years, and ninety days before the two years expires the married couple is to jointly petition DHS to “remove” the conditions. The couple may be called in for an interview at this time in which they must once again prove that their marriage is not a sham. If successful, the conditions on the alien’s permanent residency will be removed and then he or she will have the full benefits of being a lawful permanent resident—including the rights to work or study in the United States, to live here indefinitely, to leave and enter the United States as he or she pleases, and to later become a citizen of the United States. In general, the idea of the marriage fraud amendments is to prevent aliens from gaining these benefits based on their marriage to a U.S. citizen if the marriage was entered into solely to gain these benefits rather than because the couple wanted to build a life together.

Under the conditional-grant system in the section 601(a) context, a per se approach for credible males would be left in place for any indirect partners so as to avoid increasing the already heavy caseload on the BIA. However, the grant of refugee status would be made conditional on the male’s female partner later joining him in the United States, and upon the determination that she is actually his partner, and that she was actually persecuted as required under section 601(a). This approach would conform to the reality that, in many cases, males usually arrive in the U.S. first to establish some stability before their families join them. It also recognizes that males should not be too easily rejected, as even in legitimate cases of persecution there will often be little evidence. Under the proposed system, however, like under the marriage fraud context, the indirect male victims would be given a time limit, perhaps two years, which is determined to be enough time to become somewhat financially secure. At the end of this two-year time-period, the alien’s political asylum status would automatically expire, making the alien an illegal alien who is subject to removal proceedings. However, ninety days prior

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206 Id.
207 Id.
208 See supra notes 169-171 and accompanying text.
to expiration, the male would have the ability to file a petition to remove the conditions on his asylum status. The male and his female partner would then be interviewed by an immigration officer, during which the officer would have the opportunity to review the bona fides of the male applicant’s underlying story. The male would have to prove that his persecuted female partner has come to the United States, and thus his political asylum claim was a legitimate one whose status should be continued.209

With some exceptions, if the female does not join the male by the time the male has to petition for continued asylum protections, the male’s conditional grant would be revoked on the theory that if the female was the one directly persecuted, the male should not be able to gain the benefits of asylum based solely on her persecution when she does not gain refugee status on those grounds—the male should not be allowed to “ride the wife’s coattails”210 while leaving the real or imaginary female partner behind in China. Exceptions or extensions of the time limit may be granted upon the request of the applicant after an administrative decision, and any adverse determinations could be appealed to the federal courts for judicial review. Reasons for extensions or excusal of the time limit might include a female’s inability to travel due to illness, pregnancy, death, and other similar reasons that would prevent either the female from coming to the United States. However, the immigration officers must construe any such exceptions narrowly so as to not eradicate the entire purpose of the legislative amendment.

In addition to the conditional-grant system, IMFA also stiffened a number of other provisions with the goal of preventing and punishing marriage fraud. These included the strengthening of the restrictions on immigration for anyone who has ever been involved in marriage fraud211 and the establishment of criminal sanctions for involvement in marriage fraud, with harsh penalties of up to a $250,000 fine and five years in prison.212 Once again, these same ideas should be extended to include under their scope fraudulent claims made under section 601(a). Finally, the Department of Justice should start to crack down and impose harsher

209 This idea is similar to how the United States currently deals with aliens who try to obtain permanent residency based on marriage to U.S. citizens. Immigration officials assume that the marriage was entered into solely to obtain permanent resident status in the U.S., and thus the alien is only granted a two-year conditional grant of residency, after which the alien, together with his or her American spouse, must petition immigration to take away the conditions so that the alien can then become a legal permanent resident rather than a conditional legal permanent resident. See U.S. Citizenship and Immigration Services, How Do I Remove the Conditions on Permanent Residence Based on Marriage?, http://www.uscis.gov (search “How do I remove”; then follow first hyperlink) (last visited Apr. 17, 2009).


211 8 U.S.C § 1154.

212 Id. § 1325.
disciplinary sanctions on lawyers who knowingly participate in these fraudulent claims.213

Note, however, that such a system will only work to deter fraudulent claims if males actually abide by it and see a real incentive to come forward and petition for the removal of their conditional status rather than disappearing in the system as they previously would have done,214 especially when their underlying claim was a fraudulent one. However, the incentive to come forward does exist. Under the new proposed system, the alien’s visa papers will clearly be marked as expiring at the end of the two-year period. Thus, the male who fails to come forward to try to make his case will become an illegal alien, unable to legally work in the United States and unable to go and come from the United States as they please. This is unlike the system that is currently in place, in which there is no conditional element at all—once the refugee is accepted under section 601(a) that status can last forever. The idea here is that a Chinese male whose female partner has not actually been persecuted under section 601(a) might not go through all the trouble of trekking to the United States on an often costly and difficult journey, and hoping that the couple’s fraudulent claim will at least initially be believed, where, even if it is believed, in two years time they will become illegal aliens, subject to deportation when they fail to petition to remove the conditions on their asylum status.215 Just like in the marriage fraud context, the reduction of the potential benefits of using a fraudulent claim, coupled with the increased costs of being caught using such a fraudulent claim, can act a strong deterrent to making these fraudulent claims in the first place.

Not only would the conditional-grant system ideally act as a strong deterrent, it would also serve the often-discussed congressional intent of keeping families together. Indeed, many of the circuit courts that interpreted section 601(a) to be silent regarding indirect victims, relied on the breaking-up-of-families rationale in determining that per se relief should be granted to indirect male spouses.216 The concerns of the Third Circuit that a policy granting per se relief to an indirect male spouse allows him to “capitalize on the persecution of his wife to obtain asylum even though he has left his wife behind and she might never join

213 Current immigration regulations impose disciplinary sanctions on any attorney who “knowingly or with reckless disregard makes a false statement of material fact or law, or willfully misleads, misinforms, threatens or deceives any person (including a party to a case or an officer or employee of the Department of Justice) . . . .” 8 C.F.R. § 1003.102(c) (2009).

214 Kung, supra note 1, at 1295 (“If released, they may never return to court and will simply vanish into Chinese migrant communities in the U.S.”).

215 Note, however, that the proposed legislation would probably do little to deter those aliens who do not care about being illegal aliens.

216 See, e.g., Ma v. Ashcroft, 361 F.3d 553, 561 (9th Cir. 2004) (where the court notes that not granting per se relief could lead to the absurd result of breaking up the family, which would not only be “at odds” with the purpose of section 601(a), but also with U.S. immigration policy as a whole).
him and he might intend that she not do so” would also be relieved. 217 A male who is claiming asylum based solely on his wife’s persecution should not be able to gain the benefits of asylum based on his wife’s persecution if the wife herself does not gain those benefits.

CONCLUSION

Until Congress adopts new legislation, the Lin decision is the best of the circuit decisions and should be adopted by the Supreme Court if it decides to grant certiorari to resolve this circuit split. However, the best possible solution would be for Congress to adopt legislation that puts into place a system of conditional grants of asylum relief for indirect male partners of female victims of Chinese birth control policies. Not only will such an approach eliminate the current confusion regarding how far C-Y-Z-’s holding extends in protecting such victims, but it will also help to keep families together by preventing males from abandoning their wives in China once they have gained refugee status in the United States. Furthermore, and most critically, a conditional grants system will help ensure that females who have been persecuted in China will be able to take advantage of the protections of section 601(a) more often, and it will reduce exploitation of section 601(a) by deterring males from memorizing tales of their partner’s persecution as a mere pretext to gain asylum in the United States. In light of the ongoing human rights violations in China under the guise of population control, the U.S. should do whatever it can to help those who have really been persecuted, while also trying to limit section 601(a) from becoming a tool under which any Chinese citizen can easily gain the benefits of refugee status in the United States. The system of conditional grants described above appears to be the best way to achieve these dual goals.

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† Juris Doctor Candidate, May 2009, Brooklyn Law School. The author wishes to thank her family and her husband, Dror Gez, for all their love and support. Additionally, the author expresses her thanks to Sara Cisco for all her helpful suggestions. Finally, the author sincerely thanks the entire Brooklyn Law Review staff for their incredible help.
An Appealing Split

FILING AN APPEAL AFTER A PLEA BARGAIN:
IS COUNSEL OBLIGED TO FILE A MERITLESS APPEAL?1

INTRODUCTION

Plea bargains dominate our criminal justice system.2 Approximately 90% of criminal defendants accept plea bargains, waiving their right to trial.3 Two-thirds of these plea bargains also include a defendant’s waiver of the right to appeal.4 However, does a defendant’s waiver of appeal in a plea bargain relieve counsel of the duty to file a notice of appeal upon a defendant’s request?

A criminal defendant’s right to “represent[ation] by counsel is a fundamental component of [the United States] justice system.”5 In fact, a defendant is not only guaranteed representation, but must also receive reasonably effective assistance of counsel.6 Still, although the Constitution promises the right to the effective assistance of counsel, there is no constitutional right to an appeal.7 Nevertheless, a criminal defendant has a statutory right to appeal.8 While a plea bargain may

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1 This Note is an updated version of an article previously published in the New York State Bar Association’s 2008 Law Student Legal Ethics Award Compendium. See Tamar Kaplan-Marans, Filing An Appeal After a Plea Bargain, NEW YORK STATE BAR ASS’N 2008 LAW STUDENT LEGAL ETHICS AWARD COMPRENDIUM, Oct. 2008, at 27. Although a student Note was recently published on the same topic, the original version of this Note was published first in the Compendium. See Gregory P. Lavoy, Note, Neither a “Moose” Nor a “Puppet”: Defining a Lawyer’s Role When Directed To Pursue An Appeal Notwithstanding a Valid Waiver of Appellate Rights, 7 AVE MARIA L. REV. 265 (2008).


5 United States v. Cronic, 466 U.S. 648, 653 (1984); see also U.S. CONST. amend. VI ("In all criminal prosecutions, the accused shall enjoy the right to . . . have the Assistance of Counsel for his defense."). In criminal cases, lawyers “are necessities, not luxuries,” guaranteed by the Constitution. Gideon v. Wainwright, 372 U.S. 335; 344 (1963).


provide for a waiver of defendant’s statutory right to appeal,9 it does not waive a defendant’s constitutional right to effective counsel.10 Thus, after agreeing to a waiver of appeal, if a defendant asks his or her attorney to file an appeal, must counsel do so in order to meet the required standard of effective counsel dictated by the Sixth Amendment?

In Nunez v. United States, the Seventh Circuit broke with seven other circuit courts, holding that a plea bargain in which a defendant waives the right to appeal relieves counsel of a duty to file an appeal.11 However, the Second, Fourth, Fifth, Eighth, Ninth, Tenth, and Eleventh Circuits require counsel to file an appeal upon the defendant’s request even after the defendant has waived his or her right through a plea bargain.12 These circuits hold that counsel’s failure to file an appeal is automatically considered ineffective assistance of counsel, therefore entitling a defendant to an appeal.13 Even though a defendant’s waiver

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9 See United States v. Wiggins, 905 F.2d 51, 53 (4th Cir. 1990) (“It is clear that a defendant may waive in a valid plea agreement the right of appeal under 18 U.S.C. § 3742.”); United States v. Clark, 865 F.2d 1433, 1437 (4th Cir. 1989) (“If defendants can waive fundamental constitutional rights such as the right to counsel or the right to a jury trial, surely they are not precluded from waiving procedural rights granted by statute.”) (citation omitted).

10 Campusano v. United States, 442 F.3d 770, 777 (2d Cir. 2006).

11 See Nunez v. United States (Nunez I), 495 F.3d 544 (7th Cir. 2007), vacated, 128 S. Ct. 2990 (2008); see also Nunez v. United States (Nunez II), 128 S. Ct. 2990 (2008); Nunez v. United States (Nunez III), 546 F.3d 450 (7th Cir. 2008); Pamela A. MacLean, 7th Circuit Breaks With Six Other Circuits Over Waiver of Appeal, NAT’L L.J., Aug. 13, 2007, available at http://www.law.com/jsp/article.jsp?id=1187254928176. The procedural history behind the Nunez cases is quite extensive. After the Seventh Circuit decided Nunez I, the defendant petitioned the Supreme Court for certiorari. See Petition for Writ of Certiorari at *1, Nunez II, 128 S. Ct. 2990 (2008) (No. 07-818), 2007 WL 4466866. Although the Supreme Court granted certiorari, it then remanded the case to the Seventh Circuit. Nunez II, 128 S. Ct. at 2990. Upon remand, the Seventh Circuit decided Nunez III. Nunez III, 546 F.3d at 450; see also infra note 48. However, even though Nunez III is the Seventh Circuit’s more recent decision, this Note mainly cites to Nunez I because the language in Nunez I and Nunez III is exactly the same, almost word for word (except for a new introduction provided by the court in Nunez III). As noted by the Seventh Circuit in Nunez III: “Instead of sending readers to our first opinion, we will repeat much of what was said there. Recapitulation is better than leaving our reasoning scattered across volumes of the Federal Reporter.” Nunez III, 546 F.3d at 453. In other words, even though there are two Seventh Circuit opinions relevant to this Note, they are one and the same. As such, the above-the-line text of this Note simply refers to them as “Nunez,” treating them as one case. However, the two cases are differentiated in the footnotes here as Nunez I and Nunez III. Nunez II refers to the Supreme Court decision to remand to the Seventh Circuit.


13 See Watson, 493 F.3d at 964; Poindexter, 492 F.3d at 268; Tapp, 491 F.3d at 266; Campusano, 442 F.3d at 771-72; Gomez-Diaz, 433 F.3d at 790; Sandoval-Lopez, 409 F.3d at 1197-98; Garrett, 402 F.3d at 1263.
renders an appeal futile and therefore frivolous, counsel is still required to file one under the Sixth Amendment.

An analysis of the Supreme Court’s general jurisprudence on a lawyer’s responsibility to file an appeal reveals that the Court has not adopted a consistent approach or a bright line, per se rule stating when a lawyer must file an appeal. In fact, the inconsistency of the Court’s approach over the last forty years is evidenced by the circuit split at hand. Highlighting the Court’s inconsistency, both the majority circuits and the Seventh Circuit engage in completely different, yet equally valid analyses of the Court’s previous decisions in this area.

This lack of clarity has major practical implications for the criminal defense system. Given the high volume of plea bargains containing appeal waiver provisions, it is imperative that criminal defense lawyers have clear guidance on how to proceed when a defendant requests an appeal despite a waiver of the right to appeal. But this very practical issue derives from the more theoretical question of what a lawyer’s role should be within the lawyer-client relationship. The contrary holdings of the circuits are a result of contrasting models of the allocation of power in a client-lawyer relationship. The majority circuits adopt a paradigm in which the client dominates the lawyer-client relationship, whereas the Seventh Circuit follows a model in which the lawyer maintains autonomy over the client. The Court has been inconsistent on which model is correct, vacillating between a lawyer-dominated relationship and a client-controlled one. Further complicating this issue, the various codes of legal ethics are also inconsistent on the relationship between a lawyer and client, with some ethical rules favoring client autonomy and others encouraging a more paternalistic approach toward clients. Given this lack of clarity in Supreme Court jurisprudence as well as the ethics codes, a policy analysis is imperative in determining whether the view of the majority circuits or the view of the Seventh Circuit should prevail.

This Note explores the split among the circuit courts on this issue of a lawyer’s responsibility to file an appeal once a defendant has waived the right to appeal. It addresses the legal and theoretical analyses behind the differing views as well as the policy implications. Part I discusses the facts and history behind the Seventh Circuit’s decision in Nunez. Part II argues that both the Seventh Circuit and the majority

14 Such an appeal would be futile because an appellate court will dismiss the appeal based solely on the fact that the defendant waived the right to appeal in the plea bargain.
15 See Watson, 493 F.3d at 964; Poindeaster, 492 F.3d at 268; Tapp, 491 F.3d at 266; Campusano, 442 at F.3d at 771-72; Gomez-Diaz, 433 F.3d at 790; Sandoval-Lopez, 409 F.3d at 1197-98; Garrett, 402 F.3d at 1263.
16 See infra Part II.A for a more extensive analysis of this issue.
17 Throughout this Note, I will use the term “majority circuits” to refer to the Second, Fourth, Fifth, Eighth, Ninth, Tenth, and Eleventh Circuits, specifically their holdings in Watson, Campusano, Poindeaster, Tapp, Sandoval-Lopez, Garrett, and Gomez-Diaz.
18 See supra note 4 and accompanying text.
circuits’ approaches can be reconciled with Supreme Court precedent. Part III contends that the contrary holdings of the circuits is a result of their adoption of contrasting models of the allocation of power in a client-lawyer relationship and demonstrates the impact of the ethical rules of the legal profession on the circuits’ decisions. Finally, Part IV advocates for a policy-based analysis. Specifically, this Part argues that the Seventh Circuit’s approach is preferable for our criminal justice system because it benefits lawyers, defendants, the judiciary, and society at large.

I. THE CIRCUIT SPLIT: THE SEVENTH CIRCUIT IN NUNEZ V. UNITED STATES

In 2002, Armando Nunez was indicted and charged with “multiple cocaine offenses.” The government possessed substantial evidence that Nunez dealt cocaine to an undercover law enforcement official and transported drugs in his automobile from the Chicago area to distribution locations in Illinois, Indiana, and New Jersey. As often occurs in criminal cases, Nunez was assigned counsel who conducted an investigation of the government’s case against Nunez. Once Nunez’s counsel assessed that the government’s evidence against his client was extremely strong and that Nunez was unlikely to prevail at trial, he encouraged Nunez to accept the government’s offer of a plea bargain.

Pursuant to the plea agreement, the prosecutor dismissed two of the three drug charges against Nunez and recommended a reduced sentence. Nunez pled guilty to conspiring to knowingly and intentionally possess cocaine with intention to distribute. Nunez agreed to waive his right to direct appeal or collateral attack unless the sentence exceeded the statutory maximum or the waiver was otherwise invalid. Before accepting Nunez’s guilty plea, the district court

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19 Nunez v. United States (Nunez I), 495 F.3d 544, 545 (7th Cir. 2007), vacated, 128 S. Ct. 2990 (2008); see also Brief & Appendix of the United States at 3, Nunez v. United States, 495 F.3d 544 (7th Cir. 2007) (No. 06-1014).
21 Brief & Appendix of the United States, supra note 19, at 4.
22 On September 9, 2002, John M. Cutrone was appointed as Nunez’s counsel. Id. at 3.
23 “On February 27, 2003, [Nunez] filed a motion for leave to substitute Robert L. Rascia as his counsel,” which was granted by the district court. Id. at 12 n.3.
24 Id. at 4.
25 Nunez I, 495 F.3d at 548.
26 A direct appeal is “[a]n appeal from a trial court’s decision directly to the jurisdiction’s highest court, thus bypassing review by an intermediate appellate court.” BLACK’S LAW DICTIONARY 106 (8th ed. 2004). A collateral attack is “[a]n attack on a judgment in a proceeding other than a direct appeal,” such as a petition for a writ of habeas corpus (as Nunez later filed). Id. at 278.
27 Nunez I, 495 F.3d at 545. Providing such an exception in an appeal waiver is quite common. See King & O’Neill, supra note 4, at 213 (“Many defendants who waived their rights to
painstakingly questioned Nunez\textsuperscript{28} to confirm that he “was knowingly and voluntarily entering into the Plea Agreement”\textsuperscript{29} that would so drastically waive many of his rights.\textsuperscript{30} The district court asked Nunez extensive questions, and his answers indicated that he understood the exchange, notably, that he was waiving his right to an appeal.\textsuperscript{31}

Despite Nunez’s agreement to waive his right to appeal, he nevertheless requested that his lawyer appeal the case.\textsuperscript{32} Nunez’s lawyer refused to do so, given Nunez’s waiver of his right to appeal.\textsuperscript{33} In response, Nunez filed a collateral attack,\textsuperscript{34} charging counsel with

\begin{verbatim}
review obtained clauses in their agreements that limited their exposure to unexpected negative results at sentencing.

\textsuperscript{28} This questioning is required by the Federal Rules of Criminal Procedure 11(b). Rule 11 was amended in 1999 to specifically require courts to explain to defendants those plea bargains that waive the right to appeal or collateral attack. See King & O’Neill, supra note 4, at 222, 224.

\textsuperscript{29} Brief & Appendix of the United States, supra note 19, at 6.

\textsuperscript{30} The following dialogue between Nunez and the Court indicates that the district court clearly and explicitly indicated to Nunez the consequences of accepting the plea bargain:

\textit{District Court}: Do you understand that, if you plead not guilty and you went to trial and were found guilty, you would have a right to appeal every aspect of your case, including any errors that occurred during the course of the trial? Do you understand that?

\textit{Petitioner}: Yes.

\ldots

\textit{District Court}: Do you understand that [by pleading not guilty] you would have a right to appeal the sentence you ultimately receive?

\textit{Petitioner}: Yes.

\textit{District Court}: Do you understand that in this plea agreement you are giving up your right to appeal, direct appeal, of any aspects of your case, including the validity of your plea and the sentence you ultimately receive? Do you understand that, sir?

\textit{Petitioner}: Yes.

\textit{District Court}: Do you understand, the only review rights you retain would be what is called a collateral attack, which would allow you to raise a claim of involuntariness or ineffective assistance of counsel? Do you understand that, sir? And that is only related to this waiver in the plea agreement? Do you understand that, sir?

\textit{Petitioner}: Yes.

\textit{Id.} at 19-20 (alteration in original). This type of questioning is routine as required by the Federal Rules of Criminal Procedure. See supra note 28.

\textsuperscript{31} Additionally, according to Cutrone (Nunez’s counsel), counsel reviewed the written plea agreement with Nunez, explaining why Nunez should accept the plea. Brief & Appendix of the United States, supra note 19, at 4-5. “According to Cutrone, he would never allow a client to enter into a plea agreement unless [he] was certain a client understood \ldots all the terms of the plea agreement.” Id. at 5 n.2.

\textsuperscript{32} Writing for the court, Judge Easterbrook noted that it was unclear whether Nunez did in fact ask his lawyer to file an appeal. \textit{Nunez I}, 495 F.3d at 545. Still, for purposes of the opinion, the Court assumed that Nunez did make this request. \textit{Id.} at 545. This Note will work from the same assumption.

\textsuperscript{33} \textit{Id.}

\textsuperscript{34} Nunez filed a petition for a writ of habeas corpus under 28 U.S.C. \textsection 2255, a type of collateral attack. \textit{Id.}; see also supra note 26.
\end{verbatim}
providing ineffective assistance.\(^{35}\) The collateral attack was denied by both the district court\(^{36}\) and the Seventh Circuit.\(^{37}\) Because Nunez entered into the plea voluntarily, the Seventh Circuit held that the plea was valid and that the waiver must therefore be enforced.\(^{38}\) Since the waiver only allowed for two exceptions for appeal (i.e., an illegally high sentence\(^{39}\) or an invalid waiver\(^{40}\) ), Nunez’s claim of ineffective assistance of counsel fell within the provisions of the waiver and was therefore excluded as a

\[^{35}\text{In his habeas corpus petition, Nunez claimed that he did not enter knowingly and voluntarily into the plea bargain and that his counsel failed to file an appeal upon his request. Nunez stressed that he did not speak English “and that, because during some consultations with his counsel an interpreter was not present . . . , he could not understand what counsel told him and therefore did not understand the plea bargain’s terms.” Nunez I, 495 F.3d at 546. The Court made short shrift of Nunez’s claims of incomprehension, noting that the record clearly indicated that Nunez repeatedly told the district judge that he understood the consequences of entering into a plea. Therefore, the Court concluded, the plea was voluntary. The Court proceeded to analyze the facts based on this assumption that the waiver was in fact valid. Id. Of course, the holding of Nunez would not apply if the waiver was not valid. An invalid waiver would change the legal analysis drastically; a basic assumption and fact in Nunez as well as in the cases in the majority circuits discussed below is that the plea was voluntary and that therefore the waiver of appeal was valid. See infra note 40.}\n
\[^{36}\text{United States v. Nunez, No. 04 C 3385, 2005 WL 2675043, at *3 (N.D. Ill. Oct. 18, 2005), aff’d, Nunez v. United States, 495 F.3d 544 (7th Cir. 2007), vacated, 128 S. Ct. 2990 (2008).}\n
\[^{37}\text{Nunez, 495 F.3d at 546, 548-49.}\n
\[^{38}\text{Id. at 545-46; see also infra note 40.}\n
\[^{39}\text{An illegally high sentence is one that exceeds the maximum punishment provided for in the statute. Nunez’s sentence of 160 months was less than the statutory maximum provided for in 21 U.S.C. § 841(b). See Nunez I, 495 F.3d at 545.}\n
\[^{40}\text{An invalid waiver can arise when a defendant does not voluntarily assent to it. For example, if the defendant does not understand the terms of the waiver because he or she does not speak English, a waiver can later be deemed invalid. However, as stated above, the district court questioned Nunez to determine that he was voluntarily pleading guilty and waiving his rights. Nunez told the judge that he understood English:}\n
\text{District Court:} \text{Now, are you pleading guilty today of your own free and voluntary act?}\n
\text{Petitioner:} \text{Yes.}\n
\text{. . .}\n
\text{District Court:} \text{Was this plea agreement read to you before you signed it?}\n
\text{Petitioner:} \text{Yes.}\n
\text{District Court:} \text{Was it read to you in Spanish?}\n
\text{Petitioner:} \text{No.}\n
\text{[Nunez’s Attorney]:} \text{We went over it in English, Judge. I constantly asked him if he understood.}\n
\text{District Court:} \text{Are you convinced you understand the provisions of this plea agreement?}\n
\text{Petitioner:} \text{Yes.}\n
\text{District Court:} \text{You are satisfied with it having gone over it with your lawyer in English, is that right?}\n
\text{Petitioner:} \text{Yes.}\n
Brief & Appendix of the United States, supra note 19, at 7-8. Nunez’s attorney informed the district court that Nunez “often spoke in English and understood their exchanges when interpreters were not present.” Nunez I, 495 F.3d at 546. As the Seventh Circuit determined, Nunez accepted the waiver voluntarily, and it was therefore valid. \text{Id.}
potential claim. In sum, once Nunez agreed to waive his right to appeal, Nunez’s counsel was not obliged to file an appeal, despite Nunez’s wishes. Breaking with seven other circuits, the Seventh Circuit held that the failure to file an appeal did not trigger an automatic ineffective assistance of counsel claim because Nunez validly waived his right to appeal.

II. SUPREME COURT PRECEDENT

In all of the cases addressed in the majority circuits, the facts were almost indistinguishable from Nunez. Each defendant was charged with a drug crime and accepted a plea bargain because the government had significant evidence against him. As in Nunez, the defendants’ plea bargains contained a waiver of the right to appeal unless the sentence exceeded the statutory maximum or the waiver was invalid. Despite the waiver, each defendant alleged that he asked his lawyer to appeal, and counsel failed to do so. Yet, as opposed to the Seventh Circuit, the majority circuits held that even where a defendant waived the right to appeal, counsel was still required to file an appeal upon the defendant’s request.

How did the Seventh Circuit arrive at a conclusion so starkly different from the other circuits? In order to address this striking

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41 Nunez I, 495 F.3d at 546.

42 If Nunez had asked his lawyer to file an appeal based on the claim that the plea bargain and waiver were involuntary, his lawyer would have been required to file the appeal. Id. at 547 (“A defendant who wants a lawyer to argue on appeal that the plea was involuntary has a right to that legal assistance.”). Here, however, Nunez “never argued that the waiver [was] invalid” but “[i]nstead, he told his lawyer to appeal.” Id. at 545. Thus, according to the Seventh Circuit, a lawyer cannot determine independently whether a defendant voluntarily waived the right to appeal and then refuse to file the appeal. Rather, once the defendant acknowledges that the waiver was voluntary, the lawyer has no duty to file the appeal. Id. at 547.

43 Id. at 548-49.

44 See Watson v. United States, 493 F.3d 960, 961 (8th Cir. 2007); United States v. Poindexter, 492 F.3d 263, 265 (4th Cir. 2007); United States v. Tapp, 491 F.3d 263, 264 (5th Cir. 2007); Campusano v. United States, 442 F.3d 770, 772 (2d Cir. 2006); Gomez-Diaz v. United States, 433 F.3d 788, 790 (11th Cir. 2005); United States v. Sandoval-Lopez, 409 F.3d 1193, 1194-95 (9th Cir. 2005); United States v. Garrett, 402 F.3d 1262, 1263-64 (10th Cir. 2005).

45 Each defendant was extensively questioned by the judge to ensure that there was an understanding of the terms of the plea agreement. See, e.g., Poindexter, 492 F.3d at 266; Sandoval-Lopez, 409 F.3d at 1194; Garrett, 402 F.3d at 1263-64.

46 See Watson, 493 F.3d at 962; Poindexter, 492 F.3d at 267 n.4; Campusano, 442 F.3d at 772; Gomez-Diaz, 433 F.3d at 791; Sandoval-Lopez, 409 F.3d at 1195; Garrett, 402 F.3d at 1264; see also infra note 190 and accompanying text. In all of the cases in the majority circuits (except for United States v. Tapp in the Fifth Circuit) as well as in Nunez, it was unclear whether the defendant actually requested that counsel file an appeal. However, the circuits proceed on the assumption that an appeal was in fact requested by the defendant. In United States v. Tapp, however, the lawyer actually filed the appeal but it was dismissed as untimely. Tapp, 491 F.3d at 264.

47 Watson, 493 F.3d at 964; Poindexter, 492 F.3d at 268; Tapp, 491 F.3d at 266; Campusano, 442 F.3d at 771-72; Gomez-Diaz, 433 F.3d at 790; Sandoval-Lopez, 409 F.3d at 1197-98; Garrett, 402 F.3d at 1263.

48 It is important to note that in Nunez I, the Seventh Circuit denied that it was creating a circuit split by explicitly stating that it was not adopting a holding contrary to the other circuits. See
posture taken by the Seventh Circuit, it is crucial to look to the Supreme Court cases that influence both the Seventh Circuit and the majority circuits, most notably *Anders v. California*,99 *Strickland v. Washington*,50 and *Roe v. Flores-Ortega*.31 Although the circuit courts each applied the same Supreme Court cases on a lawyer’s responsibility to file an appeal, the conclusion reached by the majority circuits in applying Court precedent was distinctly opposite to the Seventh Circuit’s application. Indeed, the Court’s jurisprudence surprisingly supports both the Seventh Circuit and the majority circuits’ approach. This anomaly is a result of

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Nunez v. United States (*Nunez I*), 495 F.3d 544, 548-49 (7th Cir. 2007) (“But we need not decide whether these arguments are a sufficient response to the mandatory-appeal-notwithstanding-the-waiver-of-appeal approach that our colleagues in other circuits derived . . . .”); see also CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE AND PROCEDURE § 594.1 n.14 (3d ed. Supp. 2007) (“Citing the six circuits which have held that it constitutes ineffective assistance of counsel for a defense attorney to fail to file a requested notice of appeal where defendant had waived right to file direct appeal and collateral challenge in plea agreement, the Seventh Circuit . . . does not decide the question.”) (emphasis added). Instead, the Seventh Circuit proposed an alternate holding at the end of its opinion that attempted to distinguish the *Nunez I* facts from the cases before the majority circuits. *Nunez I*, 495 F.3d at 548. As described above, *Nunez I* consisted of a collateral attack based on an ineffective assistance of counsel claim. *Id.* at 545; see also supra Part I.A. The court noted that Nunez’s waiver contained not only a waiver of the right to direct appeal but also a waiver barring relief on collateral review. *Nunez I*, 495 F.3d at 548-49. Because of the collateral review waiver, the court opined that Nunez had effectively waived his right to make an ineffective assistance of counsel claim in a collateral attack. *Id.* Consequently, the main issue of whether counsel’s failure to file a notice of appeal would entitle Nunez to a new appeal was a moot question because relief was barred regardless by the plea bargain’s waiver of collateral review. *Id.* (“Nunez’s waiver must be enforced and his collateral attack dismissed whether or not his lawyer should have filed an appeal on demand.”) (emphasis added). As such, even though the *Nunez I* decision was a strongly-worded, five-page opinion adamantly advocating against the position of the other circuits for the majority of its text, it nevertheless did not actually create a circuit split.

However, after the Seventh Circuit’s decision in *Nunez I*, 495 F.3d 544, vacated, 128 S. Ct. 2990 (2008), Nunez petitioned the Supreme Court for certiorari, specifically requesting that the Supreme Court resolve the “conflict among the circuits.” See Petition for Writ of Certiorari, *supra* note 11, at *1. The Supreme Court granted certiorari but then vacated the judgment and remanded the case to the Seventh Circuit, ignoring the issue of a circuit split. *Nunez v. United States* (*Nunez II*), 128 S. Ct. 2990, 2990 (2008). Rather, upon the urging of the Solicitor General, the Court remanded the case in order to examine whether the Seventh Circuit misconstrued the scope of Nunez’s waiver. *Id.* at 2990. More specifically, the purpose of the remand was to examine whether the collateral review waiver precluded Nunez’s ineffective assistance of counsel claim. *Id.* at 2990-91 (Scalia, J., dissenting).

Upon remand though, the government confessed error and stated that Nunez’s waiver did not preclude Nunez’s claim for ineffective assistance of counsel. *Nunez v. United States* (*Nunez III*), 546 F.3d 450, 451-52 (7th Cir. 2008). The government urged the Seventh Circuit to consider the substantive issues of the collateral attack and to proceed on the merits. *Id.* at 452. Although the Seventh Circuit disagreed with the government’s interpretation of the waiver, noting that the waiver did in fact preclude Nunez’s collateral review, it nonetheless proceeded with a merits analysis of the collateral attack. *Id.* Still, as originally stated in *Nunez I*, the court concluded in *Nunez III* that a defendant who has waived the right to appeal via plea bargain is not entitled to a new appeal when counsel fails to file the appeal upon the defendant’s request. *Nunez III*, 546 F.3d at 453-54. *Nunez III* therefore solidified the dicta-created circuit split originally discussed in *Nunez I*.

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99 386 U.S. 738, 744 (1967) (holding that a lawyer cannot decide independently that an appeal would be frivolous).

50 466 U.S. 668, 687-88 (1984) (holding that a two-prong test is necessary to determine a claim of ineffective assistance of counsel).

51 528 U.S. 470, 478-79 (2000) (holding that a criminal defendant has a statutory right to appellate review, and that when counsel frustrates that right by failing to consult with the client regarding an appeal, counsel’s performance is automatically ineffective).
the Supreme Court’s failure to adopt a consistent approach and a bright-line, per se rule stating when a lawyer must file an appeal.

A. Supreme Court Cases on the Right to Effective Counsel and the Right to Appeal

The first case of relevance is *Anders v. California*, which occurred after an explosion of cases under the Warren Court concerning the indigent’s right to counsel as required by the Sixth Amendment. In *Anders v. California*, the Court held that a lawyer cannot make an independent decision that a defendant’s appeal would be frivolous. If counsel for a criminal defendant determines that a defendant’s claims are frivolous after a careful examination, counsel must advise the court and request permission to withdraw. The Court required, however, that counsel submit a “brief referring to anything in the record that might arguably support the appeal.” Following the submission of this brief (now known as an *Anders* brief), the court (and not counsel) then decides whether the case is frivolous. Counsel must therefore continue as the defendant’s advocate until the court agrees with counsel’s suggestion that further litigation would be frivolous.

In *Anders*, the Court rejected the lawyer’s power to dismiss an appeal as frivolous, thereby rejecting the lawyer’s ability to assert his or her professional judgment concerning the nature of the litigation. As the dissent noted, the *Anders* majority made the “cynical assumption that an appointed lawyer’s professional representation to an appellate court...is not to be trusted” and that a lawyer could not properly or honestly determine the merits of an appeal. Thus, in *Anders*, the Court adopted a mechanical rule requiring a lawyer to file an appeal (or at the very minimum, an *Anders* brief), regardless of his or her professional judgment as to the worthiness of the appeal.

Despite the bright-line rule established in *Anders*, the Court took a different approach in *Strickland v. Washington* and rejected a
mechanical rule for determining ineffective counsel claims. 62 Under the Strickland standard, in order to show that counsel was ineffective, a defendant must demonstrate first that “counsel’s representation fell below an objective standard of reasonableness,” and second, that “there is . . . reasonable probability that, but for counsel’s unprofessional errors, the result of the proceeding would have been different.” 63 The Court explicitly noted that they were rejecting the establishment of mechanical rules and that the ultimate inquiry would be one of “fundamental fairness” and “reasonableness” as opposed to a more concrete standard. 64 Because there is no exacting set of comprehensive rules that can take into account the wide variety of circumstances that a criminal defense lawyer might face, the Court held that there was no reason to create rules that would limit the independence of counsel. 65

Following in the vein of Strickland, Roe v. Flores-Ortega also rejected a bright-line rule that counsel must always consult with the defendant regarding an appeal. 66 In Flores-Ortega, counsel failed to file a notice of appeal without the defendant’s consent. 67 Instead of adopting a per se standard, the Court held that under the Sixth Amendment, counsel has a duty to consult with the defendant regarding an appeal when counsel has sufficient reason to believe that a rational defendant would want to appeal or when a defendant demonstrates to counsel an interest in appealing. 68 As in Strickland, the Court adopted a two-prong approach: first, assessing whether counsel’s failure to file an appeal was deficient, and second, examining whether the deficient performance prejudiced a defendant’s case. The Court stressed that courts must look to the “totality of circumstances,” “tak[ing] into account all the information counsel knew or should have known.” 69 Hence, in the context of an appeal, a defendant must show that there is reasonable probability that but for counsel’s deficient failure to consult with the defendant about an appeal, the defendant would have appealed. 70 Prejudice will be presumed when the “defendant [was] denied the opportunity for a proceeding at all.” 71

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63 Id. at 687-88, 703.
64 Id. at 697.
65 Strickland, 466 U.S. at 688-89 (“No particular set of detailed rules for counsel’s conduct can satisfactorily take account of the variety of circumstances faced by defense counsel or the range of legitimate decisions regarding how best to represent a criminal defendant. Any such set of rules would interfere with the constitutionally protected independence of counsel and restrict the wide latitude counsel must have in making tactical decisions.”).
66 Roe v. Flores-Ortega, 528 U.S. 470, 479 (2000). The Court specifically stated, “[W]e refuse to make this determination as a per se . . . matter.” Id. at 481 (emphasis omitted).
67 Id. at 474-75.
68 Id. at 479.
69 Id. at 480.
70 A defendant would not have to show that he or she would have prevailed on appeal but merely that he or she would have appealed had the lawyer presented it as an option.
Like *Strickland*, the *Flores-Ortega* court embraced a fuzzy standard, one that would not provide exacting guidance to lawyers and judges.

Despite the Court’s explicit and clear rejection of a per se rule that counsel must always consult with the defendant regarding an appeal, the Court made a variety of ambiguous statements in *Flores-Ortega*. At first, the Court stated the definite rule that “a lawyer who disregards specific instructions from the defendant to file a notice of appeal acts in a manner that is professionally unreasonable.”\(^{72}\) However, immediately following this bright-line rule, the Court expressly rejected the imposition of mechanical rules on counsel.\(^{73}\) Specifically, the Court stated that while states can impose specific rules on attorneys to protect defendants’ rights, the federal Constitution only requires that counsel make “objectively reasonable choices,” whatever that may entail (i.e., there is no specific definition or rule defining “reasonable choice”).\(^{74}\) Additionally, the Court emphasized that the American Bar Association’s (“ABA”) Standards for Criminal Justice are merely guidelines and not rules.\(^{75}\) Thus, despite the Court’s original statement that a lawyer may not disregard specific instructions to appeal (ostensibly a categorical rule, reminiscent of *Anders*), the Court proceeded to reject any form of mechanical rules to be imposed on lawyers.\(^{76}\)

In summary, as is evident in the trajectory from *Anders* to *Strickland* through *Flores-Ortega*, the Court adopted a mechanical rule in *Anders*, rejected a per se rule in *Strickland*, and then wavered in *Flores-Ortega* between a concrete rule and a more amorphous standard. The Court’s wavering left a question hanging in the air: should mechanical rules be imposed on lawyers in an effort to protect criminal defendants’ right to effective counsel? If yes, then the majority circuits’ mechanical view should prevail, requiring a lawyer to file an appeal regardless of the defendant’s waiver of appeal. Or should lawyers have the power to exercise their professional discretion at every twist and turn in the road? If yes, then the Seventh Circuit’s approach would be correct, granting counsel the power to determine whether an appeal should be filed once a defendant has waived the right. As analyzed below, the

\(^{72}\) *Flores-Ortega*, 528 U.S. at 477. If counsel does not “file a requested appeal, a defendant is entitled to [a new] appeal without showing that his appeal would likely have had merit.” *Id.* (alteration in original) (quoting Peguero v. United States, 526 U.S. 23, 28 (1999)) (internal quotations omitted).

\(^{73}\) *Id.* at 478. The Court found that such rules are “not appropriate.” *Id.* at 479 (citing *Strickland v. Washington*, 466 U.S. 668, 688 (1984)).

\(^{74}\) *Id.* at 479.

\(^{75}\) *Id.; see generally ABA STANDARDS FOR CRIMINAL JUSTICE PROSECUTION FUNCTION AND DEFENSE FUNCTION* (3d ed. 1993).

\(^{76}\) Similarly, in *Jones v. Barnes*, the Court rejected a per se ruling that counsel has to raise every non-frivolous argument. While a criminal defendant maintains a right to make certain fundamental choices regarding his or her case, he or she does not have a constitutional right to compel counsel to make every possible argument. *Jones v. Barnes*, 463 U.S 745, 751 (1983).
Supreme Court’s inconsistent view of a lawyer’s role is the root of the conflict within the circuits.

B. The Application of Supreme Court Precedent to Nunez v. United States

The Seventh Circuit’s decision in Nunez does not conflict with the earlier holdings of the Supreme Court in Anders, Flores-Ortega, and Strickland. As discussed below, Nunez can be reconciled with the holdings of the Supreme Court in Anders and Flores-Ortega. At the same time, Nunez implicitly follows the precedent set forth in Strickland.77

Examining Anders, it can be argued that the Anders rule—that “a lawyer cannot make an independent decision about whether an appeal would be frivolous”—only applies when a defendant actually maintains a right to appeal.78 Nunez did maintain a right to appeal if the sentence exceeded the statutory maximum or the waiver was invalid.79 However, he waived his right to appeal based on post-sentence ineffective assistance of counsel when he accepted the plea bargain.80 The Anders approach therefore is not applicable here since in this instance Nunez waived his right to appeal based on ineffective counsel.

Similarly, Flores-Ortega is also inapplicable in Nunez. In Flores-Ortega, the Court stated that filing an appeal is a purely “ministerial task” as opposed to a strategic one, and therefore counsel was required to file the appeal.81 Quite the contrary, the decision to file an appeal in Nunez qualified as a strategic decision as opposed to “ministerial.” Whereas an appeal can only help but not harm most defendants, Nunez faced the risk of harm if an appeal was filed. Specifically, because Nunez waived his right to appeal, the prosecutor could withdraw concessions already granted upon counsel’s filing of an appeal.82 Thus, given the fact that the appeal could not succeed, counsel’s filing of the appeal could have harmed Nunez by resulting in the prosecutor taking the generous concessions off of the table.83

77 Strickland, 466 U.S. at 687-88.
79 Id. at 545.
80 Id. at 548.
82 See Nunez I, 495 F.3d at 548; see also United States v. Cimino, 381 F.3d 124, 128 (2d Cir. 2004) (“[W]hen a defendant breaches his plea agreement, the Government has the option to . . . treat it as unenforceable.”); United States v. Whitlow, 287 F.3d 638, 639 (7th Cir. 2002) (“[W]e have held that a defendant who breaks a promise not to appeal entitles the prosecutor to walk away . . . .”); United States v. Hare, 269 F.3d 859, 862 (7th Cir. 2001) (“If the defendant does not keep his promises, the prosecutor is not bound either.”).
83 Nunez I, 495 F.3d at 548 (“A defendant has more reason to protest if a lawyer files an appeal that jeopardizes the benefit of the bargain than to protest if the lawyer does nothing—for ‘nothing’ is at least harmless.”). In the plea bargain, the prosecutor conceded to the dismissal of two
Moreover, *Nunez* falls outside of the scope of *Flores-Ortega* because unlike the defendant in *Flores-Ortega*, the defendant in *Nunez* waived his right to direct and collateral review. In his concurring opinion to *Flores-Ortega*, Justice Souter expressly noted that the facts of *Flores-Ortega* did not involve a defendant who waived his right to appeal as part of a plea agreement (as opposed to *Nunez*, which did). Similarly, Justice Souter specifically recognized that there can be cases that fall “beyond the margin” of *Flores-Ortega*, in which counsel would not be required to consult with the defendant regarding an appeal. For example, as he suggests, counsel would not have a duty to discuss an appeal with the defendant if the judge meticulously explained the appeal rights to the defendant during the plea colloquy. As described above, the district court did in fact ask Nunez extensive questions, and his answers indicated that he understood the exchange. Therefore, this exception noted by Justice Souter to the holding of *Flores-Ortega* certainly applies to *Nunez*.

Justice Ginsburg’s concurrence in *Flores-Ortega* also makes evident the difference between *Flores-Ortega* and *Nunez*. The question of *Flores-Ortega*, according to Justice Ginsburg, is merely whether defense counsel can abandon the defendant without counseling him or her regarding appeal rights. However, as Justice Ginsburg noted, the issue in *Flores-Ortega* is limited to the counseling aspect (i.e., lawyer must provide counsel or advice regarding an appeal) but does not rule on whether counsel has a requirement to actually file the appeal. The facts in *Nunez* extended beyond a mere consultation between a lawyer and client and instead concerned the actual filing of an appeal.

Nonetheless, even if one argued that *Nunez* fell within the scope of *Flores-Ortega*, it would not preclude the Seventh Circuit’s holding because Nunez would not be able to meet the test set out in *Flores-Ortega*. of the three drug charges against Nunez and a recommendation for a reduced sentence. See supra note 24 and accompanying text.*

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84 United States v. Mabry, 536 F.3d 231, 240 (3d Cir. 2008) (“The *Flores-Ortega* Court made clear that a presumption of prejudice applies in the context of an ineffectiveness claim because an attorney’s deficient performance deprives the defendant of his or her opportunity for an appellate proceeding. Notably, *Flores-Ortega* did not address whether this principle has any force, let alone controls, where the defendant has waived his right to appellate and collateral review.”), petition for cert. filed, 77 U.S.L.W. 3366 (2008).

85 Justices Souter, Stevens, and Ginsburg joined Part II-B of *Flores-Ortega* but dissented from Part II-A. *Flores-Ortega*, 528 U.S. at 488 (Souter, J., concurring in part and dissenting in part).

86 “[T]here is no claim here that [defendant] waived his right to appeal as part of his plea agreement.” Id. at 488 n.1.

87 Id.

88 Justice Souter does, however, dismiss this situation as highly unlikely. Id. (“Such a possibility is never very likely and exists only at the furthest reach of theory, given a defendant’s right to adversarial representation.”). Still, it certainly appears as if the district judge in *Nunez* meticulously explained the appeal rights to the defendant during the plea colloquy. See supra note 30.

89 See supra notes 28-30 and accompanying text.

90 *Flores-Ortega*, 528 U.S. at 493 (Ginsburg, J., concurring).
Ortega to determine ineffective counsel. As stated above, the first prong of this test requires that the defendant demonstrate that counsel has performed deficiently, taking into account all the information counsel knew and determining whether “a rational defendant would [have] want[ed] to appeal.” In Flores-Ortega, the Court specifically notes that in assessing the deficiency prong, “a highly relevant factor . . . will be whether the conviction follows a guilty plea . . . .” Since a plea bargain limits the appealable issues, a plea signals to counsel that the defendant is seeking an end to judicial proceedings. Therefore, counsel’s performance might not be considered deficient in this circumstance because the defendant indicated through his behavior that he did not want to appeal the case. Consequently, counsel legitimately did not file an appeal. Since Nunez’s conviction followed a guilty plea, his behavior indicated to his attorney that he was seeking an end to judicial proceedings. As such, his counsel’s performance was not deficient in failing to file the appeal, and Nunez fails to meet the first prong of Flores-Ortega, which requires deficient performance by counsel. Hence, the Flores-Ortega standard required to show ineffective counsel is not satisfied in Nunez.

Without explicitly stating so, the holding in Nunez implicitly follows the general philosophy set forth by the Court in Strickland. Nunez rejects the imposition of mechanistic rules upon lawyers, which may limit the ability of counsel to make decisions based on professional judgment, experience, and common sense. In particular, the holding of Nunez does not restrict the wide latitude counsel maintains in making strategic decisions for the client but rather, as required by Strickland, implicitly applies a standard of reasonableness when addressing whether an appeal should be filed by counsel. Following in the vein of

91 Id. at 480 (majority opinion).
92 Id.
93 Id.
94 Id. at 479.
95 Id. at 480.
96 Similarly, Nunez fails to meet the second prong of Flores-Ortega, which requires the defendant to demonstrate prejudice from counsel’s deficient performance. Id. at 482. According to Flores-Ortega, prejudice will be presumed when the defendant is denied the opportunity for a proceeding at all. Id. at 483. Here, Nunez was in fact denied the opportunity for a proceeding by his counsel’s failure to file an appeal. However, in Flores-Ortega, the Court specifically noted that in order for prejudice to be presumed, the defendant must have a right to the judicial proceeding that he or she did not receive as a result of counsel’s deficient performance. Id. ("The even more serious denial of the entire judicial proceeding itself, which a defendant wanted at the time and to which he had a right, similarly demands a presumption of prejudice.") (emphasis added). Quite the contrary here, Nunez maintained no right to an appeal proceeding because he waived the right in the plea bargain. Thus, the presumption of prejudice does not apply, and the second prong of the Flores-Ortega standard required to show ineffective counsel is not satisfied in Nunez.
97 Nunez v. United States (Nunez I), 495 F.3d 544, 547 (7th Cir. 2007), vacated, 128 S. Ct. 2990 (2008).
99 Id. at 687-88.
Strickland, Nunez calls for a lawyer to focus on “the overriding mission of vigorous advocacy of the defendant’s cause”\textsuperscript{100} and to reasonably assess whether the filing of an appeal would be a wise and appropriate decision. As stated above, the filing of an appeal could only have harmed and not helped Nunez.\textsuperscript{101} Additionally, Nunez demonstrated that he was seeking an end to judicial proceedings when he accepted the plea. Therefore, Nunez’s counsel certainly acted with “reasonableness under prevailing professional norms”\textsuperscript{102} in refusing to file an appeal as required by Strickland.

C. The Application of Supreme Court Precedent to the Majority Circuits

For the most part, the majority circuits applied Anders and Flores-Ortega in their analyses, the same Supreme Court cases used by the Seventh Circuit.\textsuperscript{103} Unlike the Seventh Circuit, however, the majority circuits prioritize the need to protect a defendant’s right to appeal, even after he or she has seemingly waived this right.\textsuperscript{104} Even though Flores-Ortega did not involve a defendant waiving his or her right to appeal, the majority circuits nonetheless apply Flores-Ortega to cases involving such a waiver. According to the majority circuits, Flores-Ortega stands for the unambiguous proposition that “it is only when the defendant either does not make his appellate wishes known or does not clearly express his wishes that an attorney has some latitude in deciding whether to file an appeal.”\textsuperscript{105} They focus on the “unequivocal”\textsuperscript{106} language in Flores-Ortega, which states “that a lawyer who disregards specific instructions from the defendant to file a notice of appeal acts in a manner that is professionally unreasonable.”\textsuperscript{107} In essence, “Flores-Ortega reaffirms the time-honored principle that an attorney is not at liberty to disregard the appellate wishes of his client”\textsuperscript{108}

\begin{itemize}
\item \textsuperscript{100} Id. at 689.
\item \textsuperscript{101} See supra note 82 and accompanying text.
\item \textsuperscript{102} Strickland, 466 U.S. at 688.
\item \textsuperscript{103} The majority circuits also looked at other cases but these three cases were the most key to their analysis as well as to the analysis in this Note. See infra note 110.
\item \textsuperscript{104} See, e.g., Campusano v. United States, 442 F.3d 770, 775 (2d Cir. 2006).
\item \textsuperscript{105} United States v. Poindexter, 492 F.3d 263, 269 (4th Cir. 2007); see also Watson v. United States, 493 F.3d 960, 964 (8th Cir. 2007); United States v. Tapp, 491 F.3d 263, 265-66 (5th Cir. 2007); Campusano, 442 F.3d at 777; Gomez-Diaz v. United States, 433 F.3d 788, 793 (11th Cir. 2005); United States v. Sandoval-Lopez, 409 F.3d 1193, 1198 (9th Cir. 2005); United States v. Garrett, 402 F.3d 1262, 1265-66 (10th Cir. 2005).
\item \textsuperscript{106} Poindexter, 492 F.3d at 269.
\item \textsuperscript{107} Roe v. Flores-Ortega, 528 U.S 470, 477 (2000).
\item \textsuperscript{108} Poindexter, 492 F.3d at 269; see also Watson, 493 F.3d at 964; Tapp, 491 F.3d at 265-66; Campusano, 442 F.3d at 777 (“The concern animating Flores-Ortega . . . is a powerful one even where the defendant is the only person who believes an appeal would be worthwhile.”); Gomez-Diaz, 433 F.3d at 793; Sandoval-Lopez, 409 F.3d at 1199 (“Nevertheless the client has the constitutional right, under Flores-Ortega . . . to bet on the possibility of winning the appeal and then winning an acquittal, just as a poker player has the right to hold the ten and queen of hearts, discard
for any reason. If the defendant can show that he or she requested an appeal and counsel failed to do so, prejudice will be presumed under the Flores-Ortega standard, and the defendant will be entitled to an appeal on an ineffective counsel claim. As required by Anders, a lawyer who believes the requested appeal is frivolous should still file the appeal and submit a brief to the court explaining the frivolous nature of the defendant’s claim.

While the majority circuits’ application of Flores-Ortega and Anders may be legally sound and reasonable, it ignores the directive in Strickland to avoid establishing “mechanical rules” in determining the standard for effective counsel. Unlike the Seventh Circuit’s analysis in Nunez, the majority circuits adopt a per se rule requiring a lawyer to file an appeal even if counsel’s professional judgment indicates that such an appeal would be frivolous or even harmful to the defendant. However, while adopting a bright-line rule for lawyers does indeed go against the general sentiment of Strickland, the majority circuits’ interpretation of Flores-Ortega is legitimate. As described above, the Court in Flores-Ortega made a variety of ambiguous statements, first stating a bright-line rule but then expressly rejecting the imposition of mechanical rules on counsel as “not appropriate.” Moreover, in Flores-Ortega, the Court continued to endorse Anders, which certainly can be categorized as a per se rule (given that it categorically prevents a lawyer from dismissing a defendant’s appeal as frivolous). Thus, although the majority circuits do not incorporate the Strickland philosophy, this omission is a reflection of the lack of clarity and inconsistency in the relevant Supreme Court jurisprudence rather than a dishonest application of the law.

III. THE ALLOCATION OF POWER BETWEEN COUNSEL AND CLIENT

This circuit split is complicated by the fact that both the Seventh Circuit and the majority circuits’ holdings can be reconciled with

109 Campusano, 442 F.3d at 772.
110 The majority circuits also look to other cases for support such as Peguero v. United States, 526 U.S. 23, 28 (1999) (“[W]hen counsel fails to file a requested appeal, a defendant is entitled to resentencing and to an appeal without showing that his appeal would likely have had merit.”) and Rodriguez v. United States, 395 U.S. 327, 330 (1969) (“Those whose right to appeal has been frustrated should be treated exactly like any other appellants; they should not be given an additional hurdle to clear just because their rights were violated at some earlier stage in the proceedings.”).
112 Watson, 493 F.3d at 964; Poindeaster, 492 F.3d at 268; Tapp, 491 F.3d at 266; Campusano, 442 at F.3d at 771-72; Gomez-Diaz, 433 F.3d at 790; Sandoval-Lopez, 409 F.3d at 1197-98; Garrett, 402 F.3d at 1263.
113 Flores-Ortega, 528 U.S. at 477 (“[A] lawyer who disregards specific instructions from the defendant to file a notice of appeal acts in a manner that is professionally unreasonable.”).
114 Id. at 479 (citing Strickland, 466 U.S. at 688).
Supreme Court jurisprudence in this area. Notably, either viewpoint can be explained as consistent with or as distinguishable from Anders and Flores-Ortega. This suggests that there is more to the circuit split than meets the eye, and what lies at the core of the courts’ disagreement is much more than a varying interpretation of Supreme Court precedent. The courts’ contrasting views reflect different philosophical approaches towards decision-making in the lawyer-client relationship. While the majority circuits embrace a model in which the client makes the fundamental choices, the Seventh Circuit adopts one in which the lawyer determines the tactical and strategic decisions. As discussed below, these two models are also present in the various codes of legal ethics, which fail to endorse one over the other. Consequently, similar to the Supreme Court cases, looking to the ethical guidelines for guidance regarding this circuit split provides yet another dead-end.

A. The Two Models of Lawyering

There are two major approaches to lawyering: “the traditional, lawyer-centered model and the participatory, client-centered approach.” In the traditional model, the autonomous lawyer maintains the discretion to assert his or her professional judgment over the significant decisions. Under this model, by retaining counsel, the defendant has accepted a passive role and implicitly agreed to allow counsel to handle the case. Decision-making is delegated to the lawyer in this paradigm because it is in the public’s best interest to entrust legal issues to lawyers, the officers of our justice system. On the other hand,

\[\text{Footnotes}\]

116 See supra Part II.B-C.
117 Id.
118 Rodney J. Uphoff & Peter B. Wood, The Allocation of Decisionmaking Between Defense Counsel and Criminal Defendant: An Empirical Study of Attorney-Client Decisionmaking, 47 U. KAN. L. REV. 1, 5 (1998); see also Mark J. Osiel, Review, Lawyers as Monopolists, Aristocrats, and Entrepreneurs, 103 HARV. L. REV. 2009, 2009 (1990) ("Two very different conceptions of the lawyer compete for ascendancy within Western society. Each claims both to describe the essential social role of the attorney and to prescribe the ethical standards entailed by it. The first conception enshrines the moral ideal of public service and conceives of the bar association—the expression of collective power—primarily as a necessary check against capitulation by individual attorneys in the face of antisocial demands by clients. The second conception upholds the ideal of loyalty to clients as the touchstone of professional ethics and conceives of bar associations as vigorous advocates for the legitimate interests of lawyers in a pluralistic society of freely competing interest groups.").
119 See Uphoff & Wood, supra note 118, at 7.
120 See id.; see also David Luban, Paternalism and the Legal Profession, 1981 WIS. L. REV. 454, 457-59; Mark Spiegel, The New Model Rules of Professional Conduct: Lawyer-Client Decision Making and the Role of Rules in Structuring the Lawyer-Client Dialogue, 1980 AM. B. FOUND. RES. J. 1003, 1003 (1980) ("The traditional rule and practice has been to allocate decision-making authority around ends and means, with ‘ends’ being the client’s decision and ‘means’ the lawyer’s.").
the client-centered model allows for a defendant to make active choices while counsel merely lays out the legal arguments, providing guidance and suggestions. Still, the defendant maintains the authority over decision-making. This model ensures that lawyers listen to their clients.

The Seventh Circuit explicitly rejects the client-centered model in *Nunez*, contending that there is nothing in the Sixth Amendment that requires a lawyer to function as “the client’s puppet.” Alternatively, the Seventh Circuit opined that “[p]rotecting a client from a lay-person’s folly is an important part of a lawyer’s job[,]” and a lawyer must therefore exercise his or her own professional discretion to provide this protection to the client. Furthermore, the court stated that it is a lawyer’s duty “to do what’s best for the client,” and it is up to the lawyer to determine what this may entail. Because *Nunez* instructed his counsel to file a potentially detrimental appeal (i.e., it could have resulted in the prosecutor withdrawing concessions), his lawyer was correct in exercising his discretion and ignoring *Nunez*’s request to file an appeal.

On the other hand, the majority circuits focus on protecting the defendant’s rights within the lawyer-client relationship by granting the client the full autonomy and power to make decisions. In this client-centered model, the client maintains the option to decide on filing an appeal because no corners should be cut when Sixth Amendment rights are at issue. Even though it may harm a defendant if counsel files an appeal, this dangerous and risky decision to appeal remains with the defendant.


124 *Nunez* v. United States (*Nunez I*), 495 F.3d 544, 547 (7th Cir. 2007), vacated, 128 S. Ct. 2990 (2008).

125 *Id.* at 548.

126 *Id.*

127 Interestingly, Judge Easterbrook’s holding in *Nunez* is consistent with his general economic analyses of the criminal justice system. For an interesting discussion on Judge Easterbrook’s view of a criminal justice system in which defendants are subject to the uncontrolled discretion of individual public officials, see Stephen J. Schulhofer, *Criminal Justice Discretion as a Regulatory System*, 17 J. Legal Stud. 43, 43 (1988). In his general jurisprudence, Judge Easterbrook supports discretion in the criminal justice system as efficient, taking the power of decision away from the defendant. He argues that “discretionary arrangements designed to pursue efficiency do not have unfair effects.” *Id.* at 44.

128 See Watson v. United States, 493 F.3d 960, 964 (8th Cir. 2007); United States v. Poindeexter, 492 F.3d 263, 273 (4th Cir. 2007); United States v. Tapp, 491 F.3d 263, 265-66 (5th Cir. 2007); Campusano v. United States, 442 F.3d 770, 777 (2d Cir. 2006); Gomez-Diaz v. United States, 433 F.3d 788, 793 (11th Cir. 2005); United States v. Sandoval-Lopez, 409 F.3d 1193, 1199 (9th Cir. 2005); United States v. Garrett, 402 F.3d 1262, 1267 (10th Cir. 2005).

129 *Campusano*, 442 F.3d at 777.
Sometimes demanding that one’s lawyer appeal is like demanding that one’s doctor perform surgery, when the surgery is risky and has an extremely low likelihood of improving the patient’s condition. But even though no one would think a doctor incompetent for refusing to perform unwise and dangerous surgery, the law is that “a lawyer who disregards specific instructions from the defendant to file a notice of appeal acts in a manner that is professionally unreasonable.” 130

In adopting the per se rule that the lawyer must file the appeal at a defendant’s request, the majority circuits are in effect stating: “We will let a defendant walk off a cliff but at least it will be his or her decision to do so.”

B. The Models of Lawyering in the Ethics Guidelines

This philosophical disagreement embodied in Nunez and the majority circuits on the correct allocation of power between lawyers and clients is vigorously debated by lawyers, legal scholars, and the judiciary. 131 As described above, the Supreme Court has vacillated between the two models. 132 The Court has not endorsed either view and its jurisprudence indicates praise and criticism for both models of lawyering. 133 Moreover, little guidance is provided in the ethical rules of conduct promulgated by the bar. The rules are unclear, inconsistent, and ambiguous, 134 mirroring the ambiguity of the Supreme Court regarding the proper role of lawyers. 135 This lack of clarity is also reflected in treatises analyzing criminal defense ethics. 136

130 Sandoval-Lopez, 409 F.3d at 1197 (quoting Roe v. Flores-Ortega, 528 U.S. 470, 477 (2000)).

131 See Uphoff & Wood, supra note 118, at 4; see, e.g., State v. Robinson, 224 S.E.2d 174, 179 (N.C. 1976) (“Trial counsel, whether court-appointed or privately employed, is not the mere lackey or ‘mouthpiece’ of his client. He is in charge . . . .”). But see Comm’r Internal Revenue v. Banks, 543 U.S. 426, 436 (2005) (“[T]he client retains ultimate dominion and control over the underlying claim.”).

132 See supra Part II.A; see, e.g., Jones v. Barnes, 463 U.S 745, 751 (1983) (holding that while a criminal defendant maintains a right to make certain fundamental choices regarding the case, he does not have a constitutional right to compel counsel to raise every nonfrivolous argument that he requests); McKaskle v. Wiggins, 465 U.S. 168, 174 (1984) (“The pro se defendant must be allowed to control the organization and content of his own defense”); id. at 187-88 (“We recognize that a pro se defendant may wish to dance a solo, not a pas de deux. Standby counsel must generally respect that preference.”).

133 See supra Part II.


135 See supra Part II.A.

136 See, e.g., JOHN M. BURKOFF, CRIMINAL DEFENSE ETHICS § 5:4 (2d ed. 2007) (“A criminal defense attorney should . . . respect his or her client’s desires with respect to how the client’s case should be defended—or whether it should be defended at all . . . . After all, it is the client’s life, livelihood, and/or liberty which is ultimately at stake in criminal proceedings. On the other hand, . . . [a]n attorney’s professionalism, sense of justice, and his or her interest in the zealous representation of a client may lead him or her to believe that a client’s desires . . . are inappropriate, unlawful, or [unwise . . . . Must a client’s every wish be accommodated in such circumstances? The answer is clearly no.”).
An attempt to apply these ambiguous ethics rules to the question of whether a lawyer must file an appeal when a defendant has waived this right in a plea agreement provides few answers. Both the Seventh Circuit and the majority circuits’ approaches can be legitimately defended and justified upon a study of the different ethical rules of the legal professions. For example, the ABA’s Standards for Criminal Justice set forth conflicting propositions for a lawyer’s role regarding an appeal. Standard 4-5.2(a)(v) states that the decision to appeal is among the decisions to be made by the defendant. Similarly, the comment to Standard 4-8.3 reads:

While Counsel has the professional duty to give his or her client fully and forcefully a candid opinion concerning the case and its probable outcome on appeal, counsel’s role, however, is only to advise. The decision whether to appeal must be made by the client.  

However, according to Standard 4-1.2(e), defense counsel is not the defendant’s “alter ego,” but rather serves as the professional representative of the accused. According to the comment of that section, the lawyer is not “strictly [the] ‘mouthpiece’ for the client” but instead maintains an “independent stance as a professional representative rather than as ordinary agent.” Thus, the ABA Standards for Criminal Justice suggest contrary propositions: the decision to appeal must be made by the defendant but at the same time, the lawyer’s role is to make professional judgments and not to merely serve as a defendant’s agent.

Likewise, the ABA Model Rules of Professional Conduct also present conflicting ideas as to a lawyer’s role. Some rules explicitly endorse the lawyer-dominated model, which assumes that clients are not capable of independently making good decisions. For example, Model Rule 2.1 encourages a lawyer to apply independent professional discretion in representing a client. In the same vein, comment 1 to Model Rule 1.3 maintains that a lawyer should exercise professional judgment in determining the means by which to pursue the case. But

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137 Despite this ambiguity pervading the legal world’s perception of the lawyer-client relationship, studies demonstrate that criminal defense attorneys “most often articulated a professional role of independent advisor rather than agent for their client.” Mather, supra note 134, at 1073.


139 ABA STANDARDS FOR CRIMINAL JUSTICE PROSECUTION FUNCTION AND DEFENSE FUNCTION § 4-5.2 (1993).

140 Id. § 4-8.3 cmt. (emphasis added).

141 Id. § 4-1.2(e).

142 Id. § 4-1.2 cmt.

143 The ABA Model Rules of Professional Conduct set out the “professional standards that serve as models of the regulatory law governing the legal profession.” Preface to MODEL RULES OF PROF’L CONDUCT (2008).


145 Id. R. 1.3 cmt.
Model Rule 1.2 grants the client the ultimate authority to decide the goals the lawyer should pursue.\textsuperscript{146} By conferring the ultimate authority to the client but allowing for the lawyer to exercise professional judgment, the Model Rules also hesitate as to the correct allocation of power between the lawyer and client.

The Restatement of the Law Governing Lawyers,\textsuperscript{147} however, is somewhat clearer. Under section 21(3), “a lawyer may take any lawful measure within the scope of representation that is reasonably calculated to advance a client’s objectives.”\textsuperscript{148} Furthermore, section 22 provides a list of certain decisions that the client maintains authority to make but specifically does not include filing an appeal in this list.\textsuperscript{149} Still, the Restatement does not unequivocally suggest that the decision to file an appeal remains within the lawyer’s authority.

The “battle” between the lawyer-dominated model and the client-controlled one is played out in the legal ethics guidelines, without a clear winner. It is unlikely that the Supreme Court, the ABA, or the legal profession as a whole will fully adopt a preferred method of lawyering, in which the allocation of power between lawyer and client is clearly set out.\textsuperscript{150} Thus, in determining whether a lawyer has a responsibility to file an appeal upon a defendant’s request after a defendant has waived this right in a plea bargain, it is imperative to look beyond the models of lawyering presented in Supreme Court precedent and codes of legal ethics. This issue must therefore be determined through a policy analysis, examining the potential effects of the circuits’ holdings on judges, lawyers, and defendants.

IV. A POLICY ANALYSIS: WHY THE SEVENTH CIRCUIT’S APPROACH IS PREFERABLE

Excusing a lawyer from filing an appeal upon a defendant’s request after a defendant has waived this right in a plea agreement will be beneficial to judges, lawyers, and defendants. Under the Seventh Circuit’s rule, lawyers are not forced to file futile and therefore frivolous appeals, thereby promoting both attorney and judicial efficiency. Furthermore, defendants are protected from the withdrawal of concessions already granted. Hence, from a public policy perspective, the Seventh Circuit’s holding is preferable to the majority circuits’ holding.

\textsuperscript{146} Id. R. 1.2.

\textsuperscript{147} The Restatement of the Law Governing Lawyers clarifies the common law applicable to the legal profession. See generally Restatement (Third) of the Law Governing Lawyers (2000).

\textsuperscript{148} Id. § 21(3).

\textsuperscript{149} Id. § 22(1).

\textsuperscript{150} See Mather, supra note 134, at 1084 (“[R]eform will be difficult, even if we agreed on the direction to take to improve how lawyers act with their clients.”).
A. Increasing Judicial Efficiency

The majority circuits’ holding encourages frivolous litigation, thereby minimizing judicial efficiency. As the Seventh Circuit points out, Nunez’s lawyer had a duty to avoid burdening the judiciary with frivolous litigation.\(^\text{151}\) Indeed, filing a futile appeal creates a burden on an already overloaded appellate system. From 1982 to 2006, the number of appeals in the U.S. Court of Appeals grew by 138%.\(^\text{152}\) In 2005, the number of federal appeals reached an all-time high after rising for eleven consecutive years.\(^\text{153}\) In addition, the number of criminal appeals in the U.S. Court of Appeals has surged by 246% since 1980,\(^\text{154}\) rising 4% over 2008.\(^\text{155}\) Similarly, state appellate courts face growing caseloads as well, with appeals doubling about every decade since World War II.\(^\text{156}\) In some states, because of overloaded dockets, an appellate case can take more than four years to finish.\(^\text{157}\)

It is shocking that with such dramatic statistics, the majority circuits would encourage increasing the number of frivolous appeals. Any appeal, even an explicitly meritless one, makes use of judicial resources almost immediately.\(^\text{158}\) When a party files an appeal, an appellate court begins to expend resources on the case as soon as it arrives at the courthouse.\(^\text{159}\) Upon the case’s arrival, the clerk confirms that the party has submitted the necessary filing fees and documents.\(^\text{160}\) At the same time, court staff creates a schedule and collects the appellate

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\(^{151}\) Nunez v. United States (Nunez I), 495 F.3d 544, 547 (7th Cir. 2007), vacated, 128 S. Ct. 2990 (2008).


\(^{156}\) Thomas B. Marvell, State Appellate Court Responses to Caseload Growth, 72 JUDICATURE 282, 283 (1989).

\(^{157}\) See Commonwealth v. O’Berg, 880 A.2d 597, 602 (Pa. 2005) (“[T]here have been instances where a direct appeal took more than four years to be completed.”); see also State v. Drakeford, 777 A.2d 202, 210 n.2 (Conn. App. Ct. 2001) (Landau, J., concurring) (“In the month that this case was argued, there were more than 300 cases ready for argument and almost 800 other appeals filed, but not yet ready for oral argument.”); McGruder v. State, 886 So. 2d 27, 35 (Miss. Ct. App. 2004) (“It is readily apparent that the Court of Appeals is handling an overwhelming amount of the docket.”).

\(^{158}\) See Wallace, supra note 154, at 192.

\(^{159}\) See id.

\(^{160}\) See id.
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materials (such as briefs) for review.\textsuperscript{161} The assigned judge then must review the materials, enforce the schedule, and make sure that litigants comply with deadlines.\textsuperscript{162} The appeal filed by a Nunez-like defendant in the majority circuits may be entirely frivolous, but it still requires courthouse attention, thereby wasting already limited judicial resources and reducing judicial efficiency.

Furthermore, the majority circuits overlook the initial historical reason behind the implementation of appeal waivers in plea bargains. When the Sentencing Guidelines went into effect in 1987, the number of criminal appeals surged, and as a result, waivers of appeal became popular among prosecutors.\textsuperscript{163} In 1995, “the Department of Justice distributed a memorandum to federal prosecutors” encouraging them to regularly include appeal waivers in plea bargains.\textsuperscript{164} The Department of Justice was concerned that “far too many government resources were being squandered on meritless appeals by defendants who were merely unhappy with their sentences but had no good legal claims.”\textsuperscript{165} Appeal waivers were also encouraged by judges facing the potential for backlog.\textsuperscript{166} The Department of Justice’s encouragement of appeal waivers was therefore specifically an attempt to prevent criminal appeals backlog in the federal judiciary.\textsuperscript{167} Similarly, in the 1990s, some state appellate courts attempted to decrease backlog by eliminating the right of appeal in plea-based convictions.\textsuperscript{168} Thus, by requiring counsel to file an appeal despite a defendant’s waiver, the majority circuits neutralize the benefits afforded by appeal waivers and disregard the major purpose for its implementation and subsequent popularity.\textsuperscript{169}

\begin{itemize}
  \item See id.
  \item See id.
  \item See King & O’Neill, supra note 4, at 219-20 (“Prior to the Guidelines, once a defendant entered a guilty plea, there was little to appeal. Because defendants waived most pretrial and trial rights when pleading guilty, and because sentencing appeals were futile, criminal appeals were primarily reserved for those few defendants who were convicted after trial. But the new sentencing statutes and the Guidelines changed that. The Guidelines provided hundreds of new sentencing issues for defendants to raise on appeal, even after pleading guilty. The hope of avoiding these sorts of challenges motivated prosecutors to include appeal waivers in plea agreements.”).
  \item See King & O’Neill, supra note 4, at 221.
  \item See Etienne, supra note 164, at 41-42.
  \item See, e.g., State v. Bulger, 614 N.W.2d 103, 106-07 (Mich. 2000) (“By 1992, the Court of Appeals had a backlog of more than 4,000 cases awaiting decision, and “[p]lea-based appeals constitute[d] approximately thirty percent of all appeals facing the Michigan Court of Appeals.” Eliminating appeals of right from plea-based convictions was one method proposed to reduce a crushing burden on our appellate courts.” (quoting Mara Matuszak, Note, Limiting Michigan’s Guilty and Nolo Contendere Plea Appeals, 73 U. DET. MERCY L.R. 431 (1996)) (citations omitted)).
  \item Indeed, the majority of circuits’ holdings create the potential for extensive judicial proceedings that needlessly drain judicial resources. Specifically, in the majority of circuits, when a Nunez-like defendant files a writ of habeas corpus claiming ineffective assistance for counsel’s failure to file an appeal, the district court must grant an evidentiary hearing to determine if the defendant did in fact instruct counsel to file an appeal. See Campusano v. United States, 442 F.3d
The majority of circuits are contributing to judicial ineffectiveness and slowing down an already bogged-down system by requiring counsel to file meritless appeals. But by excusing counsel from filing these frivolous appeals, as the Seventh Circuit suggests, judges will be free to spend time on the more serious judicial issues with actual, meritorious arguments. Of course, maximizing judicial efficiency should not trump a defendant’s fundamental right to due process, specifically the right of access to the courts, by denying defendants the opportunity to appeal. But the defendants in Nunez and the majority circuit cases did receive due process and access to the courts. The plea bargains (and waivers of appeal) were supervised and approved by the court, thereby satisfying their due process right. Furthermore, the defendants were given the opportunity to make a choice (i.e., whether or not to accept the plea bargain). While a defendant’s right to due process is fundamental to our system, a defendant does not have the right to pursue a frivolous appeal. Due process does not mean giving a defendant carte blanche to burden our judicial system by filing an appeal after agreeing not to do so.

B. Increasing Lawyer Efficiency and Commitment to the Practice of Criminal Law

In addition to draining judicial resources, requiring lawyers to file frivolous appeals after a defendant has waived the right to appeal creates an enormous burden on criminal defense attorney efficiency. In particular, because 90% of all criminal defendants are assigned public defenders, this weight falls on the already overworked public defender attorneys. Increasing the workload requirements of public defenders is highly detrimental to attorney efficiency. Currently, the vast majority of public defenders’ workloads exceed the ABA’s suggested number of cases per year, with an annual average caseload of over 1000. In fact,
their workload often prevents public defenders from meeting with clients until the day of trial. Because their clients bear no cost for appealing, public defenders already spend a large part of their time arguing frivolous appeals (or filing *Anders* briefs). Additionally, public defenders face the problem of inadequate resources such as nonfunctioning computers and limited support staff. Likewise, private defense attorneys who represent indigent defense cases on a contract basis face a similar problem of limited time and resources. Because they are paid a flat fee for each defendant, they often are forced to operate “volume practices,” in which they take on more clients than their resources can sufficiently support. Given that these criminal defense lawyers and public defenders have limited time and resources, eliminating the requirement to file an appeal once a defendant agrees to an appeal waiver will enable them to concentrate their efforts and resources on value-producing work as opposed to futile appeals.

Moreover, requiring lawyers to file these appeals may deter attorneys from practicing criminal law, and more specifically, from providing criminal defense counsel to the indigent. With salaries skyrocketing for young lawyers entering the private sector as compared to much lower salaries for public defenders, the incentive to represent the criminal indigent is already low. But by requiring the filing of this frivolous appeal, the best and the brightest of graduating law students with access to high-paying jobs will be even more disinclined to accept

Bar Association has concluded one attorney can handle effectively . . . . Public defenders in New York are handling up to 1,600 cases per year.”). According to the National Advisory Commission on Criminal Justice Standards and Goals, a lawyer’s caseload per year should not exceed 150 felonies, 400 misdemeanors, 200 juvenile, 200 mental health or twenty-five appeals. See ABA Standing Comm. on Legal Aid & Indigent Defendants, Ten Principles of a Public Defense Delivery System 5 n.19 (2002), available at http://www.abanet.org/legalservices/downloads/sclaid/indigentdefense/tenprinciplesbooklet.pdf.

See Caroline Wolf Harlow, U.S. DEP’T OF JUSTICE, BUREAU OF JUSTICE STATISTICS, DEFENSE COUNSEL IN CRIMINAL CASES 8 tbl. 17 (2000), http://www.ojp.usdoj.gov/bjs/pub/pdf/dccep.pdf (indicating that 13.6% of state inmates and 4.9% of federal inmates did not have contact with their counsel until trial).

See id. at 687 (“[T]he funding problems are so severe that attorneys do not have functioning computers, let alone adequate time and resources to investigate their cases.”).

See U.S. DEP’T OF JUSTICE, BUREAU OF JUSTICE ASSISTANCE, KEEPING DEFENDER WORKLOADS MANAGEABLE 2 (2001), http://www.ncjrs.gov/pdfsfiles1/bja/185632.pdf (“As populations and caseloads have increased, many public defender offices have been unable to obtain corollary increases in staff.”).

See Primus, *supra* note 175, at 688.

See id. at 682.

See id. at 687.

jobs as public defenders. Furthermore, those already practicing criminal
defense of the indigent often experience “burnout” and abandon their jobs as
public defenders for less challenging work.183 Requiring a lawyer to file
frivolous appeals will only add to the challenging nature of the work for
these lawyers, increasing burnout and professional frustrations, thereby
discouraging lawyers from continuing their work representing the indigent.
In essence, the majority circuits’ position will effectually serve as disincentive
for lawyers to practice criminal defense law and represent the poor.

Prosecutor efficiency is also minimized when defense lawyers
file these frivolous appeals. In general, since the surge in popularity
of appeal waivers in the 1990s,184 prosecutors have found appeal waivers to
be extremely successful and helpful in reducing their work burden,
minimizing the amount of resources expended and narrowing the issues
raised on appeal.185 However, when a defendant accepts a waiver of
appeal in a plea bargain but then proceeds to file a meritless appeal, the
prosecutor must respond with a brief or memorandum to the court.186
Additionally, since the prosecutor can withdraw concessions when a
defendant violates the terms of a plea agreement by filing an appeal,187 the
time spent by the prosecutor on working out the concessions for the initial
plea bargain becomes a retroactive waste. The prosecutor then needs to
readdress the case, utilizing resources to do so and minimizing efficiency.

In addition, the majority circuits’ holding provides an incentive
to the defendant to lie to the court, potentially damaging a lawyer’s
professional credibility. Specifically, defendants convicted through plea
bargains will have an incentive to fraudulently claim that they instructed
counsel to file an appeal and counsel failed to do so.188 According to the
majority circuits, an automatic claim for ineffective counsel is triggered
if a defendant can prove this.189 Indeed, in the cases from most of the
circuits (except for the Fifth Circuit), the defendants claimed that an
appeal was requested but counsel denied that the defendant had in fact

183 See Abbe Smith, Too Much Heart and Not Enough Heat: The Short Life and
(noting that public defenders quickly find themselves “burned out, worn out, emotionally spent”);
see also Criminal Litigation Careers: Public Defender, supra note 182 (“The public defender might
be the unsung hero of the legal system. As a government employee, he makes relatively little for a
litigator. He has little say over his cases and often works with the defendants that no one else wants.
He doesn’t have the resources that the district attorney’s office has and must often engage in his own
investigations. Many of his cases seem almost hopeless and, to the victims of crime, he appears
almost as bad as his defendants.”).
184 See supra Part IV.A.
185 King & O’Neill, supra note 4, at 230.
186 See id. at 220, 231.
187 See, e.g., United States v. Whitlow, 287 F.3d 638, 640-41 (7th Cir. 2002) (holding that
when a defendant violates a plea agreement by appealing despite a promise not to do so, the
prosecutor may withdraw concessions made as part of the bargain); United States v. Cimino, 381
F.3d 124, 128 (2d Cir. 2004) (same).
188 See United States v. Farr, 297 F.3d 651, 657 (“We have observed in the past that
criminal defendants frequently ‘demonize’ their lawyers.”).
189 See supra Introduction.
requested it. Requiring a lawyer to defend his or herself from these types of wrongful accusations could potentially prove detrimental to his or her professional reputation. Moreover, counsel may not have readily accessible evidence to demonstrate that the defendant never requested an appeal, and as a result, it could appear as if he or she provided ineffective counsel. Finally, a lawyer would have to attend an evidentiary hearing to prove that a request for an appeal was never made, using time and resources to do so, again minimizing attorney efficiency.

C. Protecting Defendants

Finally, while the majority circuits claim to be concerned about affording defendants their Sixth Amendment rights, it is the Seventh Circuit’s approach that sufficiently provides protection to defendants. When a defendant files an appeal after agreeing to a waiver of appeal in a plea bargain, the plea bargain becomes worthless to the government. The concessions originally offered no longer provide any benefit to the government since the prosecutor will now have to expend resources responding to the defendant’s appeal. As such, once a defendant’s counsel files an appeal notwithstanding the waiver, the prosecutor has the option to withdraw concessions already granted in response to the defendant’s breach of the agreement. Given the fact that the appeal cannot succeed (since the defendant has already accepted the plea), counsel’s filing of the appeal only serves to harm the defendant by potentially resulting in the prosecutor taking the concessions off of the

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190 See Watson v. United States, 493 F.3d 960, 962 (8th Cir. 2007); United States v. Poindexter, 492 F.3d 263, 267 & n.4 (4th Cir. 2007); Campusano v. United States, 442 F.3d 770, 772 (2d. Cir. 2006); Gomez-Diaz v. United States, 433 F.3d 788, 791 (11th Cir. 2005); United States v. Sandoval-Lopez, 409 F.3d 1193, 1195 (9th Cir. 2005); United States v. Garrett, 402 F.3d 1262, 1264 (10th Cir. 2005); see also supra note 46 and accompanying text.

191 Courts have expressed concern over legal proceedings that negatively affect a lawyer’s career. See United States v. Talao, 222 F.3d 1133, 1138 (9th Cir. 2000) (holding that after a district court sanctions a lawyer for an ethical violation, the lawyer can appeal the decision because the sanction may be detrimental to lawyer’s career). Additionally, courts stress the importance of maintaining a lawyer’s professional reputation. See Cooter & Gell v. Hartmarx Corp., 496 U.S. 384, 413 (1990) (Stevens, J., concurring in part and dissenting in part) (“[M]ost lawyers are wise enough to know that their most precious asset is their professional reputation.”); Addington v. Texas, 441 U.S. 418, 424 (1979) (noting that reputational interests “are deemed to be more substantial than mere loss of money”); United States v. Gonzales, 344 F.3d 1036, 1046 (10th Cir. 2003) (“An attorney’s professional reputation undoubtedly is his or her most valuable asset.”).

192 United States v. Whitlow, 287 F.3d 638, 640-41 (7th Cir. 2002); United States v. Hare, 269 F.3d 859, 861 (7th Cir. 2001) (“An appeal requires the prosecutor’s office to spend time researching the record, writing a brief, and attending oral argument. All of this time could be devoted to other prosecutions, and a promise that frees up time may induce a prosecutor to offer concessions.”).

193 See supra note 82.

194 When a defendant appeals despite an appeal waiver, the government may file a motion to dismiss the appeal based upon the waiver. See United States v. Buchanan, 131 F.3d 1005, 1008 (11th Cir. 1997). An appellate court will dismiss the appeal as meritless since the defendant waived the right to appeal. See Sandoval-Lopez, 409 F.3d at 1197.
Also, if prosecutors believe that appeals will be filed despite defendants’ promise not to do so, prosecutors will be more reluctant to make concessions to defendants. Also, if prosecutors believe that appeals will be filed despite defendants’ promise not to do so, prosecutors will be more reluctant to make concessions to defendants. Prosecutors, Judge Easterbook of the Seventh Circuit notes, “cannot be fooled in the long run” and “[d]efendants must take the bitter [waiver of appeal] with the sweet [concessions].”

Despite the potential detrimental effect of an appeal on the defendant, the majority circuits hold that this decision should lie in the hands of the defendant and that protecting defendants should mean providing them with the right to make such decisions. Under that rationale, as long as counsel informs the defendant that the appeal could be harmful and risky, the defendant should make the final decision. However, there are many instances in which the legal system protects clients by removing their right to decide. For example, in an effort to protect a client from a wily lawyer, a lawyer cannot contact the opposing client without permission from the opposing client’s lawyer. A client cannot agree to waive this rule and instead, the right to waive it belongs to the client’s lawyer. A client also cannot agree to pay an unreasonable attorney’s fee. These rules remove choice from clients in an effort to promote their best interests. Similarly, by removing the decision to appeal from defendants, the Seventh Circuit is protecting them from making poor decisions that will likely harm them.

As discussed above, given that public defenders and court-appointed attorneys have limited resources, eliminating a lawyer’s duty to file an appeal after a defendant has waived the right to appeal will enable criminal defense attorneys to concentrate their time, money, and resources defending criminals awaiting trial, which will improve the overall quality of defendants’ representation. While the Seventh Circuit’s approach does not provide an avenue for the defendant to fruitlessly pursue frivolous claims, it does protect the benefits a
defendant has already received. It also takes into account the general well-being of criminal defendants throughout the system.

CONCLUSION

This circuit split between the Seventh Circuit and the majority circuits looms over the criminal justice system and has the potential to wreak havoc and uncertainty among criminal defense lawyers and defendants.204 This dangerous ambiguity is not limited to courts that fall within the Seventh Circuit’s jurisdiction.205 In fact, in July 2008, the Third Circuit sided with the Seventh Circuit and dismissed the majority circuits’ approach.206 Thus, given the wide sweeping effect of this circuit split in criminal cases, it would behoove the Supreme Court to clarify its jurisprudence by holding that that a plea bargain in which a defendant waives the right to appeal relieves counsel of a duty to file an appeal.207 Nonetheless, there is a different approach for attorneys and judges to consider if the approach of the majority circuits prevails. A defendant can waive constitutional rights in exchange for concessions, including the Sixth Amendment right to the assistance of counsel.208 Defense attorneys and prosecutors could hypothetically contract around

204 Indeed, district courts within the Seventh Circuit have already begun citing to Nunez to support the proposition that a defendant who has waived the right to appeal via plea bargain is not entitled to a new appeal when counsel fails to file the appeal upon the defendant’s request. See, e.g., Salas v. United States, No. IP 05-111-H-F-CR-01, 2007 WL 3286611, at *3 (S.D. Ind. Nov. 6, 2007) (holding that a defendant does not receive ineffective assistance of counsel when counsel fails to file an appeal after the defendant has waived the right to appeal in a plea bargain); Hermann v. United States, No. 05-3277, 2007 WL 2700161, at *1 (C.D. Ill. Sept. 10, 2007) (same).


206 In United States v. Mabry, the Third Circuit stated:

The analysis employed in evaluating an ineffectiveness of counsel claim does not apply when there is an appellate waiver. While a defendant may be entitled to habeas relief if his attorney ineffectively fails to file a requested appeal because it is presumed to be prejudicial under Flores-Ortega, if that same defendant has effectively waived his right to habeas, he cannot even bring such a claim unless the waiver fails to pass muster under an entirely different test: one that examines its knowing and voluntary nature and asks whether its enforcement would work a miscarriage of justice . . . . We, therefore, will part ways with the approach taken by the majority of courts of appeals. Although vacated on other grounds, the Nunez opinion of the Court of Appeals for the Seventh Circuit presents the proper focus.


207 This would not require the Supreme Court to overturn any precedents. As described above, the Seventh Circuit’s holding can be reconciled with previous Supreme Court jurisprudence in this area. See supra Part II.B. Rather, such a holding would serve as a clarification to previous Court cases (such as Anders v. California, 386 U.S. 738 (1967), and Roe v. Flores-Ortega, 528 U.S. 470 (2000)) by further defining when a lawyer has a responsibility to file an appeal.

208 See United States v. Hare, 269 F.3d 859, 860 (7th Cir. 2001); see also Jason Mazzone, The Waiver Paradox, 97 NW. U. L. REV. 801, 801 (2003).
the requirement for counsel to file an appeal by explicitly including a waiver of the right to counsel as part of an appeal waiver plea agreement. By doing so, counsel would be exempt from filing the appeal not because the defendant waived the right to appeal but rather because the defendant waived the right to counsel. Assuming that the plea bargain was valid, this process would bypass those defendants requesting an appeal following the acceptance of the plea bargain. Like the Seventh Circuit approach, this method would maximize judicial and attorney efficiency by preventing frivolous appeals. Defendants would also benefit from this approach. In particular, they would not be able to breach the plea agreement by filing an appeal, thereby preventing prosecutors from withdrawing the concessions offered in the plea bargain.

Nonetheless, a defendant might be more hesitant to waive the right to counsel than to waive the right to appeal. Additionally, there is something discomforting about regularly encouraging and compelling a defendant to waive the constitutional guarantee of counsel, something that seems inherently and philosophically in conflict with the Sixth Amendment. As such, the Seventh Circuit’s holding is preferable and should be adopted by the Supreme Court. By dispensing with a lawyer’s requirement to file an appeal upon a defendant’s request after he or she has waived the right in a plea bargain, the Seventh Circuit created a policy that benefits all participants in the criminal justice system while abiding by both Supreme Court precedent and models of legal professional responsibility.

Tamar Kaplan-Marans†

209 To be valid, the plea bargain must be “voluntary” and “intelligent.” Brady v. United States, 397 U.S. 742, 747 (1970) (quoting Boykin v. Alabama, 395 U.S. 238, 242 (1969)). If the plea bargain was not valid, neither the waiver of appeal nor the waiver of counsel would be effective. See supra note 35.

210 Of course, if the defendant claimed the waiver was involuntary, then counsel would still need to file an appeal on the basis that waiver was invalid despite the defendant’s waiver of the right to counsel. See supra note 42.

211 In his appeal to the Supreme Court, Nunez was represented by the prominent and large firm Winston and Strawn, which has an active appellate and Supreme Court practice. See Petition for Writ of Certiorari, supra note 11, at *1; see also WINSTON & STRAWN LLP, http://www.winston.com/index.cfm?contentID=19&itemID=156&itemType=20&pageID=320 (last visited Feb. 6, 2009). It therefore seems likely that Nunez will petition again for certiorari. Additionally, given the import of the circuit split and the fact that the Court previously granted certiorari in this case, it is also likely that the Court will agree to hear it again.

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An Opportunity for Reform

TENNESSEE SECONDARY SCHOOL ATHLETIC ASSOCIATION
V. BRENTWOOD ACADEMY AND NCAA RECRUITING

I. INTRODUCTION

In 2004, news broke that the Colorado University football program had used sex, drugs, and alcohol to lure recruits to the school.\(^1\) An investigative panel reviewing the incidents issued a fifty-page report, in which it found that player-hosts “felt pressured to impress recruits and resorted to providing alcohol, drugs and sex, including visits to strip clubs and the hiring of strippers.”\(^2\) While the nation’s colleges and universities and their coaches condemned Colorado’s practices,\(^3\) regrettably, the truth is that Colorado University was neither the first nor the last school to engage in such scandalous recruiting.\(^4\) In fact, evidence suggests that the occurrence of these practices is increasing.\(^5\)

Unfortunately, these improper recruiting practices are a product of the current state of intercollegiate athletics. According to colleges and

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\(^2\) Id. According to the report, there was no evidence that officials condoned the misconduct; however, it did suggest that they were “lazy, ineffective or simply ignored what was going on . . . .” Id.

\(^3\) See Greg Wallace, *Winds of Change: College Recruiting Set to Get Major Overhaul*, BIRMINGHAM POST-HERALD, May 24, 2004, at 8 (discussing how the Colorado incident and another recruiting scandal at the University of Miami would lead to changes in NCAA recruiting rules and predicting that such changes would be welcomed by many coaches).


\(^5\) See Wolverton, supra note 4. According to Wolverton, the NCAA’s enforcement staff was on pace to complete twenty major infraction cases in 2007, a third more than 2006, and twice the number it handled in 2002. Id. In addition, athletic departments reported about 3500 minor rules violations for 2006, about fifty percent more than in 2002. Id.; see also Daniel F. Mahoney et al., *Ethics in Intercollegiate Athletics: An Examination of NCAA Violations and Penalties—1952-1997*, in THE BUSINESS OF SPORTS 447, 449 (Scott R. Rosner & Kenneth L. Shropshire eds., 2004) (providing data that shows the number of men’s programs penalized has risen from 7.1 per year in the 1950s to 18.5 in the 1990s).

Notably, David Price, the NCAA’s vice president for enforcement, suggests that the rise in violations may be the result of the NCAA’s commitment to speedier investigations and colleges’ devotion to greater compliance with the rules. Wolverton, supra note 4. For more on NCAA enforcement, see infra Part III.C.3.
universities, the purpose of college athletics is to enhance the educational experience of the student. To preserve this end, many of America’s schools have joined the National Collegiate Athletic Association (“NCAA”), an independent body charged with governing intercollegiate athletics. Consistent with the goals of its member institutions, the NCAA claims that college athletics is an avocation: a recreational activity meant to ensure that “the educational experience of the student-athlete is paramount.” Yet, despite this profession, college athletics has become much more than an avocation, as colleges and universities have become focused on achieving athletic prowess, even at the expense of academic excellence.

Consumed by a need to achieve athletic success, many coaches resort to questionable recruiting tactics. To prevent such measures, the NCAA has adopted an extensive set of rules governing the recruitment of student-athletes. Nonetheless, despite the NCAA’s efforts, coaches still continue to commit recruiting violations, and, perhaps even worse, engage in questionable conduct that is not proscribed by the recruiting rules. This persistent usurpation of both NCAA and ethical standards indicates that NCAA recruiting rules need to be drastically changed.

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7 The NCAA is not the only governing body of college athletics—other prominent collegiate athletic associations include, for example, the National Association of Intercollegiate Athletics (“NAIA”) and the National Junior College Athletic Association (“NJCAA”)—but it is the largest and most prominent regulator of college athletics and thus will be the focus of this Note.


9 See discussion infra Parts III.B.3, III.C.3.

10 See discussion infra Part III.B.3.


12 According to David Price, because of the recent rule changes and the emphasis on compliance, recruiting tactics have become “increasingly creative.” Wolverton, supra note 4. Throughout history, coaches have been one step ahead of the NCAA. See Staples, supra note 4 (quoting Conference USA Commissioner Britton Banowsky as saying that “[e]very time [the NCAA] change[s] the rules, somebody comes up with something”). After the NCAA passes a rule, coaches will find some creative way to get around it, after which the NCAA will pass a new rule banning the conduct, and the cycle will repeat itself. See id. (providing a history of coaches skirting NCAA recruiting rules); Dana O’Neil, Gray Scale: Recruiters Struggle with Perfectly Legal Yet Ethically Questionable, ESPN.COM, Nov. 19, 2008, http://sports.espn.go.com/ncb/columns/story?id=3710807&lpos=spotlight&lid=tab4pos1 (discussing ways in which recruiting rules are now being circumvented, in violation of the intent of the rule, as well as flat-out broken).

A good example of this is shown by the fact that, after the NCAA banned sending text messages to recruits, coaches began using different practices to get around the ban. Andy Staples, Beating the System: With Texting Outlawed, Coaches Turn to E-mail; Notes, SL.COM, Jan, 14, 2008 http://sportsillustrated.cnn.com/2008/writers/andy_staples/01/14/recruiting.notebook/index.html. One method is to e-mail recruits—currently, the NCAA allows unlimited emailing—since, for recruits able to receive e-mail on their phones, an e-mail to them is essentially the same as a text
Fortunately, a recent decision by the Supreme Court in *Tennessee Secondary School Athletic Association v. Brentwood Academy* ("Brentwood II"),\(^{14}\) can be the catalyst for such a change.\(^{15}\) In *Brentwood II*, the Supreme Court upheld a high school athletic association’s Anti-Recruiting Rule against a First Amendment challenge by one of its member schools.\(^{16}\) The Rule effectively prevented recruiting by prohibiting a school from using undue influence on a student in order to retain his admission for athletic purposes.\(^{17}\) In upholding the Rule, the Court applied its public employee speech doctrine because of Brentwood Academy’s voluntary decision to join the Tennessee Secondary School Athletic Association ("TSSAA").\(^{18}\)

This Note focuses on the *Brentwood II* decision and the potential implications it will have on NCAA recruiting. Specifically, it argues that the NCAA is entitled to the same broad authority to limit recruiting as the Supreme Court gave to the TSSAA. Ultimately, while an intercollegiate athletic association and high school athletic association are certainly different, given the reasoning of the Court in *Brentwood II* and other cases, this Note claims that the Court would, in the context of recruiting, treat the NCAA no differently than the TSSAA, and thus would permit the NCAA to effectively *ban* the athletic recruitment of high school student-athletes.

Part II begins by discussing the relevant background of the *Brentwood II* case. It then sets forth the development and parameters of the public employee speech doctrine, and how it was applied in *Brentwood II*. Part III then analyzes the implications *Brentwood II* could have on the NCAA. After briefly looking at the background of the NCAA, Part III examines whether the Court would be inclined to apply the public employee speech doctrine to collegiate recruiting. It then addresses what the likely result would be, under current public employee speech law, if the NCAA were to pass a recruiting ban similar to the
TSSAA’s. Finally, Part IV briefly discusses why the NCAA should establish a recruiting ban and how such a ban could be implemented.

II. **BRENTWOOD II**

A. **Facts**

The TSSAA is a private, voluntary association of public, independent, and parochial secondary schools from the state of Tennessee. Its purpose is “to stimulate and regulate the athletic relations of the secondary schools in Tennessee.” One of the TSSAA’s members is Brentwood Academy, an independent college-preparatory school located in Brentwood, Tennessee.

In order to prevent member schools from recruiting middle school student-athletes for their athletic programs, the TSSAA has promulgated an Anti-Recruiting Rule. The Anti-Recruiting Rule, located in TSSAA Bylaws Section 21 reads:

> The use of undue influence on a student (with or without an athletic record), his or her parents or guardians of a student by any person connected, or not connected, with the school to secure or to retain a student for athletic purposes shall be a violation of the recruiting rule.

The circumstances of the case arose in 1997, when Brentwood Academy’s head football coach, Carlton Flatt, sent a letter to middle school students, inviting them to participate in spring football practice. The letter explained that “getting involved as soon as possible would definitely be to your advantage,” and was signed, “Your Coach.” Although the boys who received the letter had already agreed to attend Brentwood Academy in the fall, they had not yet enrolled in the school as defined by the TSSAA. As a result, the TSSAA found that Coach

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19 This Note suggests implementing an NCAA recruiting ban that is similar to the TSSAA’s Anti-Recruiting Rule, which prevents coaches from asserting undue pressure on a student and his or her parents or guardians to retain the student’s services for athletic purposes. *Brentwood*, 13 F. Supp. 2d at 673. This hypothetical “NCAA recruiting ban,” referred to throughout this Note, would prevent a coach from influencing a student-athlete to attend his school for the purposes of athletics. It would not prevent unilateral activity by the student-athlete, such as sending video of themselves to coaches, in order to bolster his chance for admission. See infra Part IV.

20 *Brentwood*, 13 F. Supp. 2d at 673.

21 Id.

22 Id.


24 *Brentwood*, 13 F. Supp. 2d at 673.

25 Id. at 676. Coach Flatt also called the students to tell them that “they should not participate in spring practice if it conflicted with activities at their respective middle schools.” Id.

26 Id.

Flatt’s letter violated its Anti-Recruiting Rule and imposed sanctions on Brentwood Academy. 28

On December 12, 1997, Brentwood Academy filed an action against the TSSAA in the U.S. District Court, Middle District of Tennessee, to contest the penalties. 29 Brentwood brought suit under § 1983, 30 alleging that the Anti-Recruiting Rule violated its First Amendment right to freedom of speech. 31 After concluding that the TSSAA was a state actor subject to suit under § 1983, the district court agreed with Brentwood, holding that the TSSAA’s Anti-Recruiting Rule violated the First Amendment. 32 The Sixth Circuit reversed, holding that the TSSAA was not a state actor and thus not subject to § 1983 liability. 33 On appeal, the Supreme Court reversed the circuit court on the threshold issue, concluding that the TSSAA was indeed a state actor, and remanded the case back to the Sixth Circuit for adjudication on the merits of Brentwood’s claims. 34 After both the district court and court of appeals held that the Anti-Recruiting Rule violated Brentwood’s free speech rights, 35 the Supreme Court granted certiorari to decide Brentwood’s First Amendment claim. 36 In addressing the constitutionality of the Anti-Recruiting Rule, the Court applied a line of

28 Brentwood, 13 F. Supp. 2d at 676-77. The TSSAA also found that Brentwood coaches had violated the Anti-Recruiting Rule for: (1) admitting student-athletes to athletic contests free of charge, and (2) conducting impermissible off-season practice with Brentwood student-athletes. Id. However, for the purposes of Brentwood’s First Amendment claim, the only violation at issue was the one regarding Coach Flatt’s letter.


31 Brentwood, 13 F. Supp. 2d at 678. Brentwood also alleged (1) that the TSSAA violated its Fourteenth Amendment substantive and procedural due process rights, (2) that the TSSAA violated federal antitrust laws, (3) equitable estoppel, and (4) unfair, unreasonable, arbitrary, and oppressive action in violation of state law. Id. at 672.

32 Id. at 694.


cases traditionally reserved for determining the free speech rights of public employees.37

B. Speech Rights in Public Employment

While the First Amendment protects the right to engage in free speech without government interference,38 it is well settled that this right is not absolute.39 Throughout its history, one area in which the Court has consistently allowed government interference with free speech rights has been public employment.40 Before the 1950s, courts gave public employees no First Amendment protection, allowing public employers to restrict their employees’ speech without repercussions.41 During this time, most courts adopted the view of Oliver Wendell Holmes, who concluded in McAuliffe v. Mayor of New Bedford42 that, because there was no constitutional right to public employment, there was no right to freedom of speech in public employment.43

By the mid-twentieth century, however, courts’ refusal to recognize public employee speech rights began to erode. Beginning in the 1950s the Supreme Court began recognizing that some limited First Amendment protection extended to public employment.44 Eventually, in 1968, the Court finally rejected the reasoning in McAuliffe, officially recognizing in Pickering v. Board of Education that public employees have certain free speech rights in the workplace.45

37 Id. at 2495. The line of cases that sets the standard for the restriction of speech in public employment begins with Pickering v. Board of Education, 391 U.S. 563 (1968). See discussion infra Part II.B. Prior to the decision in Brentwood II, Pickering applied only to the speech rights of government employees and contractors, not to speech by an employee at a private school that is a member of a private athletic association. Brentwood II, 127 S. Ct. at 2499 (Thomas, J., concurring).
38 U.S. CONST. amend I. Although the Constitution only protects the right of free speech from congressional interference, the Supreme Court has since held that the right to freedom of speech is a fundamental right protected against the states by the Due Process Clause of the Fourteenth Amendment. Gitlow v. New York, 268 U.S. 652, 666 (1925); Near v. Minnesota ex rel. Olsen, 283 U.S. 697, 707 (1931).
39 Chapinsky v. New Hampshire, 315 U.S. 568, 571-72 (1942) (“[I]t is well understood that the right of free speech is not absolute at all times and under all circumstances.”).
42 29 N.E. 517 (Mass. 1892).
43 Id. at 518. Holmes’ oft-cited opinion was that “The petitioner may have a constitutional right to talk politics, but he has no constitutional right to be a policeman.” Id. at 517.
44 See Lara Geer Farley, Comment, A Matter of Public Concern: “Official Duties” of Employment Gag Public Employee Free Speech Rights, 46 WASHBURN L.J. 603, 610 (2007) (citing Wieman v. Updegraff, 344 U.S. 183 (1952)). In Wieman, the Court found unconstitutional an Oklahoma statute that required all public employees to take a loyalty oath, holding that “constitutional protection does extend to the public servant whose exclusion pursuant to a statute is patently arbitrary or discriminatory.” Wieman, 344 U.S. at 186, 192.
45 See Wells, supra note 41, at 946.
The decision in *Pickering* has remained the law regarding public employee speech rights for the past forty years without much alteration. However, the Court has added two important threshold requirements. These requirements are set forth in *Connick v. Myers* and *Garcetti v. Ceballos*. Together, these three cases have established a three-pronged test that is used when determining the free speech rights of public employees.

1. *Pickering v. Board of Education*

   The landmark public employee speech case began when Marvin Pickering, a high school teacher in Will County, Illinois, wrote a letter to a local newspaper criticizing the local school board. The letter attacked the school’s handling of a bond proposal as well as the subsequent allocation of the financial resources it received from the proposal. In response to this letter, the school board dismissed Pickering. After his dismissal, Pickering challenged the board’s decision, alleging that his speech was protected by the First and Fourteenth Amendments. The Supreme Court ruled in favor of Pickering and, in the process, established a balancing test that delineated the contours of public employee free speech rights.

   In setting forth the standard for protecting public employee speech, the Court acknowledged the unique situation public employment presented. Specifically, it noted that although a public employee has no constitutional right to employment, once employed, a public employee may not be subject to arbitrary and unreasonable conditions of employment. Thus, the problem before the Court was determining the extent of a public employee’s free speech rights in the context of these conflicting tenets. As its solution, the Court adopted a balancing test that weighs the interests of a public employee, “as a citizen, in commenting upon matters of public concern against the interest of the State, as an employer, in promoting the efficiency of its public services . . .” Applying this test, the Court concluded that since Pickering’s statements neither interfered with his duties nor disrupted the regular operation of
the schools, the school had no interest in limiting Pickering’s speech. Consequently, its dismissal of Pickering violated his First Amendment rights.\(^{58}\)

2. Connick v. Myers

After the Court’s decision in *Pickering*, the public employee speech doctrine remained mostly unchanged until the Court added a threshold requirement in 1983.\(^{59}\) In *Connick v. Myers*, Sheila Myers, an Assistant District Attorney in New Orleans, was fired after she engaged in speech at her workplace.\(^{60}\) Myers, who was upset that she was being transferred to another criminal court, prepared and distributed a questionnaire that was meant to solicit the views of fifteen assistant district attorneys on various issues, including “the office transfer policy, office morale, the need for a grievance committee, the level of confidence in supervisors, and whether employees felt pressured to work in political campaigns.”\(^{61}\) After one assistant district attorney reported that Myers was creating a “mini-insurrection” within the office, her supervisor, Harry Connick, fired her for her refusal to accept the transfer.\(^{62}\)

Myers challenged her termination, alleging that it was a violation of her free speech rights as set forth in *Pickering*.\(^{63}\) However, before addressing whether Myers’ discharge was protected under the *Pickering* balancing test, the Court held that it must first determine whether Myers’ questionnaire constituted “speech on a matter of public concern.”\(^{64}\) In so holding, the Court established a threshold requirement to the public employee speech doctrine.

The Court reasoned that this threshold requirement is necessary because an employer should be granted broad discretion to manage its employees when their speech does not relate to the concerns of the community.\(^{65}\) According to the Court, “when a public employee speaks not as a citizen upon matters of public concern, but instead as an employee upon matters only of personal interest,” the employer, except under the most unusual circumstances, is entitled to take action against the employee.\(^{66}\) Whether speech “addresses a matter of public concern” is

\(^{57}\) Id. at 572-73.
\(^{58}\) Id. at 574-75.
\(^{61}\) Id.
\(^{62}\) Id. at 141.
\(^{63}\) Id.
\(^{64}\) Id. at 146.
\(^{65}\) Id.
\(^{66}\) Id. at 147.
determined by the “content, form, and context of a given statement, as revealed by the whole record.”

Looking at the content, form, and context of Myers’ questionnaire, the Court concluded that only one of the questions survived this threshold test: whether assistant district attorneys “ever feel pressured to work in political campaigns on behalf of office supported candidates.” According to the Court, the questions pertaining to the office transfer policy, office morale, the need for a grievance committee, and the level of confidence in supervisors were “mere extensions” of Myers’ personal grievance. Ultimately, the Court found that these questions were aimed to give Myers ammunition against her superiors, and not to evaluate the performance of a public office. Such questions convey nothing except that one employee is upset with the status quo.

The Court did apply the Pickering balancing test to the one question that did address a matter of public concern—whether assistant district attorneys “ever feel pressured to work in political campaigns on behalf of office supported candidates.” Nonetheless, the Court found the speech was unprotected, and Myers’ discharge was not prevented by the First Amendment, because it touched upon a matter of public concern in only the most limited sense and her supervisor could reasonably believe the speech would disrupt the workplace.

3. Garcetti v. Ceballos

The Connick and Pickering decisions established a two-tiered test to public employee speech cases. The Court first asks whether “the employee spoke as a citizen on a matter of public concern.” If the answer is yes, the Court then asks whether the employer had an “adequate justification for treating the employee differently from any other member of the general public.” In Garcetti v. Ceballos, the Court established a second threshold requirement for public employee speech cases.

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67 Id. at 147-48.
68 Id. at 149 (quoting questionnaire created by New Orleans Assistant District Attorney) (internal quotation marks omitted).
69 Id. at 148.
70 Id.
71 Id.
72 Id. at 149 (quoting questionnaire created by New Orleans Assistant District Attorney) (internal quotation marks omitted).
73 Id. at 154.
75 Id. (citing Pickering v. Bd. of Educ., 391 U.S. 563, 568 (1968)).
76 Id. (citing Pickering v. Bd. of Educ., 391 U.S. 563, 568 (1968)). To answer this question, the Court used the Pickering balancing test.
77 See Ralph D. Mawdsley & Allan Osborne, The Supreme Court Provides New Direction for Employee Free Speech in Garcetti v. Ceballos, 214 ED. LAW REP. 457, 459 (“[T]he Supreme Court has injected a new interpretive clarification as to when employee’s speech is
Richard Ceballos was a deputy district attorney for the Los Angeles County District Attorney’s Office. In 2000, a defense attorney asked Ceballos to review an affidavit used in a search warrant. Ceballos reviewed the affidavit and found many inaccuracies. After communicating these inaccuracies to his supervisors, Ceballos claimed he was subjected to numerous retaliatory employment actions, for which he brought suit.

In denying Ceballos’ claim, the Court stressed that the “controlling factor” in the case was the fact that Ceballos’ expression was made pursuant to his official duties as a calendar deputy and not as a citizen. According to the Court, when public employees speak “pursuant to their official duties, [they] are not speaking as citizens for First Amendment purposes,” and thus are not protected by the Constitution. Because Ceballos was speaking pursuant to his official duties, the Court dismissed Ceballos’ claim without determining whether his speech addressed a matter of public concern or satisfied the Pickering balancing test. Consequently, the Court established a third prong in the test for determining whether a public employee’s speech is constitutionally protected.

Despite the addition of the two threshold requirements, the public employee speech doctrine has not been changed substantially. Moreover, all indications showed that this doctrine was limited to protecting the speech of public employees or independent contractors. Nevertheless, in Brentwood II, the Court extended the Pickering doctrine beyond public employment and independent contracting to determine whether a high school athletic association could limit the recruiting speech of its private member institutions.

C. The Decision in Brentwood II

The issue before the Court in Brentwood II was whether the TSSAA’s Anti-Recruiting Rule, which essentially prohibits the athletic recruitment of middle school student-athletes, violated Brentwood Academy’s free speech rights. In a unanimous decision, the Supreme
Court reversed the Sixth Circuit, and held that the Anti-Recruiting Rule did not violate the First Amendment.86

Eight members of the Court agreed with Justice Stevens’ application of the *Pickering* line of cases to uphold the Anti-Recruiting Rule.87 Although there was little support for the extension of the *Pickering* doctrine to a situation involving a private school in a private athletic association,88 the Court found that applying *Pickering* was appropriate here because Brentwood Academy voluntarily joined the TSSAA.89 The Court found this situation similar to the public employment context, noting that the TSSAA’s interest in enforcing its rules can sometimes warrant curtailing the speech of a member institution,90 “[j]ust as the government’s interest in running an effective workplace can in some circumstances outweigh employee speech rights . . . .”91

Applying the three-part *Pickering* doctrine, the Court did not analyze the two threshold questions, choosing instead to assume that Coach Flatt was speaking as a citizen about a matter of public concern.92 Rather, the Court focused solely on the third prong: the *Pickering* balancing test. Rephrasing the balancing test in terms of the facts of the case, the Court stated that the TSSAA’s Anti-Recruiting Rule would be upheld only if it was “necessary to managing an efficient and effective state-sponsored high school athletic league.”93

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86 Id. at 2493 (majority opinion).
87 Id. at 2495-96. It should be noted that, in addition to finding the Anti-Recruiting Rule constitutional under *Pickering*, Justice Stevens found an alternative justification for upholding the Anti-Recruiting Rule. Id. at 2495. In Part II.A of his opinion, Justice Stevens held the TSSAA’s Anti-Recruiting Rule constitutional under *Ohralik v. Ohio State Bar Assn.*, 436 U.S. 447 (1978)—which held that direct solicitation by a lawyer that exerts undue pressure on clients could be prohibited—because recruiting, which exerts undue influence on a child, could prevent informed and reliable decision-making. Id. However, only three other Justices agreed with Stevens; a majority of Justices refused to extend *Ohralik* beyond the parameters of that case—i.e., the attorney-client relationship. Id. at 2498 (Kennedy, J., concurring). Because this additional part of Stevens’ analysis was rejected by a majority of the Court, this Note will not address it.
89 *Brentwood II*, 127 S. Ct. at 2495-96. Justice Kennedy’s concurring opinion exemplifies the importance that Brentwood’s voluntary participation in the TSSAA had in the Court’s decision. According to Kennedy, absent Brentwood’s consensual participation in the TSSAA, the speech by Coach Flatt would be entitled to First Amendment protection. Id. at 2498-99 (Kennedy, J., concurring).
90 Id. at 2495 (majority opinion) (citing Brentwood Acad. v. Tenn. Secondary Sch. Athletic Ass’n, 531 U.S. 288, 291 (2001); Grove City Coll. v. Bell, 465 U.S. 555, 575 (1984)).
92 Id.
93 Id.
Analyzing the purpose of the Anti-Recruiting Rule, the Court found that it was indeed necessary for the TSSAA to operate efficiently and effectively. The TSSAA established the Rule because athletic recruiting of middle school students could “lead to exploitation [of student-athletes], distort competition between high school teams, and foster an environment in which athletics are [sic] prized more highly than academics.”

According to the Court, any one of these harms would inhibit a high school athletic association’s ability to operate “efficiently and effectively.” Therefore, since the Anti-Recruiting Rule discouraged the conduct—recruiting—that might lead to these harms, the Court held that the Rule did not violate Brentwood’s free speech rights.

III. IMPLICATIONS FOR NCAA RECRUITING

In Brentwood II, the Court granted broad discretion to a high school athletic association to limit the recruitment of student-athletes. However, given the reasoning of the decision, Brentwood II could potentially have a drastic effect on college recruiting. Although it governs college, and not high school, athletics, the NCAA is very similar to the TSSAA in its composition, purpose, and values. Moreover, the difference between the NCAA and the TSSAA is minimal in terms of athletic recruiting. Thus, the likely effect of the Court’s decision in

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94 Id.
95 Id. at 2495-96 (citing Paris Adult Theatre I v. Slaton, 413 U.S. 49, 60 (1973)).
96 Id. at 2496 (quoting Garcetti v. Ceballos, 126 S. Ct. 1951, 1958 (2006)).
97 Id.
98 Id.
99 See discussion supra Part II (TSSAA) and discussion infra Part III.A (NCAA). The glaring difference between the two is that the NCAA governs the athletics of colleges and universities throughout the country, as opposed to the athletics of high schools within a state. For the Supreme Court, this distinction has proved crucial in the context of state action. In Brentwood I, the Court held that the TSSAA was a state actor that was subject to suit under § 1983. Brentwood Acad. v. Tenn. Secondary Sch. Athletic Ass’n (Brentwood I), 531 U.S. 288, 305 (2001). Contrarily, the Court has held that the NCAA is not a state actor, and thus cannot be sued under § 1983. NCAA v. Tarkanian, 488 U.S. 179, 199 (1988). Accordingly, the NCAA could restrict all speech, making the issue as to whether the Pickering doctrine applies moot.

However, since the decision in Brentwood I, some commentators have argued that under the Court’s reasoning in Brentwood I, the NCAA may now be considered a state actor. See, e.g., Brentwood II, 127 S. Ct. 2489, 2499 (2007) (Thomas, J., concurring) (stating that the application of the majority’s entwinement test could easily change the result of Tarkanian); James Potter, Note, The NCAA as State Actor: Tarkanian, Brentwood, and Due Process, 155 U. Pa. L. Rev. 1269, 1303 (2007); Robin Petronella, Comment, A Comment on the Supreme Court’s Machiavellian Approach to Government Action and the Implications of its Recent Decision in Brentwood Academy v. Tennessee Secondary School Athletic Association, 31 Stetson L. Rev. 1057, 1082-83 (2002). Furthermore, even if the NCAA is not a state actor, its rules can be subjected to § 1983 liability if they are adopted by a college or university that is a state actor. See Howard M. Wasserman, Fans, Free Expression, and the Wide World of Sports, 87 U. Pitt. L. Rev. 525, 540 (2006) (stating that NCAA rules become subject to the First Amendment when a public university adopts them as their own). Thus, an NCAA recruiting ban could easily come under the scope of the First Amendment and, as such, this Note will work under the assumption that an NCAA recruiting ban would be subject to § 1983 liability, knowing that, if the NCAA and its member institutions are not state actors, recruiting speech could still be restricted.
Brentwood II is that, like the TSSAA, the NCAA could, if it so desired, prohibit the recruitment of student-athletes.

A. Background of the NCAA

The NCAA is a private, voluntary organization that governs intercollegiate athletics among many of America’s colleges and universities. It is comprised of over 1,200 schools, which appoint volunteer representatives who introduce and vote on bylaws and establish programs to govern, promote, and further the purposes and goals of intercollegiate athletics.

The stated purpose of the NCAA is to “govern competition in a fair, safe, equitable and sportsmanlike manner, and to integrate intercollegiate athletics into higher education so that the educational experience of the student-athlete is paramount.” Among the NCAA’s core values are its commitment to:

- The collegiate model of athletics in which students participate as an avocation, balancing their academic, social and athletics experiences.
- The highest levels of integrity and sportsmanship.
- The supporting role that intercollegiate athletics plays in the higher education mission and in enhancing the sense of community and strengthening the identity of member institutions.

To abide by these core values, the NCAA has instituted regulations that govern its member institutions in areas such as amateurism, ethical conduct, eligibility, and recruiting. The NCAA recruiting rules clearly reflect the stated core values. According to The Principle Governing Recruiting, “Recruiting regulations shall . . . shield [prospective student athletes] from undue pressures that may interfere with the scholastic or athletics interests of the prospective student-athletes or their educational institutions.”

The composition, purpose, and values of the NCAA are undoubtedly similar to the TSSAA, an organization that is also composed of voluntary member institutions and strives to create a level
playing-field, protect student-athletes, and emphasize the primacy of education. Of course, the difference between the NCAA and the TSSAA is the fact that one governs intercollegiate athletics and one high school athletics. To some, this single difference is a critical one. Ultimately, however, it is unlikely that this difference is sufficient to circumscribe the Court’s reasoning in *Brentwood II* from being applied to the NCAA.

**B. High School vs. College: Why *Brentwood II*-Pickering Jurisprudence Should Apply to NCAA Recruiting**

Unquestionably, there are some universally recognized differences between high school and college athletics. Because of these differences, an argument can certainly be made that the recruiting practices of high schools and colleges should receive different constitutional protections. Indeed, there are situations in which courts have distinguished between colleges and high schools when affording First Amendment protection. For example, courts have limited the free speech rights of high school students much more than those of college students in certain circumstances.

The basis for this distinction is the idea that “high school students are less mature and the missions of the respective institutions are different.”

Because the Court has previously distinguished between high schools and colleges when delineating free speech rights and because it applied *Pickering* without much direction, it is arguable that the TSSAA’s status as a high school athletic association was critical to the

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107 See *infra* notes 128, 129 and accompanying text.
109 See *supra* note 108.
110 See, e.g., Bd. of Regents of Univ. of Wisconsin System v. Southworth, 529 U.S. 217, 238 n.4 (2000) (Souter, J., concurring) (“[C]ases dealing with the right of teaching institutions to limit expressive freedom of students has been confined to high schools whose students and their schools’ relation to them are different . . . from their counterparts in college education.”) (internal citations omitted); see also Mark J. Fiore, Comment, *Trampling the “Marketplace of Ideas”: The Case Against Extending Hazelwood to College Campuses*, 150 U. Pa. L. Rev. 1915, 1948 (2002) (noting the “stark” distinction between the Court’s recognition of college and high school free expression). *But see* Kerry Brain Melear, *The First Amendment and Freedom of Press on the Public University Campus: An Analysis of Hosty v. Carter*, 216 Ed. Law Rep. 293 (2007) (noting that this distinction may begin to blur with the Seventh Circuit’s decision in *Hosty v. Carter*, 412 F.3d 731 (7th Cir. 2005), *cert. denied*, 126 S. Ct. 1330 (2006)). In addition, courts have also limited the rights of children to be exposed to harmful and inappropriate material. See *infra* notes 144-147 and accompanying text.
111 *Hosty*, 412 F.3d at 740 (Evans, J., dissenting). Other courts have agreed that college students are more mature than high school students. *See, e.g.*, Widmar v. Vincent, 454 U.S. 263, 274 n.14 (1981); Tilton v. Richardson, 403 U.S. 672, 686 (1970); Axson-Flynn v. Johnson, 356 F.3d 1277, 1289 (10th Cir. 2004).
Supreme Court’s decision in Brentwood II. Under this argument, because the TSSAA’s status was critical to the application of Pickering, the Court could decide that its application is improper as to the NCAA, a college athletic association.

Yet, while such a distinction is possible, it is unlikely the Court would make it in the context of recruiting for three reasons. First, the language and reasoning of the Brentwood II decision do not suggest a different analysis would apply for college athletic associations. Second, the Court has never distinguished between high schools and colleges when applying Pickering. Third, the differences between high school and college students and the missions of the respective institutions, both of which warrant granting different constitutional protections in other arenas, are largely irrelevant with regard to athletic recruiting.

1. Language and Reasoning of Brentwood II

Despite the fact that Brentwood II was a territory in which Pickering had yet to be applied—i.e., speech by a private school that is a member of a private athletic association—the Supreme Court had no problem extending the public employee speech doctrine to the TSSAA’s Anti-Recruiting Rule. There was little explanation underlying the Court’s decision to apply the Pickering doctrine to the instant circumstances. Rather, its application appeared to stem from the Court’s determination to limit Brentwood Academy’s speech rights because of its voluntary decision to join the TSSAA. So determined, the Court decided that the Pickering line should apply because an “athletic league’s interest in enforcing its rules” is similar to “the government’s interest in running an effective workplace.”

The Court’s failure to further explain exactly why it applied the Pickering doctrine in Brentwood II suggests that the doctrine’s application was based solely on Brentwood Academy’s voluntarily

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112 This extension may seem logical since the TSSAA is a state actor and § 1983 liability depends on whether the party is a state actor, not whether it is a public entity. See supra note 99. However, extending Pickering here ignores the fact that an enterprise’s public entity status is critical in the public employee speech context. See May v. Evansville-Vanderburgh Sch. Corp., 787 F.2d 1105, 1109 (7th Cir. 1986) ("[W]e acknowledge that cases such as Pickering and Connick give public employees greater rights of free speech than private employees have, but this is not just for the formalistic reason . . . that the First Amendment restricts only state action, and not private action. The behavior of public enterprises is a political question . . . and since the employees of public enterprises have insights and information about the conduct of the enterprise that the private citizen lacks, they have a distinctive contribution to make to political speech."). Arguably, the same contribution cannot be made by an employee of a private enterprise that is also a state actor.

113 Tenn. Secondary Sch. Athletic Ass'n v. Brentwood Acad. (Brentwood II), 127 S. Ct. 2489, 2496 (2007) (stating that “[h]igh school football is a game[, g]ames have rules,” and “[i]t is only fair that Brentwood follow them”) (internal quotations omitted); see also id. at 2498-99 (Kennedy, J., concurring) (stating that Justice Kennedy has “little difficulty” in finding that the recruiting rule does not violate the First Amendment based on Brentwood’s “consensual membership” in the TSSAA).

114 Id. at 2495 (majority opinion).
membership in the TSSAA. Because the NCAA is also an athletic league in which its members voluntarily participate, it seems logical to assume that the Court would apply the *Pickering* doctrine to the NCAA were an NCAA recruiting ban at issue.\(^{115}\)

Moreover, nothing in the language of the opinion suggests that the application of the *Pickering* doctrine was limited only to a high school athletic association. Notably, when choosing to apply *Pickering*, Justice Stevens referred to athletic leagues in general, and not just high school athletic leagues.\(^{116}\) This distinction is perhaps significant since, in other parts of his opinion, Justice Stevens specifically referenced a high school athletic league.\(^{117}\) Based on Justice Stevens’ usage of “athletic league” instead of “high school athletic league,” in addition to his emphasis on Brentwood Academy’s voluntary membership in the TSSAA, it seems as though an NCAA recruiting ban would be scrutinized under the *Pickering* doctrine.

2. Application of *Pickering* to High School and College Employees

Because the Court did not distinguish between high school and college athletic leagues in *Brentwood II*, it seems as though it would apply *Pickering* regardless of the differences between high schools and colleges. Moreover, the Supreme Court cases that have distinguished between high schools and colleges have dealt with the free speech rights of students, not teachers or employees.\(^{118}\) These cases would not be applicable to a rule prohibiting recruitment by colleges and universities, since such a rule seeks to limit the speech of the member institutions and its employees, not the speech of students.

The Supreme Court has never distinguished between high school teachers and college professors for the purpose of regulating employee speech—indeed, the *Pickering* doctrine has been applied at both education levels.\(^{119}\) Thus, the fact that the high school setting is markedly different from that of a college should not be of consequence in

\(^{115}\) The Court has previously held that voluntary participation permits speech restrictions even at the collegiate level. In *Grove City College v. Bell*, the Court held that, although Grove City College was a private entity, because it voluntarily participated in a federal financial assistance program, it was required to abide by Title IX as a condition of accepting the assistance. 465 U.S. 555, 575-76 (1984).

\(^{116}\) *Brentwood II*, 127 S. Ct. 2489, 2495 (2007) (“Just as the government’s interest in running an effective workplace can in some circumstances outweigh employee speech rights, so too can an athletic league’s interest in enforcing its rules sometimes warrant curtailing the speech of its voluntary participants.”) (internal citations omitted).

\(^{117}\) *Id.* at 2495-96.

\(^{118}\) See *supra* note 110 and accompanying text.

determining whether to apply the *Pickering* doctrine to restrict the speech of coaches.

Nevertheless, some courts have indicated that college professors are entitled to more First Amendment protection in order to ensure “academic freedom,”120 because universities are places of “free-wheeling inquiry” and not designed for the “selective conveyance of ideas” like high schools.121 Yet, regardless of whether or not college professors are entitled to more protection than high school teachers, the reason behind granting further protection, a teacher’s “right to choose classroom content and methodology,”122 does not apply in the context of athletic recruitment. In communicating with student-athletes about possibly attending their institution and playing for their school’s athletic team, college coaches are simply not choosing “classroom content and methodology.”123

3. Differences Between High School and College Students and Institutions

Even if the Court were inclined to find the difference between the TSSAA and the NCAA important here,124 *Pickering* should still apply. In certain areas, courts have distinguished between colleges and high schools in terms of determining free speech rights.125 Generally, there have been two reasons for such a distinction: (1) the different missions of high schools and colleges and (2) the difference in maturity between high school and college students.126 In the context of athletic recruiting, these distinctions are largely immaterial.

First, the claimed missions of the respective associations are not different in the context of athletics. Although some believe high school athletics serves an entirely different purpose than college athletics,127 the respective missions of both the NCAA and the TSSAA indicate otherwise. For example, the purpose of the TSSAA is “to stimulate and

120 See Garcetti v. Ceballos, 126 S. Ct. 1951, 1962 (2006) (recognizing that there is an argument that “expression related to academic scholarship or classroom instruction implicates additional constitutional interests” that are not fully protected by the public employee speech doctrine); Frederick Schauer, *Is There a Right to Academic Freedom?*, 77 U. COLO. L. REV. 907, 912 (2006) (discussing that lower courts allow substantially more restrictions against primary and secondary school teachers than college and university professors).
122 See Schauer, supra note 120, at 911.
123 Id.
124 The Court may, for example, find that the students have a right to access the information, putting at issue the students’ First Amendment rights.
125 See discussion supra Part III.B.
126 See supra note 111 and accompanying text.
127 See supra note 108 and accompanying text.
regulate the athletic relations of the secondary schools in Tennessee.”128 Similarly, the purpose of the NCAA is to “govern competition in a fair, safe, equitable, and sportsmanlike manner, and . . . integrate intercollegiate athletics into higher education . . . .”129 In passing its recruiting rule, the TSSAA asserted three interests: “(1) to keep high school athletics in their proper place subordinate to academics[,] . . . (2) to protect student athletes from exploitation[, and (3) to] foster[] a level playing field between the various member schools.”130 Similarly, the NCAA claims to promote “[t]he supporting role that intercollegiate athletics plays in the higher education mission,” and the “collegiate model of athletics in which students participate as an avocation . . . .”131 Moreover, the NCAA’s recruiting rules are set out “to shield [prospective student-athletes] from undue pressures,”132 and “to protect and enhance the physical and educational well-being of student-athletes.”133

Not only do the organizations’ stated missions and policies indicate that the NCAA and the TSSAA have similar purposes, but at least one court has agreed that high school and college athletics serve similar purposes. According to the Tenth Circuit, there is “no more than a difference in degree” between high school and college athletic programs.134 The court continued:

The fundamental positions are the same, the goals are the same, the stakes are pretty much the same. The same relationship also exists between the primary academic functions of the schools in each category and the athletic programs. The differences in degree or magnitude do not lead to a different result. In each, the athletic program is very important, as are the many other diverse functions, programs, and activities not within the academic core.135

Thus, while in terms of academics, the respective missions of high schools and colleges may be different,136 in terms of athletics, the missions of high schools and colleges are very similar: both seek to promote athletics as a part of the educational experience. Because of their similar missions, the Court need not distinguish between the TSSAA and the NCAA when determining the extent to which the NCAA can restrict its members’ speech.

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129 NCAA, Our Mission, supra note 8.
131 NCAA, Our Mission, supra note 8.
132 NCAA DIVISION I MANUAL, supra note 11, at art 2.11.
133 Id. at art. 2.2.
134 Colorado Seminary v. NCAA, 570 F.2d 320, 321 (10th Cir. 1978).
135 Id.
136 See Lasson, supra note 121, at 65 (Universities are places for “free-wheeling inquiry,” while high schools are designed for the “selective conveyance of ideas.”).
Second, a legal distinction between the maturity levels of high school and college student-athletes is inappropriate in the context of recruiting. Collegiate recruiting targets mostly high school students, not college students.\textsuperscript{137} Thus, the target audience for college recruiting is not college students, but rather, high school students. Consequently, in terms of college athletic recruitment, the distinction between high school and college students is inapplicable. Rather, the appropriate distinction is between high school students and middle school students, who are the subjects of high school recruiting. Hence, the critical question is whether the Court would be inclined to distinguish between high school and college recruiting on the ground that high school students are more mature than middle school students.

Scholars generally agree that middle school children are less mature than high school children.\textsuperscript{138} Interestingly though, it is not so clear whether courts have made this distinction.\textsuperscript{139} Specifically concerning free speech rights, some courts have been willing to grant greater rights to students as they progress through elementary school, middle school, and high school.\textsuperscript{140} However, in many instances the free speech rights of children—specifically what speech they have the right to be exposed to—have not been delineated along age-specific lines.\textsuperscript{141} Rather, the government and most courts tend to lump all children\textsuperscript{142} under the same rubric when determining the scope of their free speech rights.\textsuperscript{143} If the Court were inclined to do the same, it is unlikely to think they would distinguish between high school and middle school children when considering whether to apply the \textit{Pickering} doctrine to the NCAA.

Even if the Court were to distinguish between high school and middle school children, it does not necessarily follow that it would grant

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\item \textsuperscript{137} See Division I Men's Basketball Academic Enhancement Working Group, Key Research Findings Presented (Aug. 10, 2007), http://www1.ncaa.org/membership/governance/division_1/management_council/2007/October/05_Add_B_BAEWG.htm (reporting that thirteen percent of Division I student-athletes are transfer students).
\item \textsuperscript{138} See \textit{Group for the Advancement of Psychiatry, How Old is Old Enough?: The Ages of Rights and Responsibilities} 28-29 (1989) (noting that twelfth graders have a greater capacity for decision-making than seventh and eighth graders); \textit{Laura M. Purdy, In Their Best Interest?} 53-54 (1992) (noting that a child’s capacity to make rational decisions generally increases with age).
\item \textsuperscript{139} For example, in most states the age of majority for contracts is eighteen and no distinction is made amongst children under eighteen. \textit{See} \textit{Samuel Williston & Richard A. Lord, A Treatise on the Law of Contracts} § 9:3 (4th ed. 1993).
\item \textsuperscript{140} See, \textit{e.g.}, Muller v. Jefferson Lighthouse Sch., 98 F.3d 1530, 1538 (7th Cir. 1996) (noting that no decisions of the Courts of Appeals apply \textit{Tinker}-based speech rights to the elementary school setting, and that “[t]he ‘marketplace of ideas,’ an important theme in the high school student expression cases, is a less appropriate description of an elementary school, where children are just beginning to acquire the means of expression”).
\item \textsuperscript{142} The definition of “children” is unclear, but it at least encompasses all minors under the age of seventeen. \textit{See, e.g.}, Ginsberg v. New York, 390 U.S. 629, 637 (1968).
\item \textsuperscript{143} \textit{See, e.g.}, Bethel Sch. Dist. No. 403 v. Fraser, 478 U.S. 675, 684-86 (1986); \textit{Ginsberg}, 390 U.S. at 637; \textit{see also} Etzioni, \textit{supra} note 141, at 43-44.
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the NCAA less discretion to limit recruiting than the TSSAA. Notably, while the Court has held that high school students are entitled to free speech rights, it has also shown a willingness to limit these rights in order to protect high school aged children from being exposed to unsuitable speech. Accordingly, it has upheld certain government efforts to limit the amount of speech high school aged children can be exposed to both on and off school grounds. The basis for allowing such a restriction is that exposure to such material may be harmful or inappropriate for children, who may not be fully capable of making a reasonable decision.

The recruiting process similarly exposes high school aged children to sensitive materials, which are inappropriate for or harmful to them and negatively impact their decision-making. Thus, it is likely the Court would seek to protect the recruits, increasing the likelihood that it would apply the Pickering doctrine when contemplating the constitutionality of an NCAA recruiting ban.

Recruiting has been greatly affected by the rising importance of college athletics. Although colleges claim that sports are meant to serve an educational purpose, college athletics has come to serve more than just an educational purpose because athletic programs can produce a substantial amount of revenue for the NCAA, their conferences, and their schools. In addition to direct revenue, schools may accrue additional revenue through the

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144 Tinker v. Des Moines Indep. Cnty. Sch. Dist., 393 U.S. 503, 506, 511 (1969) (“It can hardly be argued that either students or teachers shed their constitutional rights to freedom of speech or expression at the schoolhouse gate.”).

145 In Ginsberg, the Court held that it is constitutionally permissible for a State to protect minors under seventeen from being exposed to potentially harmful materials—i.e., obscene sexual materials. 390 U.S. at 637. The basis of this holding was the State’s constitutional power to regulate the well-being of children. Id. at 639; see also Hazelwood Sch. Dist. v. Kuhlmeier, 484 U.S. 260, 272-73 (1988) (allowing a high school to prohibit its school newspaper from publishing what it deemed to be unsuitable material).

146 In Hazelwood School District v. Kuhlmeier, the Court allowed a high school to limit its students’ speech, in part, to ensure that “readers or listeners are not exposed to material that may be inappropriate for their level of maturity.” 484 U.S. at 271. The Court continued to hold that a school “must be able to take into account the emotional maturity of the intended audience in determining whether to disseminate student speech on potentially sensitive topics.” Id. at 272. In Ginsberg, the Court upheld the State law because it was rational for the State to conclude that exposure to sex material could be harmful to children under seventeen. 390 U.S. at 639-43.

147 See Bellotti v. Baird, 443 U.S. 622, 635 (1979) (stating that the Court’s rulings that the State could limit the freedom of children to make their own choices were based on “recognition that, during the formative years of childhood and adolescence, minors often lack the experience, perspective, and judgment to recognize and avoid choices that could be detrimental to them”).

148 See infra notes 159-175 and accompanying text.


benefits because of college athletics, including increased tuition and fees, increased exposure, and alumni donations. College athletics is also popular with the student body and public at large. Because the amount of revenue a college earns, the additional benefits it receives, and its popularity depend highly on the athletic success of the institution, coaches get paid good money and are under intense pressure to have a successful program.

While large, this figure includes only money earned from NCAA-television contracts, NCAA-conducted tournaments, and membership dues. It does not include money earned from bowl games, conference tournaments, ticket sales, and conference television contracts. See The NCAA and Conference Affiliation, in The Business of Sports, supra note 5, at 459, 464-66 [hereinafter Conference Affiliation]. Depending on the conference, the revenue that comes from these sources can be quite substantial—in excess of $100 million. For example, the Southeastern Athletic Conference (“SEC”) reported that its 2005-06 revenue was $116.1 million. SEC, 2005-2006 SEC Revenue Distribution, http://www.secsports.com/index.php?s=&url_channel_id=20&url_article_id=7426&change_well_id=2 (last visited Jan. 3, 2009) [hereinafter SEC Revenue Distribution]. The SEC is one of the “Big Six” conferences—the Atlantic Coast Conference (“ACC”), Big East, Big Ten, Big 12, Pac-10, and SEC—each of which accumulates similar annual revenues. See Conference Affiliation, supra, at 465-66.

Most of this money is distributed to the schools. NCAA Revised Budget, supra (Roughly $466 million of the NCAA’s operating revenue was distributed to the schools.). SEC Revenue Distribution, supra (noting that all of the $116.1 million was distributed to the twelve SEC schools).


A large part of the NCAA revenue is distributed to Division-I conferences according to their past success in the NCAA men’s basketball tournament. See Roger C. Noll, The Business of College Sports and the High Cost of Winning, in The Business of Sports, supra note 5, at 477, 482-85. Also, the money conferences receive for bowl games, television contracts, etc., depends highly on the success of their schools. See Keith Darcé, Boost from Bowls, SIGNONSANDIEGO.COM, Dec. 23, 2007, http://www.signonsandiego.com/news/business/20071223-9999-1b23bowls.html (reporting that the conferences whose schools played in the 2007 Poinsettia Bowl, a low-level bowl, received $750,000, the conferences whose schools played in the 2007 Holiday Bowl, considered a mid-level bowl, earned $2.5 million, and the conferences whose teams played in the BCS bowls, the most prestigious bowls, earned the most).

While many are skeptical that athletic success leads to increased alumni giving, see ZIMBALIST, supra note 150, at 196 (noting college sports’ popularity and importance in our culture).
Recruiting is vital to the success of the program. According to Bobby Bowden, the current coach of the Florida State University football team and the winningest coach in NCAA Division I-A football history, “National championships can be won in February by those who sign the best prospects.” Even low-profile sports rely heavily on recruiting. According to the former Harvard women’s swimming coach, Maura Costin Scalise, ninety-five percent of her success was due to recruiting.

Because of the importance of recruiting premiere prospects, coaches take recruiting very seriously. Many coaches are willing to use whatever means necessary to obtain recruits’ services. Examples of the measures taken by teams to lure recruits include exposing recruits to drugs, alcohol, and sex, providing recruits with money and jobs, altering grades and test scores, harassing recruits, and even misleading recruits. In addition, coaches consistently attempt to capitalize on the emotions and fantasies of the young and impressionable recruits, many of whom dream of being a college and professional sports star. By including recruits in such a corrupt process, coaches create an

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157 Bowden, supra note 155, at 57.
159 For an insightful and in-depth account of the intensity of the recruiting process for big-time college football, see FELDMAN, supra note 154; see also Bowden, supra note 155, at 57 (stating that the recruiting team at Florida State included “one full-time secretary, 10 assistant coaches and five graduate assistants”).
160 See ZIMBALIST, supra note 150, at 204 (“The incentive is clear: do all you can to win. Whatever it takes.”); Bowden, supra note 155, at 57 (discussing how the pressure to win leads some coaches to cheat); O’Neil, supra note 12 (discussing how coaches resort to ethically questionable tactics to lure recruits).
161 See supra notes 1-2 and accompanying text; see also MURRAY SPERBER, COLLEGE SPORTS INC.: THE ATHLETIC DEPARTMENT VS. THE UNIVERSITY 248 (1990) (discussing how colleges have attractive women “date” recruits for their weekend visit).
163 See id.
165 See, e.g., Ross v. Creighton Univ., 957 F.2d 410 (7th Cir. 1992). Ross was a promising high school basketball player recruited to play at Creighton University. Id. at 411. According to Ross, he was assured that he “would receive a meaningful education while at Creighton.” Id. (internal quotations omitted). However, it was evident that Ross was not capable of receiving such an education. See id. at 412; see infra note 176 and accompanying text; see also ROONEY, supra note 162, at 136 (noting that coaches sometimes “promis[e] one package of financial aid and deliver[] another” to recruits).
166 See SPERBER, supra note 161, at 249 (claiming that the recruiting process “offer[s] a fantasy world filled with free and almost unlimited pleasures”); Bowden, supra note 155 (stating that part of the recruiting process is “inflating the egos of 17-year-old athletes,” only to deflate them later); Staples, supra note 4 (quoting the director of football recruiting at Oregon University as saying that “[w]e had to find a way to make [recruits] larger than life”) (internal quotations omitted); College Recruiting: Are Student Athletes Being Protected: Hearing Before the Subcomm. On
environment that is harmful and inappropriate for high school aged children. This is evidenced by the inability of recruits to make a well-reasoned decision amidst this environment.

While high school students may be more capable of making a reasonable decision than eighth graders, some scholars suggest that even twelfth graders’ decision-making ability is hampered by their yet-uncontrolled emotions. According to Anna Freud, the decision-making capabilities of adolescents are negatively impacted by their emotions and fantasies more so than adults, lessening the likelihood that an adolescent will make a well-reasoned decision. Perhaps, by catering to the fantasies and emotions of student-athletes, the recruiting process inhibits the ability of recruits to make a reasonable decision as to where to attend college. Specific evidence supports the idea that many prospective student-athletes make a less than well-reasoned decision when determining which college to attend. For example, recruits have chosen schools based solely on their dreams of playing professional sports, fake books and magazine covers that played on these dreams, their weariness with the recruiting process, and even what number they can wear. Moreover, when committing to a school, recruits sign letters of intent that are borderline unconscionable.

Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce, 108th Cong. 20-25 (2004) (testimony of Don McPherson, Executive Director, Sports Leadership Institute, Adelphi University) [hereinafter McPherson Testimony]. According to Don McPherson, the Executive Director of the Sports Leadership Institute at Adelphi University, for many elite student-athletes, “higher education is not in their plans” and they have little interest in being in college. Rather, college sports is a “stepping stone” to the next level of play: professional sports. See NARIA, Estimated Probability of Competing in Athletics Beyond the Interscholastic High School Level, http://www.ncaa.org/research/prob_of_competing/ (last visited Jan. 4, 2009).

See Staples, supra note 4 (noting that several recruits chose to attend the University of Oregon because of fake comic books, in which the recruits led the team to a national championship, and fake Sports Illustrated covers, in which a recruit was holding the Heisman Trophy).

See Feldman, supra note 154, at 304. Feldman recounted the press conference of Robert Elliott, a recruit who decided to attend Mississippi State University because
The fact that recruits engage in such suspect practices when deciding where to go to college indicates that the recruiting process may be inappropriate for many recruits, or, at worst, even harmful to them.\(^{176}\) Since the Supreme Court has shown a predisposition to protect high school aged children from being exposed to inappropriate or harmful materials, it is reasonable to believe that the Court would not afford high school student-athletes greater access to recruiting speech than it gave to middle school student-athletes in *Brentwood II*.\(^{177}\)

4. Summary

Although the NCAA and the TSSAA govern student-athletes of different ages, there are a variety of reasons why the Supreme Court would not distinguish between the two in the context of recruiting. Specifically, the language and reasoning of the *Brentwood II* decision and prior Supreme Court jurisprudence suggest such a difference is immaterial. Consequently, it seems that the same legal standards the Supreme Court used to evaluate the TSSAA’s Anti-Recruiting Rule would govern an NCAA recruiting ban. Under these standards, the NCAA would have the authority to impose restrictions so long as those restrictions do not contravene the *Pickering* doctrine. Accordingly, an NCAA recruiting ban would only be upheld if it would survive scrutiny under the *Pickering* doctrine.

Coach Croom told me I could come in and wear No. 2. It was really where I could go and feel comfortable and rock my No. 2. I’ve been wearing it since Pee Wee, and that’s the only number I can rock. If I put something else on, it won’t look right on me. I figure, you’ve got to look good to play good. I can’t wear those double-digit numbers.

*Id.*

\(^{175}\) See Seth Davis, *To Sign or Not to Sign*, SL.COM, Nov. 14, 2008, http://sportsillustrated.cnn.com/2007/writers/seth_davis/11/13/national.letter/index.html. Letters of Intent are forms signed by recruits which bind the recruits to a school. *Id.* They are voluntary, overly restrictive, non-negotiable, and very difficult to rescind. *Id.* While recruits get some benefit from them, according to Davis they are unfair and even “farcical.” *Id.* According to Pete Rush, a lawyer quoted in the piece, they may be unconscionable. *Id.* Nonetheless, every year over “30,000 [student-]athletes sign national letters of intent” because, according to Davis, “that’s what everybody does.” *Id.*

\(^{176}\) See Ross v. Creighton Univ., 957 F.2d 410, 412 (7th Cir. 1992). Ross enrolled at Creighton from 1978 to 1982 but did not receive nearly enough credits to graduate. *Id.* After he left Creighton, Ross enrolled “for a year of remedial education at the Westside Preparatory School[,] . . . attend[ing] classes with grade school children.” *Id.* He later enrolled at Roosevelt University. *Id.* After dropping out of Roosevelt, Ross had a “‘major depressive episode,’ during which he barricaded himself in a Chicago motel room and threw furniture out the window” in an expression of anger against “Creighton employees who had wronged him.” *Id.*

\(^{177}\) Importantly, this Note is not suggesting that *Ginsberg* or *Hazelwood* would be the basis for limiting recruiting speech. Rather, it is suggesting that, because the Court has previously protected high school students from inappropriate and harmful speech, it would be less inclined to distinguish between high school and college recruiting when determining whether to apply the *Pickering* doctrine to a hypothetical NCAA recruiting ban.
C. Why an NCAA Recruiting Ban Would Survive Scrutiny Under Pickering

If the Court were inclined to subject an NCAA recruiting ban to the Pickering doctrine, the next inquiry would be whether such a ban would be constitutional under the three-pronged test. As indicated above, the first part of this test asks whether the employee is speaking as a private citizen.\(^{178}\) If the employee is speaking as a private citizen, a court must then determine whether the employee is speaking on a matter of public concern.\(^{179}\) Finally, if the employee meets these threshold requirements, a court must apply a balancing test to determine whether the employee’s interests as a citizen in commenting upon matters of public concern outweigh the employer’s interest in promoting the efficiency of its operation.\(^{180}\) Put more succinctly, the three-pronged Pickering doctrine holds that, when employees are speaking as citizens about matters of public concern, their speech can be restricted only when necessary for their employers to operate efficiently and effectively.\(^{181}\)

1. Employee Speaking as a Citizen

Although in Brentwood II the Court did not address this threshold issue, assuming instead that Coach Flatt was speaking as a citizen,\(^{182}\) it is likely that a college coach’s recruiting speech would not survive scrutiny under Garcetti.\(^{183}\) In Garcetti, the Supreme Court concluded that “when public employees make statements pursuant to their official duties, the employees are not speaking as citizens for First Amendment purposes . . . .”\(^{184}\) Although it did state that a formal job description is not dispositive of an employee’s official duties,\(^{185}\) the Court did not provide a framework for defining the scope of an employee’s official duties, leaving the task to the lower courts.\(^{186}\) As a result, lower courts have relied on the rationale of Garcetti\(^ {187}\) as well as their own

\(^{178}\) See discussion supra Part II.B.3.

\(^{179}\) See discussion supra Part II.B.2.

\(^{180}\) See discussion supra Part II.B.1.


\(^{182}\) Id.

\(^{183}\) Notably, in Garcetti, the Court declined to decide whether the threshold requirement would apply to speech involving “academic scholarship or classroom instruction.” Garcetti v. Ceballos, 126 S. Ct. 1951, 1962 (2006). However, since recruiting involves neither “academic scholarship” nor “classroom instruction,” there is no reason to think the Court would not extend Garcetti to an NCAA recruiting ban.

\(^{184}\) Id. at 1960.

\(^{185}\) Id. at 1961-62. The Court’s fear was that an employer could overly restrict an employee’s rights by creating broad job descriptions. Id.

\(^{186}\) Id. at 1961.

\(^{187}\) See, e.g., Williams v. Dallas Indep. Sch. Dist., 480 F.3d 689, 692 (5th Cir. 2007) (“Garcetti did not explicate what it meant to speak ‘pursuant to’ one’s ‘official duties’ . . . . Thus, in order to determine whether Williams wrote these memoranda pursuant to his responsibilities as
definitions of “official duties” in determining whether speech could be restricted. Under either analysis, recruiting speech does not pass this threshold test.

First, the rationale behind Garcetti indicates that recruiting speech is spoken pursuant to a college coach’s official duties. In Garcetti, the Supreme Court stipulated that an employer can restrict speech that “owes its existence to a public employee’s professional responsibilities.” Accordingly, it distinguished Garcetti, in which Richard Ceballos, because of his duties as a deputy district attorney, notified his superiors about misstatements made in affidavits, from Pickering, in which Pickering challenged a school’s allocation of financial resources. The Court explained that Pickering’s speech “had no official significance and bore similarities to letters submitted by numerous citizens every day.” Certainly, recruiting speech is much closer to Ceballos’ speech than Pickering’s. Unlike the speech in Pickering, recruiting speech is promulgated only as a requirement of the position and bears little resemblance to other citizens’ communications. Clearly then, recruiting speech “owes its existence” to a college coach’s responsibility to recruit student-athletes.

Second, recruiting also falls under the “official duties” of a college coach, as defined by lower courts. Lower courts have commonly defined “official duties” as activities performed by an employee that are required as part of his or her job. Recruiting speech is certainly a required part of a college coach’s job. Most, if not all, college coaches’ official job descriptions include recruiting prospective student-athletes. This requirement is not hollow; given the importance of recruiting, it is unquestionable that recruiting is a required part of the job.

Athletic Director, we must also look to the facts and rationale underlying Garcetti.”); Jackson v. Jimino, 506 F. Supp. 2d 105, 109-11 (N.D.N.Y. 2007) (rejecting the notion that Garcetti created a bright-line rule, choosing instead to apply a fact-based inquiry when determining whether an employee speaks as a citizen).

See infra note 192 and accompanying text.

Garcetti, 126 S. Ct. at 1960.

Id.

Id.

See, e.g., Williams, 480 F.3d at 693 (holding that job-required speech is unprotected because it falls within a public employee’s official duties); Pittman v. Cuyahoga Valley Career Ctr., 451 F. Supp. 2d 905, 929 (N.D. Ohio 2006) (same).


See supra notes 157-159 and accompanying text. As further evidence of the importance of recruiting, see Shulman & Bowen, supra note 170, at 259, in which the authors discuss just how prevalent recruiting is. According to Shulman and Bowen, almost twenty years ago, about ninety percent of the men who played basketball, football, and hockey, and two-thirds of men playing other sports, reported that they were recruited. Id. Moreover, the authors reported that when
Since recruiting is an “official duty” of a college coach and recruiting speech “owes its existence” to this duty, a challenge to an NCAA recruiting ban would not survive scrutiny under Garcetti.\textsuperscript{195} Failure to satisfy this threshold requirement would end the inquiry immediately and result in the upholding of an NCAA recruiting ban as a valid restriction of its members’ speech.

2. Speech as a Matter of Public Concern

   Even if a court does conclude that a coach recruiting prospective student-athletes speaks as a private citizen, that speech must address a matter of public concern in order to survive the second threshold inquiry.\textsuperscript{196} As the Supreme Court stated in Connick v. Myers, whether an employee speaks on a matter of public concern is determined by the “content, form, and context” of the speech.\textsuperscript{197} In Myers, the Court concluded that Myers’ questionnaire to fellow assistant district attorneys did not constitute a matter of public concern because it was a “mere extension[...]” of a personal grievance with the employer.\textsuperscript{198}

   Since Connick, the contours of the public concern test have not been distinctly defined;\textsuperscript{199} however, subsequent cases have provided some guidance. For example, in Rankin v. McPherson,\textsuperscript{200} the Court held that private remarks made to a co-worker expressing support for an assassination attempt on the President constituted a matter of public concern.\textsuperscript{201} Through its holding, the Court emphasized that speech need not be made public, and can be either inappropriate or controversial, to

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\textsuperscript{195} Although the applicable relationship here might be the NCAA-member institution arrangement, an argument that the Court would look at the member institution’s official duties is misguided given the Court’s language in Brentwood II. By assuming that Coach Flatt was speaking as a citizen on a matter of public concern, and not Brentwood Academy, the Court seemed to indicate that the duties of the coach were at issue in a Garcetti inquiry, not the school. Tenn. Secondary Sch. Athletic Ass’n v. Brentwood Acad. (Brentwood II), 127 S. Ct. 2489, 2495 (2007).

\textsuperscript{196} See discussion supra Part II.B.2.


\textsuperscript{198} Id. at 148.

\textsuperscript{199} City of San Diego v. Roe, 543 U.S. 77, 83 (2004) (per curiam) (“Although the boundaries of the public concern test are not well defined, Connick provides some guidance.”).

\textsuperscript{200} 483 U.S. 378 (1987).

\textsuperscript{201} Id. at 386-87. While engaged in a private conversation about an assassination attempt on the President, McPherson told a co-worker “if they go for him again, I hope they get him.” Id. at 381. The comment was overheard by another employee and reported to the employer, who fired McPherson. Id. at 381-82.
constitute a matter of public concern. In *City of San Diego v. Roe*, the Court held that a police officer’s sexually explicit videos did not constitute a matter of public concern. In its holding, the Court attempted to clarify the definition of what constitutes public concern, stating that “public concern is something that is a subject of legitimate news interest; that is, a subject of general interest and of value and concern to the public at the time of publication.”

Despite this guidance, lower federal courts have found the public concern test to be imprecise. As a result, courts have taken different approaches in determining what constitutes a matter of public concern. Some courts have focused on whether the speech was made as an employee or as a private citizen. Other courts have focused on whether the content of the speech was of private interest or of concern to the community as a whole. This disagreement over how to define “a matter of public concern” only demonstrates that the public concern test is a fact-based inquiry, the outcome of which depends on the content, form, and context of the particular speech.

The content, form, and context of recruiting speech indicate that it would not constitute speech on a matter of public concern. Recruiting speech entails one-on-one communications between coaches and players that focus on student-athletes’ ambitions to attend and compete at the respective institution. This type of speech concerns an individual

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202 *Id.* at 386-87.
203 *Roe*, 543 U.S. at 79, 84.
204 *Id.* at 83-84.
206 See *Sparr v. Ward*, 306 F.3d 589, 594 (8th Cir. 2002); *Gillum v. City of Kerrville*, 3 F.3d 117, 120-21 (5th Cir. 1993); see also Charles W. Rhodes, *Public Employee Speech Rights Fall Prey to an Emerging Doctrinal Formalism*, 15 WM. & MARY BILL RTS. J. 1173, 1181 (2007). Of course, with the Court’s decision in *Garrett*, it would seem that this issue would be addressed prior to asking whether the speech touches on a matter of public concern.
208 See Campbell v. Galloway, 483 F.3d 258, 271 (4th Cir. 2007) (“Our fact-specific resolution of individual cases has done little to sharpen the line between cases where the complaints about discrimination are matters of public concern and those where such complaints are not matters of public concern.”); Stephen Allred, *From Connick to Confusion: The Struggle to Define Speech on Matters of Public Concern*, 64 INDIAN L.J. 43, 75 (1988) (suggesting that lower courts have been inconsistent in determining what constitutes speech on a matter of public concern because of the “almost unbridled discretion given [to] the courts under Connick”); Rhodes, *supra* note 206, at 1184 (calling public concern standards “fact-dependent and not always predictable”).
209 For an example of the kind of issues the recruits and coaches discuss, see *Feldman*, *supra* note 154, at 154-75 (detailing the efforts of The University of Mississippi coaches to get a recruit to meet minimum eligibility requirements, which focused solely on the young man’s eligibility, and, of course, football—two interests entirely personal to the recruit).

Of course, some speech that could be considered recruiting speech would not be so personal in nature—i.e., billboards or brochures advertising the school and its athletic program. While such speech could presumably be considered as addressing a matter of public concern, it is not at issue here since a NCAA rule similar to the TSSAA’s rule would not prohibit such speech.

student’s personal interest in playing athletics at a particular institution. It cannot be said to concern community-wide interests, such as discrimination or governance, since it is not the “subject of legitimate news interest” or “of general interest and of value and concern to the public.”

Moreover, the intent of the speech is not to address a matter of public concern, which, according to at least one Circuit Court of Appeals, is important in discerning whether the employee was addressing a matter of public concern.210 Rather, the goal of recruiting speech is to attract prospective student-athletes to the school’s athletic program.212 Thus, even if some discussion took place that was of a general interest to the public, it would still not necessarily constitute speech on a matter of public concern.213 Combining this with the fact that coaches recruit as part of their professional duties,214 it is evident that speech intended to recruit a student-athlete to a college or university does not address a matter of public concern.215

3. Pickering Balancing Test

If a court were to determine that a college coach recruiting a student-athlete is an employee speaking as a citizen on a matter of public concern—or if it assumes as much, as did the Brentwood II Court—the final determination would be whether the NCAA’s interest in efficiency

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210 City of San Diego v. Roe, 543 U.S. 77, 83-84 (2004) (per curiam). An example of private remarks that implicate the general interest of the public is displayed in Rankin v. McPherson, 483 U.S. 378 (1987). In Rankin, an employee made private remarks to another employee about her views on the attempted assassination of the President. Id. at 381-82. The Court held these remarks to be a matter of public concern, given the fact that they were delivered on the heels of “heightened public attention” on presidential assassinations. Id. at 386. Discussions over a recruit’s ability to compete at a college or university does not similarly pique the interest of the public.

211 Salehpoor v. Shahinpoor, 358 F.3d 782, 787 (10th Cir. 2004) (“The court will also consider the motive of the speaker to learn if the speech was calculated to redress personal grievances or to address a broader public purpose.” (citing Workman v. Jordan, 32 F.3d 475, 482-83 (10th Cir. 1994))).

212 See supra note 209.

213 In Connick, the Court stated, “[S]peech] not otherwise of public concern does not attain the status because its subject matter could, in different circumstances, have been the topic of a communication to the public that might be of general interest.” Connick v. Myers, 461 U.S. 138, 148 n.8 (1983). Following this reasoning, even if the subject matter of recruiting speech could, in some circumstances, be considered addressing a matter of general interest to the public, because the intent of the speech is to address personal, and not public, concerns, it does not necessarily attain public concern status.

214 See discussion supra Part III.C.1.

215 For an example of what courts have found to be matters of public concern, see Johnson v. Ganim, 342 F.3d 105, 112-14 (2d Cir. 2003) (letter criticizing mayor’s administration was a matter of public concern); Victor v. McElveen, 150 F.3d 451, 456 (5th Cir. 1998) (protest against racial discrimination was a matter of public concern). For an example of the what courts have not found to be matters of public concern, see Alexander v. Eeds, 392 F.3d 138, 145-46 (5th Cir. 2004) (complaints about police department’s promotion process were not a matter of public concern); Salehpoor, 358 F.3d at 788 (complaint of theft of student’s research was not a matter of public concern).
and effectiveness outweigh the school’s free speech rights. The Court’s most recent articulation of the *Pickering* balancing test—in *Brentwood II*—is that when an employee speaks as a citizen about matters of public concern, an employer can only impose those restrictions that are necessary for it to operate efficiently and effectively. Like the threshold inquiries, in applying the *Pickering* balancing test, the Court requires a fact-based, case-by-case assessment of both the employer’s interest in operating efficiently and effectively and the employee’s interest in free speech.

The *Brentwood II* decision provides some valuable guidance for evaluating an NCAA recruiting ban. According to the *Brentwood II* Court, there are a number of harms that could prevent a high school sports association from operating efficiently and effectively. These harms include exploitation of students, lack of competition, and an athletic-centric environment. Because the TSSAA’s Anti-Recruiting Rule discourages these harms, the Court held that the Rule is necessary for the association’s efficient and effective operation and thus a valid speech restriction. Thus, it follows that if (1) recruiting high school student-athletes leads to similar harms; (2) these harms detract from the NCAA’s ability to operate efficiently and effectively; and (3) an NCAA recruiting ban discourages these harms, then it would be upheld under the *Pickering* balancing test.

While the Supreme Court did not rely on empirical evidence to support its conclusion that recruiting middle school students could lead to exploitation, distortion of competition, and creation of a culture that values athletics over academics, specific evidence shows that collegiate recruiting harbors these evils. First, the recruitment of student-athletes has lead to their exploitation. As discussed above, the NCAA, its conferences, and its schools receive substantial revenue as a result of college athletics. Despite this fact, none of the revenue is distributed directly to the players themselves. Rather, for their athletic

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216 See discussion *supra* Part II.B.1.
218 *See* Bd. of County Comm’rs, Wabaunsee County, Kan. v. Umbehr, 518 U.S. 668, 677 (1996) (“*Pickering* requires a fact-sensitive and deferential weighing of the government’s legitimate interests.”); *Pickering v. Bd. of Educ.*, 391 U.S. 563, 569 (1968) (“Because of the enormous variety of fact situations in which critical statements by . . . public employees may be thought by their superiors . . . to furnish grounds for dismissal, we do not deem it either appropriate or feasible to attempt to lay down a general standard against which all such statements may be judged.”).
220 *Id.* at 2495-96.
221 *Id.* at 2496.
222 *Id.* at 2495-96.
223 *See supra* note 150.
224 *See* NCAA DIVISION I MANUAL, *supra* note 11, at art. 12.1.2 (establishing that an individual is ineligible for participation in intercollegiate athletics if he or she accepts payment for playing).
participation, the majority of student-athletes are compensated with a free college education and any other benefits that exist from playing an intercollegiate sport.\textsuperscript{225} Whether or not this consideration is sufficient, the basis of this exchange is undermined by recruiting.\textsuperscript{226}

Because of the emphasis placed on winning in college athletics, the importance of acquiring physically gifted student-athletes cannot be understated.\textsuperscript{227} To acquire these top athletes, many coaches recruit student-athletes based solely on their physical skills, paying little attention to their academic qualifications, so long as they meet the minimum NCAA requirements.\textsuperscript{228} As a result, many of these physically gifted athletes are not academically qualified to attend the institution,\textsuperscript{229} but are able to attend because college admissions offices lower their academic standards in order to ensure the student-athletes’ admission.\textsuperscript{230}

This is problematic because it will be harder for these unqualified student-athletes to receive a meaningful education.\textsuperscript{231} Coming into school, the recruits are at a disadvantage because they are academically unqualified to attend the school. Moreover, while attending school they have to devote much of their time to athletics, instead of focusing on academics.\textsuperscript{232} Because of the combination of these two factors, it is arguable that many, or at least some, student-athletes are not receiving the requisite college education.\textsuperscript{233} By depriving many recruits

\begin{footnotesize}
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\item \textsuperscript{225} See James J. Duderstadt, \textit{Intercollegiate Athletics and the American University: A University President's Perspective}, in \textit{THE BUSINESS OF SPORTS}, supra note 5, at 560-61.
\item \textsuperscript{226} See id. at 561 (claiming that “recruiting college athletes based entirely on physical skills rather than academic promise undermines [the premise of this exchange]”).
\item \textsuperscript{227} See supra notes 157-159 and accompanying text.
\item \textsuperscript{228} Feldman, supra note 154, at 157-75; see also infra note 242.
\item \textsuperscript{229} See Jim Naughton, \textit{Athletes Lack Grades and Test Scores of Other Students}, \textit{THE CHRON. OF HIGHER EDUC.}, Jul. 25, 1997, at A43.
\item \textsuperscript{230} Bowen and Levin provide a detailed analysis of the admissions advantage for recruited athletes. \textit{BOWEN & LEVIN}, supra note 158, at 69-79. Specifically, the statistics they provide show that a high percentage of academically unqualified athletes get admitted to the country’s most prestigious universities. \textit{Id.} at 74-75; \textit{see also} Lynch, supra note 151, at 602 (discussing how athletes that fail to meet school’s admissions requirements can still be admitted through special admission processes, often with “no questions asked”).
\item \textsuperscript{232} See Sperber, supra note 161, at 303 (reporting that many teams require fifty hours of participation a week).
\item \textsuperscript{233} While graduation rates are roughly the same for athletes and non-athletes, \textit{see} NCAA, Overall Division I Graduation Rates, http://web1.ncaa.org/app_data/instAggr2007/1_0.pdf (last visited Jan. 3, 2009), that does not necessarily mean they are receiving a quality education. \textit{See, e.g., Bowen & Levin, supra note 158, at 129-34, 146-49 (providing statistics that show recruited athletes generally perform worse than the remaining student body); Sperber, supra note 161, at 301 (stating that many athletes, including those in low-profile Division I sports, “receive degrees but no education”); Zimbalist, supra note 150, at 39-41 (arguing that even student-athletes that graduate sometimes receive “totally hollow degrees”) (internal quotation marks omitted); Dowling, supra note 231, at B9 (claiming that big-time college athletes cannot succeed in school); Pete Thamel, \textit{Top Grades and No Class Time for Auburn Players}, \textit{N.Y. TIMES}, Jul. 14, 2006, at A1 (discussing how football players at Auburn University took classes that did not require attendance and received substantially higher grades for them).}
\end{itemize}
\end{footnotesize}
of a meaningful college education, colleges undermine the basic exchange with student-athletes and exploit them for athletic success.234

Second, the recruitment of student-athletes has led to a distortion of competition between colleges. Although a new team or two may contend each year, for the most part, every year the same teams compete for an NCAA championship.235 This trend is neither limited to the high profile sports of men’s basketball and football,236 nor to Division I.237 This lack of competition is a direct result of recruiting. Given coaches’ claims as to the importance of recruiting to a program’s success,238 it should be no surprise that success on the recruiting trail has led to success on the playing field.239 Therefore, since recruiting is integral in

234 Walter Byers & Charles Hammer, Unsportsmanlike Conduct: Exploiting College Athletes 299 (1995) (claiming “that the college admissions office and faculty exploit the athlete by taking on board a poorly prepared student and providing to him or her course work of minimum quality so the athlete can meet minimum eligibility standards”).


237 See supra notes 156-158 and accompanying text.

238 Many of the teams that consistently place in the top ten of the final AP college football poll have also been recognized as having a top ten recruiting class by college football pundits. See Rivals.com, Football Recruiting: Team Rankings, http://rivals100.rivals.com/TeamRank.asp? (last visited Jan. 24, 2008). From 2002-2008, several teams placed among the top ten in terms of strength of recruiting class multiple times according to Rivals.com, including Georgia University seven times, and Oklahoma University, Louisiana State University, and University of Southern California five times. Rivals.com, Football Recruiting: Team Rankings, http://rivals100.rivals.com/TeamRank.asp?
establishing success on the playing field, it follows that it is a, if not the, driving force behind the current lack of competition in college athletics.

Third, the recruitment of student-athletes fosters an environment in which athletics is valued more than academics. Because of the heightened importance of college athletics to institutions, the fact that education is the primary reason for attending college is sometimes lost.²⁴⁰ Thus, instead of an environment which attempts to integrate athletics and academics, a different environment emerges which often forces the student-athlete to choose between athletic and academic success.²⁴¹ Recruitment of student-athletes encourages such an environment, since recruiting focuses on the physical skills of a student-athlete, often at the expense of academic qualifications.²⁴² By allowing this type of recruiting and by encouraging it through the admission of academically unqualified student-athletes, colleges are contributing to a culture that values athletic excellence at the expense of academic success, the third harm mentioned by the Brentwood II Court.

Like the effect of these harms on the TSSAA, each one of these harms impacts the NCAA’s ability to operate efficiently and effectively.

²⁴⁰ This fact gets lost on both the players and coaches. See Dowling, supra note 231, at B9 (discussing a scandal at the University of Minnesota, in which a tutor revealed that she had completed 400 assignments for men’s basketball players from 1993 to 1998); Mark Schlabach, Younger Harrick Blamed for Fraud, ATLANTA J.-CONST., May 21, 2003, at C1 (reporting an investigation that revealed that the assistant men’s basketball coach at the University of Georgia, Jim Harrick, Jr., lied about his teaching credentials to get a physical education position at the school, misled the university as to how the class would be taught, and gave an “A” to three players who failed to attend class, do class work, and take the final exam); Andy Staples, Economics of Recruiting, SLCOM, Feb. 6, 2009, http://sportsillustrated.cnn.com/2008/writers/andy_staples/01/23/recruiting.economics/1.html (reporting on a study which found that, for top college football recruits, graduation rates had no measurable effect on their choice of school).

²⁴¹ This fact also gets lost on schools. See Lynch, supra note 151, at 602-06, 608. Lynch’s article provides a detailed analysis of the relationship between college athletics—specifically basketball—and academics. In arguing that many elite college programs may have lost sight of “educational primacy,” id. at 605, Lynch highlights instances where the desire for athletic success impedes on the academic missions of universities. Id. at 602-06, 608. Some of the examples relevant to this Note include: coaches steering athletes to less demanding majors or courses to ensure they will meet NCAA eligibility requirements, athletes spending forty to sixty hours a week on their sports, and regular season games and postseason tournaments infringing on class attendance. Id.

²⁴² According to Bowen and Levin, recruitment of athletes in the high-profile sports “has become so aggressive that not even lip service is paid to educational values.” Bowen & Levin, supra note 158, at 303.
The Supreme Court has provided some guidance for determining whether a restriction is necessary for an employer to operate efficiently and effectively. According to the Court, relevant considerations in this test include whether the employee speech “impairs discipline by supervisors or harmony among co-workers, has a detrimental impact on . . . working relationships, . . . or interferes with the regular operation of the enterprise.”

Because the instant situation is not the traditional employer-employee relationship, the only applicable inquiry seems to be whether the harms of recruiting speech interfere with the regular operation of the NCAA.

Indeed, recruiting harms have impeded the regular operation of the NCAA and, consequently, detracted from its ability to operate efficiently and effectively. Among the NCAA’s stated purposes are: protecting the well-being of student-athletes, ensuring fair and equitable competition, and respecting the supporting role that athletics plays to education. Part of the NCAA’s regular operation includes enacting measures to ensure these purposes are upheld. Nonetheless, recruiting has lead directly to exploitation of student-athletes, unequal competition, and diminishment of the educational predominance, each of which strikes at the core of the NCAA’s purposes. In undermining the NCAA’s values, recruiting interferes with its regular operation and detracts from its ability to operate efficiently and effectively.

The negative impact of recruiting on the NCAA’s efficient and effective operation can be seen in the failures of the NCAA’s current enforcement system. To uphold its rules, the NCAA has an enforcement division that investigates and punishes rules violations. However, the high number of recruiting and other violations has significantly negated the enforcement division’s ability to quash this conduct. Because

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244 See supra notes 129, 131-133 and accompanying text.


246 Cf. Hinshaw v. Smith, 436 F.3d 997, 1007-08 (8th Cir. 2006) (holding that speech which miscommunicated the employer’s interpretation of a recently-passed law undermined the board’s efforts and was thus unprotected under Pickering); Pappas v. Giuliani, 290 F.3d 143, 149 (2d Cir. 2002) (holding that a police officer’s speech, reinforcing perception that police department is racially biased, undermined the efforts of the police department and thus impaired its ability to operate efficiently).


248 For the number of rules violations in recent years, see Wolverton, supra note 4. Notably, those numbers include only detected violations; a substantial amount of violations go undetected. See infra notes 253-254 and accompanying text.

Significantly, out of all areas of NCAA rules violations—i.e., academic, recruiting, eligibility, unethical conduct, illegal participation—half occur from recruiting. Sperber, supra note 161, at 245.
of the NCAA’s small enforcement division, it relies heavily on the college or university to investigate itself in many cases. This tactic is obviously suspect given an institution’s desire to act in its own self-interest. Consequently, the NCAA has increased its efforts to limit infractions. However, this strategy has produced mixed results. While there is speculation that these efforts have curtailed NCAA violations, the fact remains that many violations still go undetected. For example, the NCAA staff, which receives seven or eight tips a day concerning possible rules violations, still pursues only one of every fifteen leads.

Because the NCAA has to rely so heavily on the individual institutions to report violations, it has encouraged schools to cooperate with its enforcement division in exchange for a reduction in penalties. As a result, the penalties the NCAA has implemented to enforce violations have been relatively weak. The most common penalties for major violations of NCAA rules are the loss of scholarships, a limitation on the number of recruiting visits, and probation. These penalties have little effect on the coaches and schools that receive them.

Thus, the NCAA’s enforcement efforts have created a system in which (1) an overwhelming majority of violations go undetected and (2)
those that are detected result in rather minimal penalties. For an
association committed to detecting and punishing violations in order to
prevent unwanted conduct, undoubtedly this system is inefficient and
ineffective. By fostering such a system, recruiting is directly responsible
for the ineffective and inefficient operation of the NCAA.

Fortunately, an NCAA recruiting ban discourages the recruiting
harms that cause this inefficiency. In Brentwood II, the Court accepted,
without inquiry, that the TSSAA’s Anti-Recruiting Rule discouraged the
harms of recruiting.\(^{259}\) Logically, it does not seem as though inquiry is
necessary since a rule that bans recruiting is naturally going to
discourage the harms that result from it.\(^{260}\) Moreover, a recruiting ban
would serve much better than the current framework, which is a
complicated and extensive set of rules that contain loopholes that allow
for easy evasion of the NCAA’s recruiting restrictions.\(^{261}\) An all-out ban
would not allow any room for interpretation, preventing coaches from
engaging in legal but ethically questionable conduct.

Ultimately, recruiting and the harms that result from it prevent
the NCAA from the efficient and effective implementation of its
purposes. To discourage these hindrances and increase the likelihood of
an efficient and effective NCAA, a recruiting ban, and not merely
stronger recruiting rules, is necessary. Consequently, a recruiting ban
would survive the Pickering balancing test, the final prong of the
Pickering doctrine.

IV. WHAT’S NEXT?: PASSING A RECRUITING BAN

While the NCAA may have the ability, legally, to pass a
recruiting ban, whether the NCAA would be willing to impose such a
ban is an entirely different question. Indeed, the NCAA should pass a
recruiting ban. Recruiting student-athletes has undermined not only the
purpose of the NCAA, but also of college sports in general. Colleges and
universities’ primary purpose is educating its students.\(^{262}\) Sports are
supposed to play a supporting role to academics and supplement the
institution’s mission.\(^{263}\) Thus, while athletics certainly serves a purpose in
the educational mission of an institution, its position is firmly inferior to

\(^{259}\) Tenn. Secondary Sch. Athletic Ass’n v. Brentwood Acad. (Brentwood II), 127 S. Ct.
2489, 2496 (2007).

\(^{260}\) Of course, an argument could be that a recruiting ban will have no effect because even
if the NCAA passed a recruiting ban, exploitation, unequal competition, and the primacy of athletics
would still continue. However, merely because such conduct might continue to occur does not mean
that a recruiting ban does not discourage it.

\(^{261}\) See O’Neil, supra note 12.

\(^{262}\) According to the University of Connecticut’s Athletic Department, “[i]ntellectual
growth and academic progress is the primary purpose for [the student-athlete] being [in college].”
UNIVERSITY OF CONNECTICUT DIVISION OF ATHLETICS, supra note 6.

\(^{263}\) Id.
education. For all the reasons discussed in Part III, recruiting crosses this line, and therefore should be banned.

Moreover, the disadvantages of a recruiting ban are minimal. Banning recruiting does not have a harmful impact on prospective student-athletes. A recruiting ban need not affect generally qualified and physically gifted student-athletes who wish to use their athletic abilities to gain admission. Coaches would still know who to support in this process since a recruiting ban would not restrict unilateral action by the student, such as sending video of themselves to coaches. The student would still be able to access the necessary information in order to make an informed decision about the institution he or she wishes to attend. Finally, it would not harmfully impact the student-athlete’s ability to play an intercollegiate sport.

The only real negative impact of a recruiting rule is on the schools that will be unable to attract highly touted high school athletes through recruiting. However, if schools were committed to their mission of educational primacy, this would not be a negative at all. Athletic success, while desired, is not critical to achieving the educational goals of athletics.

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264 It may have an impact on those high schoolers with professional aspirations who want to be at the best program to succeed athletically; however, college is an educational institution, not a professional minor league.

265 Colleges have special admissions procedures in which they give beneficial treatment to student-athletes who may not otherwise be admitted but whose athletic abilities will enrich the student body. Deirdre Carmody, Colleges Bend Admissions for More than Athletes, N.Y. TIMES, Jan. 25, 1989, at B6. This treatment also accrues to musicians, artists, and others who would benefit the student body. Id. While these applicants may be not be the best qualified, they are nonetheless still qualified to attend the institution according to the institution’s, and not NCAA minimum, standards. See id. So long as this procedure is used to admit under-qualified, but not unqualified, student-athletes, there is little problem with it. Of course, this process would have to be regulated to ensure that it is not abused. See Elliott Almond, Athletes Go to the Front of Admission Line, L.A. TIMES, May 3, 1991, at C1 (discussing how the special admissions process is used to get admission of unqualified athletes).

266 See supra note 19.

267 A recruiting ban in no way prevents a school from generally advertising their athletic programs. Tenn. Secondary Sch. Athletic Ass’n v. Brentwood Acad. (Brentwood II), 127 S. Ct. 2489, 2495 (2007). Moreover, given the popularity of college athletics and the easy access to information via the Internet, it is likely that a prospective student-athlete would be able to gain substantial information about a school’s athletic program without having to talk to the coach. Importantly, with the elimination of recruiting, the emphasis of this decision would hopefully be on academics rather than on athletics since, without communicating with the coach, a student-athlete would not be certain whether he or she could participate in athletics at the school.

268 Certainly, without recruiting there is a chance that schools will admit too many athletes, such that some will not be able to make a team. However, this does not mean a student-athlete will never play sports. Schools have intramural sports, see, e.g., Univ. of Mich., Intramural Sports Homepage, http://www.recsports.umich.edu/intramurals/ (last visited, Jan. 3, 2009), and students are permitted to transfer. See NCAA DIVISION I MANUAL, supra note 11, at art. 14.5. In fact, without recruiting, the opportunity to play intercollegiate sports may increase because the stigma of the “walk-on” will be eliminated. See SHULMAN & BOWEN, supra note 170, at 39 (odds of making a team without knowing coach are “essentially zero”).

269 See Univ. of Mich. Athletic Dep’t, Mission Statement, supra note 149. In fact, less focus on athletic success could improve a school’s academic programs. While athletic success can bring substantial revenue to a university, most universities, even those with successful athletic
Unfortunately, many schools are not committed to educational primacy because college athletics is such a lucrative business. As discussed earlier in this Note, schools receive a great deal of money from their athletic programs, the amount of which is integrally tied to their athletic success. By jeopardizing the ability to obtain premiere prospects, a recruiting ban has the potential to cripple an athletic program’s success, and, consequently, cut the amount of revenue a school receives. With the possibility of losing a substantial amount of revenue, the schools comprising the NCAA would likely not support a recruiting ban.

Moreover, the NCAA, as an entity separate and distinct from the member schools, would have little incentive to support such a ban. College athletics has likewise generated a substantial amount of operating revenue for the NCAA. Unfortunately, the NCAA’s financial success has come while undermining its own principles. Therefore, while supporting a recruiting ban would help the NCAA uphold its values, it would also undermine the importance of athletics and potentially uproot the financial base of the NCAA. As the NCAA’s record has shown, if such a choice presented itself the NCAA would likely opt for maintaining the status quo.

Thus, while the NCAA seems to have the legal endorsement to pass a recruiting ban, it is unlikely that the NCAA would be willing to pass one. As a result, it may be necessary for reform to come from a higher power. Since its formation in 1905, the NCAA has largely governed itself; Congress has usually refused to take part in any reform efforts. However, in extreme circumstances, the government has

programs, lose money from their athletic programs. See supra note 150; see also Murray Sperber, Beer and Circus: How Big-Time College Sports Is Crippling Undergraduate Education 219-22 (2000). To remedy this, every year, schools use their additional financial resources to “zero out” the athletic department’s books. Sperber, supra, at 221. As a result, “[m]oney that could go to academic programs, student scholarships and loans, and many other educational purposes annually disappears down the athletic department financial hole.” Id.

See Lynch, supra note 151, at 605-07 (discussing how schools have allowed their educational missions to be infringed upon in order to maximize revenue from athletics).

See supra notes 150-151 and accompanying text.

See supra note 153.

See supra notes 157-158 and accompanying text.

See Lynch, supra note 151, at 605-08. This is critical because the persons that introduce and vote on rules are volunteers from the NCAA’s member institutions. NCAA, Overview, supra note 102.

The NCAA’s current operating revenue is $614 million. See supra note 150.

See Wetzel, supra note 253 (arguing that the NCAA has forfeited extensive enforcement in order to protect its big-time programs and television money).

Id.


stepped in, pressuring the NCAA to make changes. For example, in 1978, the United States House of Representatives’ Subcommittee on Oversight and Investigation held hearings to investigate the NCAA’s enforcement processes amidst public criticism that the processes were unfair. Subsequently, the NCAA altered its rules to better address the concerns discussed in these hearings.

According to some commentators, the current trend of the NCAA towards the commercialism of college sports is a call for government intervention. Moreover, Congress itself has recognized a need to protect student-athletes from harmful collegiate recruiting. After the Colorado University recruiting scandal in 2004, Congress held a hearing on whether student-athletes were being protected in the recruiting process. Hopefully, the NCAA’s current subjugation of academic values and exploitation of student-athletes through the recruiting process will inspire further government action, giving the NCAA the necessary motivation to pass a recruiting ban.

V. CONCLUSION

The purpose of colleges and universities is to educate. College athletics is supposed to play a supporting role in this purpose by fostering leadership, physical fitness, and athletic excellence in an effort to enhance the educational experience. Unfortunately, for a variety of reasons, many have forgotten the professed athletic-academic relationship. Nowhere is this loss more evident than in recruiting. Driven by the desire for academic success, recruiting has become a corrupt process that exposes high school student-athletes to inappropriate situations, exploits the student-athletes, and sacrifices academic success for athletic excellence.

Fortunately, Brentwood II provides the NCAA with an opportunity to reestablish the proper role of college athletics. In finding that a high school athletic association can limit the speech of its member institutions and their coaches, the Court provides a template for a college

280 Smith, supra note 279, at 16.
281 Id.
282 Id.
283 Id. at 22 (“If the NCAA and those who lead at the institutional and conference levels are unable to maintain academic values in the face of economics and related pressures, the government may be less than a proverbial step away.”).
285 Notably though, given the importance of college athletics in popular culture, commentators speculate that such a drastic reform may not be realistic. See ZIMBALIST, supra note 150, at 196.
286 Id.; NCAA DIVISION I MANUAL, supra note 11, at art. 1.2.
athletic association to do the same. Hopefully the NCAA, whether pressured or not, will act on this endorsement and ban athletic recruiting.

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MANDATING A FINANCIAL OVERSIGHT COMMITTEE IN NEW DISASTER RELIEF NONPROFIT ORGANIZATIONS

INTRODUCTION

In recent years, nonprofit organizations have formed in the wake of major disasters in order to supplement disaster relief efforts. After the tragedies of September 11th and Hurricane Katrina alone, the number of newly created nonprofit organizations designed to serve disaster victims totaled three hundred forty-two and four hundred, respectively. The explosion in the number of nonprofit organizations is matched by the growth of their assets. From 1975 through 1995, the assets of all tax-exempt organizations in the sector tripled. From 1994 through 2004, the assets of all tax-exempt organizations grew by an astounding ninety percent. The sector employs a larger portion of the workforce than that of utilities and construction, and its growth outpaces that of the economy in general.

Nonprofit organizations operate with very little regulation. As a result, it is no surprise that the nonprofit sector has produced high-profile scandals that mirror similar problems in the for-profit sector. Even more

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1 MICHAEL F. MELCHER WITH ALEX MANDL., THE PHILANTHROPIC RESPONSE TO 9/11 15 (2003) (quoting September 11th Fund head’s criticism of new nonprofit disaster relief providers: “[N]ewly created charities, decided to enter the cash-assistance business even though they lacked the experience and infrastructure . . . . It was compassion, but not competence”).
3 Stephanie Strom, Many Charities Founded After Hurricane Are Faltering, N.Y. TIMES, Mar. 13, 2006, at A12.
7 FISHMAN & SCHWARZ, supra note 4, at 150 (describing scandals at American University and Adelphi University); Katherine Boozang, Does an Independent Board Improve Nonprofit Corporate Governance?, 75 TENN. L. REV. 83, 87-98 (2007) (describing huge nonprofit scandals at the University of Medicine & Dentistry of New Jersey and the formerly nonprofit New York Stock Exchange); James J. Fishman, Improving Charitable Accountability, 62 MD. L. REV. 218, 219, n. 1 (2003) (describing scandals in nonprofit sector exhaustively, including incidents at United Way and Hale House where executives used charity funds for personal gain). Smaller nonprofit scandals also commonly emerge in the news headlines. See Ralph Blumenthal, Ex-University Head in Texas on Trial for Money Misuse, N.Y. TIMES, Aug. 25, 2007, at A8 (Dr.
worrisome is the assumption that the majority of nonprofit scandals likely go unreported. Aside from scandals that reveal illegal activity, the nonprofit sector has also been described as inefficient and wasteful.

This Note addresses the crisis of accountability in disaster relief nonprofit organizations and, by extension, the nonprofit sector as a whole, by arguing for the formation of a legally mandated financial oversight committee within new disaster relief organizations where no such governance mandate has so far existed. Part I explores how theft, fraud, waste, and the unique circumstances of the disaster relief context pose particular nonprofit accountability issues that warrant specific legal reforms. Part II demonstrates that the existing legal framework does not address and mitigate the particular problems laid out in Part I. Finally, Part III proposes the creation of a financial oversight committee on the boards of new disaster relief nonprofit organizations. This Part illustrates how such a governance structure will address financial accountability issues such as theft, fraud, and waste in the nonprofit disaster relief sector, and responds to likely criticisms of such a proposal.

I. DISASTER RELIEF ORGANIZATIONS: THEFT, FRAUD, AND WASTE

Disaster relief nonprofit organizations tend to receive rapid infusions of money for administration and program expenses that are spent on a faster timeline than in other contexts in which nonprofits serve even the neediest of victims. Charities received over two billion dollars after September 11th, with the majority of those funds coming in just two months after the tragedy. The enormous level of aid donated for victims of 9/11 resulted in flooded coffers at established disaster relief organizations and the fast expansion of budgets at existing foundations or new nonprofit organizations. On an even greater scale, charities
received more than $4 billion dollars in donations following Hurricane Katrina. Given the potential for cash to flow into these new organizations, the fact that these organizations are often run by inexperienced people, and the unpredictable and urgent nature of disaster relief work, these organizations face unique circumstances that make easy for funds to be stolen by staff, fraudulently obtained by users, or simply wasted. Simply put, disasters create the perfect storm for a lack of nonprofit financial accountability.

A. Theft

A new disaster relief organization that grows from inception to receiving large amounts of revenue will generally not face the public scrutiny directed towards the large, established Red Cross. Funds donated for disasters can appropriately be set aside and used for administrative expenses for services unrelated to cash assistance, such as mental healthcare, that may be provided to victims in distress on an ongoing basis. However, because funds pour into the organization while the organization is creating ways to spend them, funds can also easily be stolen. As an example, one executive of a new September 11th charity formed to provide supportive services to all children who lost a parent in the attacks was later accused of stealing from his organization and using some of the stolen funds to pay his mortgage and credit card bills. The executive, whose brother was killed in the World Trade Center, also confessed to feeling continually grief-stricken and "hid[ing] from 9/11 in 9/11." The confession may not reflect the general attitude of executives running new disaster relief organizations. However, the wide latitude given to this grief-stricken founder of a disaster relief

\[\text{\textsuperscript{14}}\text{ Howard Kunreuther, Op-Ed, Who Will Pay for the Next Hurricane?, N.Y. TIMES, Aug. 25, 2007, at A15 ("Because of increasing development in hazard-prone areas and the effects of climate change, we are in a new era of catastrophic losses from natural disasters. Ten of the 20 most costly natural disasters have occurred during the past five years—all 10 of them hurricanes, typhoons or tropical storms.").}\]

\[\text{\textsuperscript{15}}\text{ N.Y. ATTORNEY GEN., supra note 11, at 2 ("Some of those funds were created spontaneously by organizations with no prior experience in administering charitable assets. All of the September 11th charities—whether newly-formed or long-established—have confronted a daunting administrative burden that has severely taxed their staffs and resources.").}\]

\[\text{\textsuperscript{16}}\text{ Id. at 3 ("The demand for relief was huge. The logistics of dispensing aid were further complicated at the early stages of the disaster by the incapacitation of the communications and transportation infrastructure of Lower Manhattan.").}\]

\[\text{\textsuperscript{17}}\text{ See infra Part II.A.2 for a discussion about the limited role of state Attorneys General in regulating charities.}\]


\[\text{\textsuperscript{19}}\text{ James Barron, Behind Relief to 9/11 Families, A Man’s Flaws, N.Y. TIMES, Apr. 3, 2006 ("I realized as I sat there with that $250,000 check in my hand, I was the only one who knew anything about it...and I could direct it as I saw fit.").}\]

\[\text{\textsuperscript{20}}\text{ Id.}\]
organization to receive and spend large checks by himself without a mandated financial oversight committee is the norm.\(^{21}\)

\section*{B. Fraud}

The propensity for money to be distributed to fraudulent disaster victim aid applicants further justifies the need for a governance mandate. The flow of funds and the ease with which they are distributed led to the creation of over four thousand websites run by scam artists just one month after Hurricane Katrina.\(^{22}\) Alternatively, new disaster relief organizations also run the risk of having their funds ferreted away through fraudulent applications in the rush to disburse funds. Because the Red Cross received public scrutiny for allocating 9/11 donations towards long-term goals and services,\(^{23}\) all disaster relief providers now feel pressure to distribute cash assistance quickly despite the fact that this may hinder their ability to screen out fraudulent applicants.\(^{24}\) While the majority of cash assistance pools come from large public agencies like the Federal Emergency Management Agency (FEMA) and large nonprofits like the Red Cross, new or small organizations do indeed raise funds for short-term cash assistance despite their lack of experience in the distribution of aid to disaster victims.\(^{25}\)

After September 11th and Hurricane Katrina, the level of fraudulently obtained money dispensed to alleged victims by governmental and nonprofit organizations led to an astounding loss of $2.6 billion dollars.\(^{26}\) By one report, fraudulent applications for September 11th aid totaled at least $5.8 million,\(^{27}\) while Hurricane Katrina fraud alone amounted to over $2 billion.\(^{28}\) Where the vast majority of the Katrina fraud involved false applications to FEMA programs, The \textit{New York Times} reported that the Red Cross was

\begin{enumerate}
\item See infra Part II.B.2 for discussion of limited state and federal financial reporting requirements for new disaster relief organizations.
\item See infra note 93.
\item Jacqueline L. Salmon, \textit{Fraud Alleged at Red Cross Call Centers}, WASH. POST, Dec. 27, 2005, at A5 (“[C]harity experts say that in this era, when a highly visible disaster can trigger an outpouring of hundreds of millions of dollars, relief groups are under enormous pressure to disburse the money as quickly as possible or risk the ire of donors.”).
\item Erica Pearson, \textit{Money for Rebuilding}, \textit{GOTHAM GAZETTE}, Feb. 3, 2002, http://www.gothamgazette.com/article/issueoftheweek/20030203/200/271 (describing “9/11 scam artists” who “invented brothers, husbands, [and] wives” in their applications to large relief funds which succeeded because a complete list of the dead and the families was not available until several months after the attacks).
\item Thomas Zambito, \textit{Con Artists Cashed in on $5.8M from 9/11 Tragedy}, N.Y. DAILY NEWS, Sept. 9, 2007.
\end{enumerate}
investigating over 7000 possible instances of fraud. In New York alone, the Manhattan District Attorney had charged 245 people with making over $3 million dollars in fraudulent 9/11 relief claims. In another case after Hurricane Katrina, employees of the Red Cross schemed with outside individuals in order to steal money from the agency. All new disaster relief organizations that raise and disburse funds quickly face this particular risk of distributing aid to fraudulent applicants.

C. Waste

Like all new nonprofit organizations, new disaster relief organizations can waste their assets as a result of weak governance, particularly when the board is dominated by a founder. In general, organizations run by founders are distinct from those run by successors because founders are often entrepreneurial as opposed to managerial. In this context, directors who attempt to engage with the founder may only do so in futility. Founder-led organizations with less board oversight of daily operations can be poorly managed and inefficient. Oftentimes, founder-led nonprofits are governed by family members, friends, and business associates despite the fact that these “interlocking relationships” can undermine the “the level of independent judgment required of all board members.” Particularly in disaster relief, if the founder provides

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29 Id.
31 Jacqueline L. Salmon, Fraud Alleged at Red Cross Call Centers, WASH. POST, Dec. 27, 2005, at A5.
32 N.Y. ATTORNEY GEN., supra note 11 (“The public understandably has demanded that relief be made quickly with minimal red tape. The public has also expressed strong concerns that the charities take steps to avoid fraud and waste, to ensure some measure of equity in the distributions and to guard against any victim falling between the cracks.”) (internal quotation marks omitted).
33 Boozang, supra note 7, at 124 (“Smaller nonprofits and [those] reliant on a single significant donor must resist the board acting as the alter ego of the entity’s founders or original board members. Fidelity to mission must guide all decisions, and the board is obliged to monitor management.”); Stephen R. Block & Steven Rosenberg, Toward an Understanding of Founder’s Syndrome: An Assessment of Power and Privilege Among Founders of Nonprofit Organizations, 12 NONPROFIT MGMT. AND LEADERSHIP 353, 354 (2002) (analyzing “unhealthy organizational situations in which founders are more heavy-handed and indifferent about the imbalance of their control over organizations”). Block and Rosenberg concluded that “founders are not necessarily skilled managers” and that founder-led organization board members were less involved in decision-making. Id. at 364-66.
34 Id. at 365.
35 FISMAN & SCHWARZ, supra note 4, at 169 (“Powerful group dynamics constrain the willingness of directors to voice concern or dissent, discouraging them from openly questioning or contradicting management except in extraordinary circumstances.”).
36 Block & Rosenberg, supra note 33, at 364 (“The new leadership that replaces the founder is likely to have more experience and skill in efficiently managing and maintaining an organization.”).
poor operational oversight, the new disaster relief organization will waste money and provide ineffective disaster relief. While it would not be desirable to completely quash the motivation and drive of visionary founders, governance mandates will improve disaster relief nonprofits by separating entrepreneurial pursuits from managerial duties.

The short-term and long-term needs of disaster relief victims are best met through coordination and collaboration among the public, private, and non-governmental sectors. At least in part, such coordination is necessary to determine which victims need aid and which victims have already been served. Because of this, new nonprofit organizations have been criticized for undermining such coordination and collaboration. With no formal or centralized leadership from within the nonprofit sector to coordinate efforts to serve disaster victims, new nonprofit organizations with weak governance are likely to continue undermining disaster relief efforts. Despite condemnation of government relief services and public distrust of large charities after the Red Cross

38 Block & Rosenberg, supra note 34, at 364 (Smaller nonprofits are often solely run by their founders who “are less concerned with the opinions of others” and “may not be interested in the ideas and directional advice of others.”).

39 MELCHER, supra note 1, at 33; SEESSEL, supra note 12, at 9.

40 Gloria Simo & Angela L. Bies, The Role of Nonprofits in Disaster Response: An Expanded Model of Cross-Sector Collaboration, 67 PUB. ADMIN. REV. 125, 126-32 (2007) (discussing the cross-sector collaboration necessary for disasters such as Hurricane Katrina); DISASTER RELIEF AND RECOVERY: THE ROLE OF NONPROFITS BEYOND GROUND ZERO AND THE LEGAL IMPLICATIONS OF THEIR WORK 16 (Elizabeth M. Guggenheimer et al. eds., 2003) (“Alongside long-term plans for recovery and rebuilding from the September 11 attacks, nonprofit organizations throughout New York City are taking stock of lessons learned and creating plans for future crisis. They are recognizing the need for contingency plans to ensure that relief efforts are better coordinated and more effective in the event of a future large-scale disaster.”); MELCHER, supra note 1, at 11-12 (describing how use of existing charities reduces risk, but also conceding that new organizations can be innovative).

41 Gene Steurle, Charities and Disaster Relief, Making Choices & Planning for the Future, 35 TAX-EXEMPT ORG. TAX REV. 159, 160 (“Clearly, when many charities become involved, they can trip over each other. . . . [T]he small charity may believe that it enhances its own future by running its own little program, no matter how inefficiently. However, the sector as a whole could witness lesser charitable giving as a result.”).

42 Id. (assailing “waste” of small nonprofits that undertake disaster relief); MELCHER, supra note 1, at 15 (“Creating new programs poses risk and can be counterproductive. Some new organizations created after 9/11 had overly narrow purposes that could not keep up with quickly evolving needs. . . . In a crisis, organizations may attempt actions that are beyond their capabilities and inconsistent with their missions.”); SEESSEL, supra note 12, at 9 (“Philanthropic planning was complicated by the proliferation of new charities created to address 9/11 relief and recovery, many of which had inexperienced leadership and vaguely defined plans.”).

43 MELCHER, supra note 1, at 16 (describing leadership problem that was partially resolved through September 11th Fund); Simo & Bies, supra note 40, at 135 (“Perceptions of government failure or inadequate relief efforts were widespread and described as serving to stimulate alternative relief and re-building solutions in the form of cross-sector collaborations.”); Debra Blum, Review of 9/11 Response Finds Charities Missed Opportunity to Lead, CHRON. OF PHILANTHROPY, Dec. 8, 2003, http://216.105.98.11/content/Practices/Practices57_2.

new disaster relief organizations that may fill some gap in the disaster response system should still be the subject of governance reform.

D. Unique Challenges of the Disaster Relief Context

While all nonprofit organizations face challenges and are under-resourced, the urgent and complex nature of disaster relief work is particularly prone to fraud, theft, and waste of assets when carried out by inexperienced staff. “[C]reating and managing a new charitable organization involves expense, administrative responsibilities, and attention to legal compliance obligations... that are likely to be complex and challenging.” The highly emotional nature of the work can lead staff to discontinue their work due to “burn-out.” In addition, the administrative responsibility of fundraising in the years after a disaster can lead to organizational failure. For instance, none of the twelve to fifteen organizations founded by nonprofit “rookies” after the Oklahoma City bombing survived for more than two years. Even extremely high-profile charities suffered after September 11th. When organizations that aspire to help victims fail shortly after inception, this raises legal and policy issues involving the extent to which the board could have prevented its failure.

Lastly, to the extent that new disaster relief organizations are run by inexperienced people, they are ill-equipped to handle the diffuse,

45 Strom, supra note 3 (people wanted to form their own charities as opposed to donate to large charities).
46 Lipman, supra note 2 (“These organizations that pop up run a high risk of waste, inefficiency, and outright fraud. Even when you have individuals with the best intent, they are not experienced at raising and distributing money.” (quoting Marc Owens, head of the IRS oversight of nonprofits from 1999-2000) (internal quotation marks omitted)); Strom, supra note 3.
48 Domenica Marchetti, September 11 Charities Face Challenges Beyond the Ordinary, CHRONICLE OF PHILANTHROPY, Mar. 7, 2002, www.philanthropy.com/free/articles/v14/i10/10001101.htm (“Very often there is a desire to memorialize someone ... But if there is no fundamental understanding of the issue you’re trying to address, the passion will eventually burn out and you’re left with a somewhat inexperienced group of people tackling something they aren’t equipped to tackle.” (quoting Oklahoma City Community City Foundation Executive Director Nancy B. Anthony) (internal quotation marks omitted)); cf. Families of September 11, http.fos11.org (last visited Mar. 20, 2009).
49 DISASTER RELIEF AND RECOVERY, supra note 40, at 29.
50 Marchetti, supra note 48 (“Sustaining a charity over the long term is probably the biggest challenge a September 11 groups face,” one disaster relief expert stated.).
51 Id. The Todd Beamer Foundation sought to provide mental health support for traumatized children who lost a loved one in the September 11th attacks, expanded its mission to support children traumatized by events other than September 11th, and yet spent more on consultants than on services and is now faced with financial problems. Beamer Foundation Making Hard Choices, THE NONPROFIT TIMES, Feb. 12, 2007, http://nptimes.com/07Feb/news-070212-1.html (“Renamed Heroic Choices some three years ago, the organization ended 2005 with $177,539 in net assets, according to its most recent Form 990, down from more than $2.7 million at the same time two years ago, while spending more on fundraising and consultants than program services or contributions. The past two years have seen more than a third of the nonprofit’s $2.8 million in total expenses go for ‘fundraising expenses’ with less than $1 million listed for ‘program services.’”).
unpredictable, and often long-term nature of disaster victims’ needs.\footnote{See infra Part I.C for discussion of consequences of disaster relief organization ineffectiveness. The best support for this proposition comes from the strong disapproval of such organizations by leading sector experts, lawyers, and even the Internal Revenue Service.} Disaster relief is a comprehensive process that encompasses acute and long-term needs and extends well beyond the mere provision of blankets, food, and medical care in the days after a tragedy.\footnote{DISASTER RELIEF AND RECOVERY, supra note 40, at 6-10. See generally Carol J. De Vita & Elaine Morley, Providing Long-Term Services After Major Disasters, URBAN INST., Aug. 2007, at 1.} For example, the attacks of September 11th took a direct toll on thousands of lives and left hundreds of thousands of people economically deprived and psychologically traumatized.\footnote{SEESSEL, supra note 12, at 1 (reporting that a total of 2823 people were killed on four hijacked airplanes, in the Twin Towers, and at the Pentagon). In the months following the attacks, 700 businesses closed and over 100,000 jobs were lost. Seven thousand people were displaced from downtown Manhattan. Id.} Many relief providers in New York City were influenced by the response to other disasters, such as the Oklahoma City bombing, where the mental health needs of victims worsened as time went on instead of vice versa.\footnote{Id. at 5 (describing opinion of Nancy B. Anthony, Executive Director of the Oklahoma City Community Foundation).} Accordingly, aid encompassed cash assistance, loans for small businesses, government benefits, as well as ongoing mental healthcare for several years.\footnote{DISASTER RELIEF AND RECOVERY, supra note 40, at 6-9, 13-14.} Service providers after Hurricane Katrina, Rita, and Wilma similarly assisted a large evacuee population with short-term subsistence measures, and long-term assistance with housing, healthcare, mental healthcare, and education.\footnote{The Face of Recovery: The American Red Cross Response to Hurricane Katrina, Rita & Wilma, 2-9 (2007) (on file with author).}

The waste of donor dollars or resources by new disaster relief organizations may also be rooted in, or at least partially explained by, the wide range of disaster relief goals. The Chronicle of Philanthropy reported that disaster relief organizations fast-tracked for tax-exemption after September 11th sought to create animal-friendly license plates in Missouri and Kansas, promote music education in Colorado, support orphans in Bangladesh, and stop bias against the practice of chiropractic medicine in Ohio.\footnote{See generally IRS, DISASTER RELIEF Report, supra note 18. See infra Part II.B. for discussion of federal tax-exempt guidelines and expedited application process for disaster relief organizations; see also Harry Lipman, IRS Handling of September 11th Charities Shows Weakness of Approval System, Critics Say, CHRON. OF PHILANTHROPY, Mar. 7, 2002, http://www.philanthropy.com/free/articles/v14/i10/10000802.htm.} Similarly, The New York Times reported that disaster relief organizations fast-tracked for tax-exempt status after Hurricane Katrina provided leather jackets to sadomasochists and sent money to children in China.\footnote{Strom, supra note 3.} To the extent that such wide-ranging goals undermines donor intent after a disaster, directors of new nonprofit organizations should prevent this from occurring.
The problems outlined in this section have already been the subject of widespread criticism. One commentator has derided these new organizations as “knee-jerk reactionary efforts” that waste “money and administrative resources.” The former head of the Charity Bureau in the New York Attorney General’s office described new disaster relief organizations as follows: “I doubt they have much impact. There were plenty of existing, accountable vehicles for donors to give to.” One charity watchdog group urged donors to “[a]void newly-formed charities” after a disaster, and urged charities to refrain from entering into the field of disaster relief when other organizations already had an infrastructure in place. Similarly, a report on the role of nonprofits after Hurricane Katrina revealed that new disaster relief organizations actually created conflict among existing public and nonprofit relief providers due to their lack of expertise. Finally, despite the fast-track tax-exemption...
program implemented after September 11th and Hurricane Katrina by Congress,\textsuperscript{65} even the Internal Revenue Service has conceded that disaster relief organizations with an established infrastructure are better equipped to serve disaster victims. The Internal Revenue Service described existing charitable organizations, such as the Salvation Army, United Way, and Red Cross as:

\begin{quote}
a more practical approach than the establishment of a new charitable organization. . . . In the rush to provide help, organizers spend time and funds establishing and qualifying a new charitable organization. This may be appropriate when the organizers have long-term goals or where no suitable existing charity is present.\textsuperscript{66}
\end{quote}

The echoed sentiment of these lawyers, self-regulatory and governmental agencies, clearly supports the proposition that new disaster relief nonprofit organizations, while lawfully formed, should be required to have active, responsible board members who can guide the organization’s staff as it raises money and serves disaster victims.

II. OVERVIEW OF STATE AND FEDERAL LAW

Nonprofit organizations are governed by state nonprofit corporation law and federal tax law.\textsuperscript{67} The disaster relief organization is typically a state incorporated nonprofit organization and a federally tax-exempt organization.\textsuperscript{68} This Part argues that state and federal laws fail to enforce fiduciary duties in such a way as to make new disaster relief organizations more financially accountable.

A. State Law

Nonprofit organizations can become state incorporated entities for any lawful purpose and are not pre-screened by the state or the judiciary.\textsuperscript{69} State judicial scrutiny over the nonprofit incorporation process, once the norm, eroded as a result of ideological changes and creating conflicts and even ignoring other organizations that had been working in the neighborhoods for years.

\textit{Id.} (quoting respondents to study of nonprofit participation in disaster relief).

\textsuperscript{65} See infra Part II.B for discussion of IRS “expedited” process.

\textsuperscript{66} See IRS, \textsc{Disaster Relief Report}, supra note 18; see also Lipman, supra note 2 (“When there’s a disaster, people’s first instinct is to say, ‘Let’s form an organization and collect money or goods. Let’s accomplish something.’ What we want people to do is take a breath and see if there’s an existing organization that could use their support before they go through all the expense related to forming a new organization. But if one does not exist, then we’re saying we will offer this expedited process.” (quoting Marvin Friedlander, senior manager in IRS exempt-organizations division) (internal quotation marks omitted)).

\textsuperscript{67} \textsc{Fishman & Schwarz, supra} note 4, at 60-61. Part II will address the law as it relates to charitable organizations as opposed to mutual benefit organizations and trusts.

\textsuperscript{68} Katz, \textit{supra} note 25, at 258.

\textsuperscript{69} \textsc{Norman I. Silber, A Corporate Form of Freedom: The Emergence of the Modern Nonprofit Sector} 83-115 (2001).
new scholarly arguments that constitutional rights of association and speech justified lenient rules for nonprofit formation. The nonprofit formation process mirrors that of corporations. However, unlike corporations, new nonprofit organizations normally incorporate and operate in the same state as a result of costs and the need to attract local donors. Today, as a result of the liberalization of state incorporation rules for nonprofit formations, new disaster relief organizations can form with ease despite the presence of numerous large and established public and nonprofit organizations already in the business of responding to disasters.

1. Fiduciary Duties

State law requires that board members abide by the duties of care, loyalty, and obedience. The duty of care merely obligates board members to make reasonably informed decisions, act in good faith, and carry out their role with the care of an “ordinarily prudent person.” The duty of loyalty requires board members to act in the best interests of the organization and bars them from engaging in a self-dealing transaction carried out at the expense of the organization. Accordingly, fiduciaries must make decisions with objectivity and receive approval from the corporation to complete any transaction involving a conflict of interest that impairs their objectivity. Lastly, the duty of obedience requires directors to faithfully carry out the goals of the organization. In general,

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70 Id. (discussing how the civil rights and women’s movements led to greater mainstream appreciation of the role that marginalized groups play in a strong political democracy when they are allowed to formally associate with one another through nonprofit legal entities).

71 Ellen P. Aprill, What Critiques of Sarbanes-Oxley Can Teach About Regulation of Nonprofit Governance, 76 FORDHAM L. REV. 767, 787 (2007); Jenkins, supra note 6, at 1165-68.

72 Lipman, supra note 2.

73 REVISED MODEL NONPROFIT CORP. ACT (RMNCA) § 8.30 (1987) (“A director shall discharge his or her duties as a director, including his or her duties as a member of a committee: (1) in good faith; (2) with the care an ordinarily prudent person in a like position would exercise under similar circumstances; and (3) in a manner the director reasonably believes to be in the best interests of the corporation.”). The American Bar Association’s RMNCA (1987) was adopted in twenty-three states and its original version (1952) was adopted in six states and the District of Columbia. PANEL ON THE NONPROFIT SECTOR, supra note 37, at 22; N.Y. NOT-FOR-PROFIT CORP. LAW § 717(a) (2005) (providing that “[d]irectors and officers shall discharge the duties of their respective positions in good faith and with that degree of diligence, care and skill which ordinarily prudent men would exercise under similar circumstances in like positions”); FISHMAN & SCHWARZ, supra note 4, at 167.

74 RMNCA § 8.31 (1987) (barring directors from engaging in a transaction where they have a direct or indirect financial interest unless it is disclosed to and approved by the board); N.Y. NOT-FOR-PROFIT CORP. LAW § 715 (2005) (when a board member has a “substantial financial interest” in a transaction it must be disclosed in good faith to the rest of the board); FISHMAN & SCHWARZ, supra note 4, at 176-79.


76 FISHMAN & SCHWARZ, supra note 4, at 219 (describing how a director may be sued if a corporation enters into an ultra vires transaction that is not contemplated by its governing legal documents); Smith, supra note 75, at 26.
the duty of obedience is less important today in order to allow a nonprofit organizations to operate with flexibility.77

The duties of care and loyalty are not meaningful constraints on management for numerous reasons.78 The duty of care is ambiguous because state statutes do not clearly specify the extent to which a board member should monitor the activities of the organization.79 The duty of loyalty is difficult to enforce because conflicts of interest are extremely common in the nonprofit sector.80 More significantly, donors and consumers of nonprofit services do not have a private right of action against a nonprofit’s directors.81 Finally, while the duties of care and loyalty can be enforced by state Attorneys General in lieu of donors and consumers, enforcement by the public sector is rare.

2. Enforcement by State Attorneys General

Despite its limited resources, prosecution by the charity bureau of the state Attorney General for fiduciary duty violations is the most valuable state regulatory constraint over nonprofits.82 The Red Cross scandal illustrates this fact. Just after the terrorist attacks of September 11, 2001, the Red Cross created the “Liberty Fund,” which, rather than merely assisting September 11th victims, more closely resembled a “war

77 FISHMAN & SCHWARZ, suprarnote 4, at 219 (describing the duty of obedience as analogous to the “emasculated” ultra vires doctrine in corporate law); Linda Sugin, Resisting The Corporatization of Nonprofit Governance: Transforming Obedience into Fidelity, 76 FORDHAM L. REV. 893, 897 (2007) (explaining that fiduciary “duty of obedience” has become the “stepchild” of nonprofit fiduciary duties because charity goals simply could not be met if nonprofits were held to such a narrow, rigid standard, and arguing for a more flexible duty of obedience standard).

78 FISHMAN & SCHWARZ, supra note 4, at 149 (“The fiduciary obligation is notably elusive as a concept. The particular duties it imposes vary in different contexts, as does the justification for imposing the obligation itself.”).

79 Karyn R. Vanderwarren, Note, Financial Accountability in Charitable Organizations: Mandating an Audit Committee Function, 77 CHI.-KENT. L. REV. 963, 968 (2002) (“Noticeably absent from the Model Act are any expectations that directors ensure that management is engaging in sound practices.”).

80 FISHMAN & SCHWARZ, supra note 4, at 176-78 (“Conflicts of interest, divided loyalties, and transactions among directors, officers, and charitable corporations abound in the nonprofit sector. Breaches of loyalty are not only much easier to identify than breaches of care, they are more prevalent.” Typical breaches may include using the organization’s property for more than de minimis personal use and paying high salaries to directors that are not in the best interest of the organization.).

81 Evelyn Brody, Agents Without Principals: The Economic Convergence of the Nonprofit and For-Profit Organizational Forms, 40 N.Y.L. SCH. L. REV. 457, 466-67 (1996) (“[B]ecause of the lack of classes of private persons with standing to sue, in many ways this fiduciary duty is really a legal obligation without a legal sanction.”) (footnotes omitted); Evelyn Brody, From the Dead Hand to the Living Dead: The Conundrum of Charitable Donor Standing, 41 GA. L. REV. 1183, 1188 (2007) (“[T]he traditional rule that a donor lacks standing to complain in court about a charitable donee’s use of a restricted gift can baffle and even infuriate.”); Manne, supra note 9, at 236.

82 Manne, supra note 9, at 251 (“The attorney general is the most important, and probably least well-equipped, source of enforcement in the charitable sector.”).
fund” for new, imminent terrorist attacks and possible military action.\(^{83}\) This was a departure from the typical practice, used for more than a century of serving disaster victims, where the Red Cross had put all donations into one general, multi-disaster fund.\(^{84}\) Donors, media, and Congress scrutinized and condemned the broader purpose of the Liberty Fund.\(^{85}\) The Attorney General of New York accused the Red Cross of acting fraudulently and ordered the agency to spend its funds on only 9/11 victims’ families.\(^{86}\) The agency soon changed its position and allocated all present and future donations to the Liberty Fund—over $1 billion—to the short and long-term needs of victims’ families.\(^{87}\)

The New York Attorney General’s actions represented a rare example of a threat of prosecution against a charity for violating its duty of care, which encompasses the obligation to honor the intent of donors.\(^{88}\) Yet, fiduciary duty violations in the nonprofit sector are said to occur elsewhere “with unsettling frequency.”\(^{89}\) Prosecution by state Attorneys General occurs on behalf of the public only in extreme cases due to limited staff and resources.\(^{90}\) Extreme lapses commonly include cases of intentional wrongdoing, such as embezzlement, by a nonprofit staff or board member,\(^{91}\) whereas fraudulent aid applicants are themselves prosecuted by the district attorney pursuant to criminal law. Lastly, Attorneys General have incentives not to prosecute problems in the

\(^{83}\) Katz, supra note 25, at 308-09 (“When she created the Liberty Fund, Dr. Bernadine Healy believed that future terrorist attacks were imminent, and that the United States Government was mobilizing for military action. She was summoning the agency to shift into war mode, and to do so on a scale not seen since the world wars. In this respect, the Liberty Fund was a war fund. Its monies were restricted in the sense that they would only be used to support agency activities related to preparing and responding to anti-U.S. terrorist attacks and U.S. military action. The Red Cross retained discretion to allocate funds among this broad set of activities as it saw fit.”) (internal quotations omitted).

\(^{84}\) Deborah Sontag, Who Brought Bernadine Healy Down?, N.Y. TIMES, Dec. 23, 2001, § 6 (Magazine), at 81 (“Since the Red Cross can raise serious money only in the wake of a high-profile disaster, it uses the high-profile disasters to beef up general disaster-relief funds. . . . This practice of the Red Cross has come under fire many times—after the San Francisco earthquake of 1989, the Oklahoma City bombing of 1995, the Red River floods of 1997, the wildfires in the San Diego area last January.”).

\(^{85}\) Katz, supra note 25, at 312.

\(^{86}\) Id. at 316-18 (discussing the difficulty in ascertaining donor intent).

\(^{87}\) Id. at 280-81(explaining that despite the broad discretion given to charities to spend the money the way that they want, and despite the Internal Revenue Service’s initial reluctance to allow victims’ families to receive funds even when they were not financially needy, the Red Cross scandal prompted a change in tax law).

\(^{88}\) Id. at 280, 287.

\(^{89}\) Fishman & Schwarz, supra note 4, at 150.

\(^{90}\) Brody, supra note 81, at 486 (discussing Attorney General standing in place of shareholders but only in the “extreme case of malfeasance”); Dana Brakman Reiser, There Ought to Be a Law: The Disclosure Focus of Recent Legislative Proposals for Nonprofit Reform, 80 CHI.-KENT L. REV. 559, 598 (2005) (discussing that state AGs offices have very limited resources); see also Boozang, supra note 7, at 115-16 (“[A]ttorneys general have great difficulty obtaining information about nonprofit corporations’ internal operations, and most states are functionally and financially incapable of dealing with anything but the most egregious nonprofit behavior.”); Manne, supra note 9, at 237.

\(^{91}\) Fishman, supra note 7, at 236.
nonprofit sector aggressively. They are elected by the public and pursue nonprofit cases when it is politically advantageous. Yet, the public is rarely interested in seeing do-gooders prosecuted. The New York Attorney General’s role in pressuring the Red Cross to allocate all of its 9/11 donations for the aftermath of that disaster was unique in that regard.

Even if a suit is brought against directors of a disaster relief organization, the business judgment rule provides significant protection from liability for “unwise or erroneous” decisions. Further strengthening this shield from liability is the fact that it is difficult to link a director to any damage done to the organization because a nonprofit organization lacks a “bottom line” of profit. Even if the business judgment rule did not apply, rigorous enforcement of fiduciary duty obligations would likely not be pursued due to policy considerations, including the fact that the threat of litigation against nonprofit fiduciaries interferes with everyday decision-making, impedes innovation, and deters people from volunteering to join boards. Thus, relying on state Attorneys General to enforce the fiduciary duties of new disaster relief organizations does not prevent the fraud, theft, and waste that may plague such organizations.

B. Federal Tax Law

Nonprofit governance is under the jurisdiction of state law. Yet, federal tax law can indirectly enforce state fiduciary duty law more effectively than state law or state Attorneys General because the Internal Revenue Services screens applications for tax-exempt status and examines tax returns. While the entire tax code does not even include the word “governance,” the Internal Revenue Service is becoming more effective in enforcing nonprofit accountability, as evidenced by the increased scrutiny of nonprofit financial reports and the imposition of penalties for noncompliance.

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92 Manne, supra note 9, at 251.
93 Katz, supra note 25, at 258, 312; Sesele, supra note 12, at 32 (describing the “public outcries” over the Red Cross allocation of money for future disasters though it had been soliciting funds for what people thought was an exclusively 9/11-related “Project Liberty” Fund).
95 Fishman & Schwarz, supra note 4, at 142 (“The bottom line, the talisman of profit-seeking activity, is easier to measure than nonprofit effectiveness.”).
96 Katz, supra note 25, at 279-80 (discussing how courts do not order nonprofits to spend their money in particular ways based on the deference to nonprofits under the “best judgment rule,” the nonprofit analogue to the private sector “business judgment rule”).
97 Brakman Reiser, supra note 94, at 231-33.
98 Fishman & Schwarz, supra note 4, at 157-58 (describing the “widespread attitude that nonprofit directors are essentially volunteers, and aggressive attempts to enforce their responsibilities are inappropriate and will discourage individuals from board service” and concluding that “courts and attorneys general tend to be overly solicitous of directors, which may explain why so few cases reach trial”).
99 Fishman, supra note 7, at 265 (“Though the attorney general historically has been responsible for charities’ accountability, because of a lack of resources, the IRS has become the primary regulator of nonprofit behavior. The IRS’s Division of Tax-Exempt and Government Entities is responsible for regulatory oversight.”).
involved in promoting good governance due to the belief that it will lead to tax law compliance.\textsuperscript{100}

1. Weak Enforcement

Three main tax rules could make disaster relief organizations more financially accountable and effective: the bar against private benefit, the bar against inurement, and the intermediate sanctions rule. Section 501(c)(3) of the Federal Internal Revenue Code provides that a tax-exempt organization must be organized for charitable purposes.\textsuperscript{101} Accordingly, tax-exempt disaster relief organizations must serve the poor, distressed, or underprivileged.\textsuperscript{102} Tax-exempt organizations are barred from allowing any person with a personal or private interest in the organization to receive any undue financial benefit.\textsuperscript{103} Similarly, they are barred from allowing any disinterested outsider to receive a substantial financial benefit even if it is incidental to the charitable operation of the organization.\textsuperscript{104} Violations of either rule can lead to revocation of tax-exempt status.\textsuperscript{105} As an alternative to revocation of its tax-exempt status, an organization may merely receive penalties for any “excess economic benefits” under the intermediate sanctions rule.\textsuperscript{106} However, this penalty is only imposed after there has been some misuse of funds and does not preempt fraud, theft, and waste of funds.\textsuperscript{107}

2. New Governance Reporting

Federal tax reporting requirements are, by their very nature, unable to deter fraud, theft, and waste and do not incentivize compliance with fiduciary duties so as to prevent such malfeasance from occurring.\textsuperscript{108} Ongoing compliance for tax-exempt status requires the filing of a Form 990 tax return that declares income, assets, expenses, fundraising

\textsuperscript{100} See Remarks of Steven T. Miller, Commissioner of Tax and Government Entities of the Internal Revenue Service, Given at the Panel on Nonprofit Governance at the Western Conference on Tax Exempt Organizations in Los Angeles, California (November 20, 2008), http://www.irs.gov/pub/irs-tege/stm_loyolagovernance_112008.pdf [hereinafter IRS Commissioner Speech] (describing the IRS’s new involvement in governance).
\textsuperscript{102} IRS DISASTER RELIEF REPORT, supra note 18, at 4.
\textsuperscript{103} Treas. Reg. § 1.501(c)(3)-1(c)(2) (2007).
\textsuperscript{104} Id. §§ 1.501(c)(3)-1(c)(1), 1.501(c)(3)-1(d)(ii) (2007).
\textsuperscript{105} Id.; see supra note 103.
\textsuperscript{106} I.R.C. § 4958 (2006); FISCHMAN & SCHWARZ, supra note 4, at 476 (“Historically, the Service has invoked the inurement limitation only in the most egregious cases of insider conduct. Since the only sanction was the ultimate death sentence—revocation of exemption—enforcement was lax.”).
\textsuperscript{107} SILBER, supra note 69, at 151-58 (arguing that regulation of organizations should not be based on federal tax law, which primarily reviews revenue, and does not look for other problems).
\textsuperscript{108} Id.
expenses, and a list of the highest paid salaries.\textsuperscript{109} Medium to large organizations that fail to file a Form 990 are fined, but only a continuous failure to file will result in the revocation of an organization’s tax-exempt status.\textsuperscript{110} Small organizations with budgets of less than $25,000 that were not previously required to file a Form 990 tax return are now required to file an “electronic postcard” tax return and will similarly have tax-exempt status revoked if they do not do this for three years.\textsuperscript{111} To the extent that reporting requirements deter malfeasance, the public remains unable to sue even if the itemized financial information, made available to the public, allowed for allegations of fraud, theft, or waste.\textsuperscript{112}

In a major new initiative to promote good governance practices, the Internal Revenue Service revised the annual Form 990 to include a detailed set of questions about governance, management, and disclosure.\textsuperscript{113} An entire section in the new annual tax return form includes questions about internal controls and the board’s composition, compensation, and independence.\textsuperscript{114} “We care about governance because we believe . . . that a well-governed organization is more likely to be compliant with the tax law, while poor governance can easily lead to trouble.”\textsuperscript{115} The agency commissioner also remarked that the IRS would enter into a “dialogue” and make “recommend[ations]” with an organization about good governance practices whether or not there was a link between governance and a tax law compliance problem.\textsuperscript{116} Additionally, the commissioner stated that the IRS would use new software in 2009 that would ask tax-exempt status applicants questions about governance in order to educate and promote good governance practices at the outset of the tax-exemption process.\textsuperscript{117} It is unclear to what extent the IRS can require organizations to have certain governance structures in place.\textsuperscript{118}

\textsuperscript{110} IRS COMPLIANCE GUIDE, supra note 109, at 10.
\textsuperscript{111} Id. at 9-10.
\textsuperscript{112} Vanderwarren, supra note 79, at 974.
\textsuperscript{113} IRS Commissioner Speech, supra note 100.
\textsuperscript{115} IRS Commissioner Speech, supra note 100, at 3.
\textsuperscript{116} Id. at 5.
\textsuperscript{117} See id. at 6.
\textsuperscript{118} Christopher Quay & Fred Stokeld, IRS’s Lerner Details Discussion Draft of Resigned Form 990, TAX NOTES TODAY, June 15, 2007 (“It is relevant to both ask whether the IRS should be incentivizing behavior which is not required by the Internal Revenue Code and for which there is no direct connection to requirements of the Internal Revenue Code.” (quoting Suzanne Ross McDowell, Steptoe & Johnson LLP) (internal quotation marks omitted)).
3. Disaster Relief Compliance with Tax-Exempt Criteria

All disaster relief organizations have to abide by specific criteria, though no federal enforcement that is specifically tailored to the disaster relief context ensures that these criteria are met. To apply for tax-exempt status, one need only fill out a formal application and provide a description, with supporting documents, of the organization’s current and future financial activities, services, and governance structure.119 A new organization that has been incorporated to serve victims of disasters can apply for tax-exempt status when it serves a charitable purpose fulfilled through assistance to disaster relief victims.120

According to an IRS publication, the disaster relief organization must abide by three main criteria.121 First, the organization must provide aid to a “large or indefinite” charitable class in such a way as to benefit a community that has been affected by a disaster, as opposed to a few injured individuals hurt in an accident.122 For example, in the case of September 11th, the narrowest legal class involves families of groups such as uniformed personnel, those on the airplanes, or those killed in the World Trade Center.123 A more expansive and acceptably defined class might include low-wage workers or displaced residents of lower Manhattan.124 Second, the organization must establish and use a “needy or distressed test” that objectively evaluates individual victims to determine whether they are financially needy at the time of the grant.125 Third, the organization must maintain records demonstrating that the assistance was provided to meet a victim’s particular needs.126 Even a wealthy disaster victim could be “needy and distressed” in the immediate aftermath of a disaster and a relief organization could lawfully provide that victim with blankets, food, and crisis counseling.127 Documentation should describe the aid, why it was given, the charity’s objective criteria of a victim’s needs, how that analysis was done for each victim, contact information and award size for each victim, and disclosure of any relationship between an assisted victim and an organizational insider.128

The problem with the needy and distressed test is that the IRS defers to the organization to analyze and provide relief for victims in a

119 PANEL ON THE NONPROFIT SECTOR, supra note 37, at 10.
120 Adler & Rosen, supra note 47, at 297; see IRS DISASTER RELIEF REPORT, supra note 18, at 2.
121 IRS DISASTER RELIEF REPORT, supra note 18, at 5-10; see also Katz, supra note 25, at 259-61.
122 IRS DISASTER RELIEF REPORT, supra note 18, at 5-7; Catherine E. Livingston, Disaster Relief Activities of Charitable Organizations, 35 EXEMPT ORG. TAX REV. 153, 156 (2002).
123 See Katz, supra note 25, at 267.
124 See id.
125 IRS DISASTER RELIEF REPORT, supra note 18, at 7-8.
126 Id. at 9-10.
127 Id. at 7.
128 Id. at 9-10.
way that furthers the charitable purpose of the organization. As a result, disaster relief organizations run by inexperienced people have latitude in how to disburse funds and can be particularly prone to fraud, theft, and waste. The organization must simply use its best efforts to further its charitable purpose and evaluate “all pertinent circumstances” of a victim’s financial situation to avoid bestowing upon them the impermissible private financial benefit. Nonprofits do not have any obligation to make victims “whole” again, yet disaster relief organizations may use the needy and distressed test to provide wealthy victims with longer-term assistance in the form of services.

Finally, two further legal developments impacted the field of nonprofit disaster relief work. First, the relaxation of the needy and distressed test in 2001 enabled disaster relief organizations to provide cash to wealthy victims who were no longer needy and distressed as the test was traditionally construed. While not enacted after later disasters, the new law established an ongoing social norm that disaster relief organizations’ proper and effective role is to raise and expeditiously give away money to a narrow class of victims. Second, an expedited tax-exempt process established after September 11th and Hurricane Katrina has reinforced a social norm that disaster relief organizations can be run by inexperienced people despite the existence of established, existing disaster relief organizations. Any individual, regardless of past professional experience, can easily form a federally tax-exempt nonprofit corporation to serve victims of a disaster.

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129 Id. at 8 (“A charitable organization is responsible for taking into account the charitable purposes for which it was formed, the public benefit of its activities, and the specific needs and resources of each victim when using its discretion to distribute its funds.”).

130 Id. at 11; Katz, supra note 25, at 263-64 (“In addition to aiding a sufficient number of persons, a charity cannot provide too much aid relative to the charitable goals that it ostensibly advances. . . . More broadly, an exempt organization cannot provide excess benefits to any private entity or individual, including organizational outsiders. This is known as the ‘private benefit’ doctrine.”) (footnotes omitted).

131 Id. at 7-8 (emphasizing that disaster relief aid is not tantamount to providing something akin to insurance payouts); Katz, supra note 25, at 271 (“[D]isaster relief is not insurance.”); Livingston, supra note 122, at 156.

132 IRS DISASTER RELIEF REPORT, supra note 18, at 7.

133 Victims of Terrorism Tax Relief Act of 2001, 26 U.S.C. § 501 (2006); IRS DISASTER RELIEF REPORT, supra note 18, at 7, 10-11. This resulted in families of 9/11 victims receiving approximately $1.78 million each. See Press Release, Department of Justice, Monday, December 22, Is Deadline to File Claim in September 11th Victim Compensation Fund (Dec. 18, 2003), available at http://www.usdoj.gov/opa/pr/2003/December/03_civ_708.htm (“The average amount of compensation paid to date to the families of those who died on September 11 is $1.78 million. Individual death compensation amounts have ranged from $250,000 to $6.9 million. Those physically injured as a result of the attacks have received Fund compensation ranging from $500 to $7.9 million.”).

134 Stephanie Strom, Here’s My Check, Spend It All at Once, N.Y. TIMES, Jan. 20, 2008 (providing support for the proposition that after a disaster donors now expect to direct their funds wherever they choose despite the fact that the victims may not need additional funds and the organization may need to use funds for another purpose).
Through the disaster-relief specific expedited process, individuals have received tax-exempt status in a mere few days, rather than sixty days or six months in the normal application and approval process. The goal of the expedited process is to allow nonprofit providers to raise money through a tax-exempt organization to meet the unmet needs of disaster victims. While the number of disaster relief groups formed through the expedited process represents a small number of the total applications approved for tax-exempt status every year, the policy has received heavy criticism. Because the federal law and regulations have allowed formation of new disaster relief organizations run by inexperienced people, governance reform is needed to ensure that these organizations reduce the potential for theft, fraud, and waste.

III. PROPOSED FINANCIAL OVERSIGHT COMMITTEE IN NEW DISASTER RELIEF ORGANIZATIONS

Part III proposes that new disaster relief organizations can be effectively regulated by a financial oversight board committee specifically geared to reducing theft, fraud, and waste. This Part describes the type of comprehensive financial oversight committee tasks that may improve the financial accountability of new disaster relief organizations and considers the limits of such a proposal. This Part further considers the advantages and limitations to the enforcement of the financial oversight committee by public agencies, accrediting agencies, and large funders. Part III ultimately argues that despite the limitations discussed, the prevention of theft, fraud, and waste will improve the accountability of new disaster relief organizations, better meet the acute

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135 See IRS DISASTER RELIEF REPORT, supra note 18, at 3 (requiring only a cover letter and brief description of the disaster and explaining why there is a need for urgent processing of tax-exempt status); Strom, supra note 3 (describing how an organization called “Drop Yer Drawers” received tax-exempt status within eight days after applying, and another organization, Angel Pray Child Charity Foundation, of Pennsylvania, received tax-exempt status in fifteen days though as of 2006 it had not served any children victimized in the Hurricane).

136 Strom, supra note 3.

137 IRS DISASTER RELIEF REPORT, supra note 18, at 2-3; Where Most Needed, IRS Too Responsive after Katrina, Say Critics, http://www.wheremostneeded.org/2006/03/irs_too_respons.html

138 Where Most Needed, supra note 137 (describing how IRS adds 80,000 new organizations per year); see also Lipman, supra note 2; Strom, supra note 3; supra Part I.D (describing new organizations that received expedited tax-exempt status, and criticism of the expedited process).

139 FRANCIE OSTROWER, NONPROFIT GOVERNANCE IN THE UNITED STATES: FINDINGS ON PERFORMANCE AND ACCOUNTABILITY FROM THE FIRST NATIONAL REPRESENTATIVE STUDY 16 (2007), available at http://www.urban.org/UploadedPDF/411479_Nonprofit_Governance.pdf (last visited Jan. 21, 2008) (concluding that even though small nonprofit organizations reported to the study that they would have difficulty implementing governance reforms, “[h]aving organizational members that elect one or more board members was positively associated with activity in multiple internal and externally oriented roles (e.g., fundraising, financial oversight, planning, monitoring programs, setting policy).”)
and long-term needs of disaster victims, and restore the nonprofit sector’s tarnished reputation.

A. Overview

The financial oversight committee should primarily ensure that a new disaster relief organization has systems in place to assess and manage the risks involved in receiving and allocating large sums of money.\(^{140}\) The concept of a financial oversight committee improves upon existing reforms that call for audit committees only when an organization reaches a certain size.\(^{141}\) Instead, a board committee focused on financial oversight should be mandated regardless of the organization’s size. Such a mandate should be enforced through government agencies, self-regulatory bodies, and large funders because current legal channels cannot ensure financial accountability until after fraud, theft, or waste have already occurred.\(^{142}\)

While the formalization of a board committee specializing in financial oversight may be the most traditional type of governance reform in terms of mirroring governance structures required in publicly held corporations,\(^{143}\) it is also the most appropriate governance reform for new disaster relief organizations precisely as a result of its “concreteness.”\(^{144}\) This will ground the board in refining policies and procedures around one metric, as opposed to metrics that are hard to define such as whether or not the organization is best serving disaster relief victims. Moreover, the clear delineation of responsibilities among board members, a rarity in new nonprofit organizations,\(^{145}\) may even

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\(^{140}\) Vanderwarren, supra note 79, at 986-87 (persuasively arguing how a formalized audit committee can prevent theft at small organizations despite the fact that it is widely assumed that small organizations do not need formalized board committees).

\(^{141}\) The California Nonprofit Integrity Act of 2004 requires nonprofit organizations to have an audit committee comprised of people who do not serve as staff members when gross revenues reach $2 million per fiscal year. CAL. GOV’T CODE § 12586(e)(2) (West 2009); Aprill, supra note 71, at 770-73 (describing how the Nonprofit Integrity Act requires an audit committee for organizations with revenue of $2 million per year, whereas the Panel on the Nonprofit Sector had proposed that organizations with revenues of $1 million per year should have audit committees, and the Senate had proposed that organizations with revenue of just $250,000 per year should have audit committees).

\(^{142}\) Analyses of how to enforce reforms through public and private channels is common in nonprofit legal scholarship. For some examples of these analyses, see Fishman, supra note 7, at 272-75 (arguing for state “charity commissions” situated in each judicial district and composed of private citizens appointed by the governor); Mark Sidel, The Guardians Guarding Themselves: A Comparative Perspective on Nonprofit Self-Regulation, 80 CHI.-KENT L. REV. 803, 830-34 (2005) (lauding the self-regulatory standards established by the Maryland Council of Nonprofit Associations); Vanderwarren, supra note 79, at 987 (arguing that governance oversight can potentially prevent scandals).

\(^{143}\) Brakman Reiser, supra note 94, at 258-68. New governance requirements proposed in New York and Massachusetts, and incorporated into in California law, were based on Sarbanes-Oxley corporate requirements of board composition, committees and duties. Id.

\(^{144}\) Cf. id. at 222 (describing the “concreteness” of financial accountability as suitable focus of the Attorney General).

\(^{145}\) Fishman & Schwarz, supra note 4, at 218.
trigger the formation of similar committees in other areas of governance and provide for an altogether better board of directors.146

1. Composition

First, the financial oversight committee should be comprised of “independent” members. This requirement responds to the assumption that a dispassionate and objective perspective results in improved decision-making and financial accountability.147 Board members are considered independent when they are not employed by the organization, receive no financial compensation from the organization, and are not in the immediate family of other board or staff members.148 The need for independent directors reflects an ongoing debate in corporate and nonprofit law.149 Therefore, the requirement of a financial oversight committee composed of independent members at even new disaster relief organizations would be consistent with some state laws and recent governance proposals.

The ever-present problem of how to form this committee at a small organization150 could be solved by allowing the committee to be flexibly comprised of any number of board members that best suits the size of the organization.151 In fact, disasters may provide the best environment for new organizations to be connected to independent financial oversight committee members. Because disasters galvanize emotion and support, new organizations may have access to numerous pro bono, financially literate volunteers who want to help victims in a meaningful way.152 Accordingly, financial oversight committees might

146 Boozang, supra note 7, at 131 ("A strong and qualified board will work only if it knows what is really going on inside the organization.").
148 PANEL ON THE NONPROFIT SECTOR, supra note 37, at 23 (proposing that two-thirds of the board of a charity should be “independent” in that they (1) do not receive compensation as an employee; (2) do not receive compensation that is determined by someone who is compensated by the organization; (3) do not stand to materially, financially benefit from the organization; and (4) are not related to and do not live with individuals described in (1), (2) or (3)).
149 See supra notes 145-147; see supra note 37 (proposing a supermajority of independent directors who meet certain criteria). In contrast, New Hampshire requires that all boards comprise a minimum of five members who are not “of the same immediate family or related by blood or marriage.” N.H. REV. STAT. § 292.6-a (1999); California requires that not more than forty-nine percent of a board may be “interested,” in that they cannot be compensated by the organization or cannot be a “brother, sister, ancestor, descendant, spouse, brother-in-law, sister-in-law, son-in-law, daughter-in-law, mother-in-law, or father-in-law” of any compensated person. CAL. CORP. CODE. § 5227 (2009).
150 OSTROWER, supra note 139, at 22 (describing how small organizations have reported themselves to have difficulty implementing governance mandates).
151 Boozang, supra note 7, at 129 (endorse as least a few “formally designated” monitoring directors to improve governance); Vanderwarren, supra note 79, at 983 (describing how a committee convened specifically to monitor the external auditor does not need to be “one-size-fits-all”).
152 Id. at 770 (describing how criticism of independent director requirements has centered on the low likelihood that anyone would have “adequate time, incentives, and information to conduct effective oversight” (internal quotations omitted)).
easily draw members from accountant trade associations who are able to fulfill the committee roles with very little training and oversight. Finally, in a new disaster relief organization with a sizable budget, a committee with multiple board members may be appropriate. However, even in a new and small disaster relief organization, the financial oversight committee function could be accomplished through even one board member.

B. How a Financial Oversight Committee Will Mitigate Theft, Fraud, and Waste

1. Reduced Theft and Fraud

The committee should guide the staff and board in the decision-making process so that the organization spends funds in accordance with tax-exempt guidelines. Because the circumstances in which new disaster relief organizations operate allow inexperienced managers and staff easy access to liquid assets, it is imperative that such liquid assets are not solely received and spent through the “complete and unchecked access” of management and staff. In doing so, financial oversight committees should strive to check the behavior of the grief-stricken disaster relief executive director who, in receiving checks left and right, can siphon funds away. Additionally, if the organization provides cash assistance that requires a needy and distressed test analysis, the financial oversight committee should regularly review how that analysis is being done. At a minimum, the financial oversight committee should be educated and trained to understand that the unique circumstances of disaster aftermath can lead an organization to experience a cash windfall, and appreciate the risk involved in rushing to provide aid to individuals whose claims may be fraudulent.

2. Reduced Waste

Through continuous review of policies and procedures grounded in receiving and allocating money, the financial oversight committee will also serve a programmatic function. The committee should decide which programs to fund in order to protect the long-term health of the organization. This requirement would essentially formalize the

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153 Vanderwarren, supra note 79, at 981 (“Many CPA societies have a public interest section geared at helping small nonprofit organizations recruit board members.”).
154 IRS DISASTER RELIEF REPORT, supra note 18, at 5-8 (describing the requirements of analyzing needy and distressed victims, and recording the information adequately).
155 See supra Part II.A for a description of embezzlement by the founding director of a new disaster relief organization.
156 Vanderwarren, supra note 79, at 983.
157 Barron, supra note 19.
158 IRS DISASTER RELIEF REPORT, supra note 18, at 7.
recommendation made by existing regulators that board members should evaluate programs, particularly in the wake of a disaster. Additionally, an independent financial oversight committee should oversee how money is spent by highly charged, emotional, and even grief-stricken staff members.

Critics of board committee requirements contend that nonprofits should spend their resources on more process-oriented reforms. The nonprofit sector is already resource-strapped and new organizations may be less inclined to expend resources on implementing novel governance practices. Additionally, donors might dislike the fact that disaster relief organizations will focus on governance, not victims. However, the promulgation of sector-wide standards for a financial oversight committee, especially if enforced effectively, may diffuse donors’ anxieties about more Red Cross type scandals and enable new disaster relief organizations to form and rely on financial oversight committees.

Finally, while some optimism in the less bureaucratic channels of small disaster relief organizations is warranted, this should not be taken to mean that no governance committee is necessary. Small, new disaster relief organizations providing cash assistance might screen victims more carefully than a large organization like FEMA or the Red Cross in order to eliminate fraudulent applicants. However, small nonprofit organizations are as likely, if not more so, to experience theft and waste of funds as larger nonprofit organizations. Furthermore, the intimacy and informality of small nonprofits warrant a greater need for

160 See generally Mulligan, supra note 8; see also Aprill, supra note 71, at 771; Brakman Reiser, supra note 90, at 593.
161 Nonprofit legal scholars commonly argue that government regulation of nonprofit governance leads to agency costs that may detract from the money spent on the mission. For examples of these arguments, see Brakman Reiser, supra note 90, at 586 (“If the burdens of compliance with regulation push nonprofits to scale back their programs or force them out of existence, beneficiaries, communities, and society will bear a real loss.”); Manne, supra note 9, at 244 (condemning costs bound to be incurred by nonprofits through state review boards); Mulligan, supra note 8; Wendy K. Szymanski, An Allegory of Good (and Bad) Governance: Applying the Sarbanes-Oxley Act to Nonprofit Governance, 2003 UTAH L. REV. 1303, 1316-20 (2003) (government mandated board duties designed for private corporations are inapplicable to nonprofits that depend on donations for operating costs).
162 Strom, supra note 134 (providing timely support for the proposition that donors following a disaster do not want their money going to the organization’s overhead or administrative expenses).
163 See infra Parts III.A-C for a discussion of how various entities may offer effective enforcement of a financial oversight committee function within new disaster relief organizations.
164 Small nonprofit organizations are generally more community-oriented and therefore can interact in a more flexible way with victims of a disaster. See DISASTER RELIEF AND RECOVERY, supra note 40, at 8 (“Nonprofits organizations with roots in the community are well-positioned to provide appropriate services, such as skills training, resume services and job placement, and to take advantage of wage subsidies.”).
165 Vanderwarren, supra note 79, at 986-87 (describing the “small-time scandal” of Illinois Federation of Families, where nearly $50,000 was stolen); Barron, supra note 19.
segregation of duties and a financial oversight committee that prevents management’s unchecked access to funds.\textsuperscript{166} No governance reform can guarantee an end to theft, fraud, and waste. However, board members with a “blueprint”\textsuperscript{167} of how to run a good organization with strong accounting practices and internal controls are unequivocally in a better position to mitigate and prevent such problems.\textsuperscript{168}

C. Enforcement

1. Government Enforcement

New state statutes requiring financial oversight committees for such a narrow category of nonprofit activity is unlikely. However, public sector agencies should mandate the formation of financial oversight committees in the boards of directors of new disaster relief organizations. This would formally integrate the federal and state governments’ liberal tax-exempt and incorporation laws, respectively, with their own recommendations for good governance practices.\textsuperscript{169} Such heightened fiduciary duties might be effectively enforced by the Internal Revenue Service or state Attorneys General.

The federal government can successfully enforce a financial oversight committee at a new disaster relief organization for various reasons. First, the federal government already regulates financial reporting of tax-exempt organizations,\textsuperscript{170} it has already recommended standards for good governance for tax-exempt organizations,\textsuperscript{171} it already regulates governance requirements in publicly-traded corporations,\textsuperscript{172} and it already leads disaster relief efforts through the Federal Emergency Management Agency (FEMA). However, it is likely too farfetched to suggest that a blending of all of these responsibilities would occur at the federal level. While commentators have advocated the creation of a federal agency that regulates nonprofit governance analogous to the Securities and Exchange Commission, the day has not yet come.\textsuperscript{173}

\begin{footnotesize}
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\item \textsuperscript{166} OSTROWER, supra note 139, at 22 (“Smaller nonprofits that engage in financial transactions need to have more formal policies in place . . . .”); Vanderwarren, supra note 79, at 983.
\item \textsuperscript{167} Brakman Reiser, supra note 90, at 590.
\item \textsuperscript{168} Id. (discussing how internal controls, when defined, can “provide a blueprint for how to accomplish such improvements . . . by demanding the creation of individualized internal controls within organizations”).
\item \textsuperscript{169} See IRS, GOVERNANCE AND RELATED TOPICS—501(c)(3) ORGANIZATIONS 8, available at http://www.irs.gov/pub/irs-tege/governance_practices.pdf (last visited Mar. 6, 2009) (“[A] charity with substantial assets or revenue should consider obtaining an audit of its financial statements by an independent auditor. The board may establish an independent audit committee to select and oversee an independent auditor.”).
\item \textsuperscript{170} See supra Part II.B.2.
\item \textsuperscript{171} Id.; Aprill, supra note 71, at 783.
\item \textsuperscript{172} ARTHUR PINTO & DOUGLAS M. BRANSON, UNDERSTANDING CORPORATE LAW 128-32 (LexisNexis 2004).
\item \textsuperscript{173} Fishman, supra note 7, at 268.
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Federal Emergency Management Agency (FEMA), with its pre-existing grantor-grantee relationships with numerous, smaller disaster relief organizations, should perhaps be required to make its own post-disaster grants contingent upon the formation of a financial oversight committee function in new disaster relief organizations. However, the reputation of FEMA is so mired in controversy surrounding its own lack of financial accountability that it would also be unrealistic to expect it to require good governance practices in grant recipient organizations after the next disaster. Lastly, if the IRS required a financial oversight committee, it is unclear what it would do to penalize organizations that do not comply. Tax revocation is not clearly within the remit of the federal government on the issue of nonprofit governance. Ultimately, the limited resources of the federal government might make it impossible for the federal government to effectively regulate the governance of the nonprofit sector, in all of its breadth, and perhaps its role should be limited to reflect this. Critics that wish to maintain regulation in states, despite states’ very lax regulatory environment, disapprove of the general extension of this “federalization” of the nonprofit sector.

The IRS may only be left with a limited but important role of education at the outset of the tax-exemption process and also in response to information gathered in Form 990s. First, governance recommendations for financial accountability after a disaster should be included in the application process for tax-exempt status. Second, the two pamphlets cited in this Note, one for disaster relief, and another one for good governance practices, should at the very least be integrated, published, and disseminated each time a new disaster relief organization receives tax-exempt status. Finally, the IRS should base renewal of tax-

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175 Spencer S. Hsu, Leaders Lacking Disaster Experience, WASH. POST, Sept. 9, 2005, at A01 (“[I]nexperience in FEMA’s top ranks is emerging as a key concern of local, state and federal leaders as investigators begin to sniff through what the government has admitted was a bungled response to Hurricane Katrina.”).

176 See supra Part II.B.2.

177 Fishman, supra note 7, at 272 (“It is doubtful that there will be a substantial increase in funding for enforcement activity at either the federal or state levels. The only realistic way to increase nonprofit accountability and to create new norms of fiduciary behavior is to leverage existing regulators’ efforts by making them more efficient.”).

178 Vanderwarren, supra note 79, at 973 (“The IRS is not the appropriate agency to regulate charities; its role should continue to be limited to collecting revenue.”).

179 Aprill, supra note 71, at 769, 792 (proposing that the IRS should only establish minimum nonprofit governance standards and withdraw from regulating nonprofit governance if state law is adequate).

180 The broader idea of educating board members as a means of governance reform is not original. See, e.g., id. at 792; Brakman Reiser, supra note 94, at 276-78 (describing the importance of “[t]raining and [e]mpower[ment] [of] [n]onprofit [a]ctors” as a reform mechanism).

181 See supra text accompanying note 116.
exempt status upon directors’ completion of educational programs that address the problem of financial accountability after a disaster.\footnote{182}{Aprill, supra note 71, at 792.}

Alternatively, the regulation of new disaster relief organizations’ financial oversight committees may better belong to the office of the each states’ Attorney General. In New York, the Attorney General recommends that all nonprofit organizations have internal controls, such as “policies and procedures that . . . promote compliance with laws and regulations and achieve effective and efficient operations . . . and include procedures for . . . handling funds received and expended by the organization . . . [and] evaluating staff and programs.”\footnote{183}{ANDREW CUOMO, supra note 159, at 2.} The Attorney General further recommends that the board be separate from management, that no one person receive or deposits checks, and that board members perform a periodic evaluation of the nonprofit’s programs for efficiency and effectiveness.\footnote{184}{Id. at 2-8, 12-13 (Many other policies and procedures are recommended, including conflict of interest statements, the establishment of a code of ethics, training, job descriptions, personnel policies, and a CPA).} However, the Attorney General must do more than make recommendations for general governance practices that can be easily ignored after a disaster.

To the extent that a state Attorney General cannot enforce fiduciary duties because of its lack of resources and the rarity of prosecution power, one scholar has proposed the creation of a state Attorney General “charity commission” to fill the gap in regulation.\footnote{185}{Fishman, supra note 7, at 240-46 (arguing that citizen-staffed charity commissions under the auspices of the state Attorney General will improve adherence to fiduciary duties); see also FISCHER & SCHWARZ, supra note 4, at 249.} A charity commission might have more flexibility than the Attorney General’s office to rapidly and continually monitor the work of new disaster relief organizations after they are incorporated by the state. The commission should review the composition and performance of an organization’s financial oversight committee. While regulation from a new state entity might lead to “regulating some charities out of existence,”\footnote{186}{Id. at 267 (“Centralized standards are bound to have needlessly disastrous effects on the margin, even regulating some charities out of existence.”).} the benefits of centralized, state leadership to all nonprofits in the aftermath of a disaster may outweigh the costs.

2. Self-Regulatory Approaches

A financial oversight committee norm\footnote{187}{FISCHER & SCHWARZ, supra note 4, at 243 (“Norms are informal social regularities that individuals feel obligated to follow because of an internalized sense of duty or a fear of external nonlegal sanctions. Norms can transform the abstract mandates of the statutory fiduciary requirements into practice guides.”).} can also be enforced by self-regulatory agencies after a disaster. Self-regulatory approaches to nonprofit accountability are based on establishing and applying best
practices in governance. After a disaster, charity watchdog organizations should evaluate new disaster relief organizations and rate them according to whether or not they have a financial oversight committee. Watchdog groups should also educate donors about which organizations have strong enough financial oversight to justify donations. Self-regulatory nonprofit accountability is inexpensive, promotes voluntary adherence to best practices and preempts the need for government regulation. When a watchdog organization rates a new disaster relief organization, it can provide a “seal of approval” that helps donors, and potentially users, access comparative information on nonprofit governance to show that the board is committed to closely reviewing the receipt and allocation of funds. Both sophisticated and small-time donors should rely on self-regulatory disaster relief ratings to be better informed in the rush to donate after a disaster. Moreover, founders or board members of new organizations will comply with self-regulatory standards in order to compete for donations.

The self-regulatory evaluation of new disaster relief organizations requires funding and staff that the sector’s private

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188 PANEL ON THE NONPROFIT SECTOR, supra note 37, at 60; Brakman Reiser, supra note 94, at 273 (specifically describing benefits of rating agencies). As an example of one rating agency’s standards, see BETTER BUSINESS BUREAU, STANDARDS FOR CHARITY ACCOUNTABILITY, http://www.bbb.org/us/Charity-Standards (last visited Apr. 1, 2009).

189 PANEL ON THE NONPROFIT SECTOR, supra note 37, at 52-59 (cataloging numerous watchdog organizations that set standards and evaluate nonprofit organizations).

190 See supra note 62 and accompanying text (discussing Charity Navigator, a watchdog group that evaluates and rates 5000 nonprofit organizations and that has urged donors after Hurricane Katrina not to contribute to “newly formed charities” after a disaster); see also Charity Navigator, http://www.charitynavigator.org/ (last visited Apr. 1, 2009); Charity Navigator, 5 Lessons For Donors to Take to Heart, available at http://www.charitynavigator.org/index.cfm?bay=katrina.article&pid=454 (last visited Apr. 1, 2009).

191 Brakman Reiser, supra note 94, at 273 (describing how such private sector “intermediaries” such as Better Business Bureau can rate charities and therefore lead to improved performance); Sidel, supra note 142, at 835 (arguing that self-regulation can prevent government involvement, which creates a situation where nonprofits are “diluted from their crucially important social roles or some charities are pushed out of the picture due to their size, a strong sense of autonomy, or their innovative spirit”).

192 See PANEL ON THE NONPROFIT SECTOR, supra note 37, at 62. Self-regulatory approaches function in a variety of ways, including “accreditation, best practices, codes of ethics, seals of approval, and ratings.” Id. at 58.

193 Brakman Reiser, supra note 94, at 274 (“Donors do seem interested in information regarding the percentage of donated funds used for charitable purposes, as opposed to administrative costs. Similarly, they might like to know whether an organization to which they plan to contribute adheres to its mission and operates in line with its legal governance structure.”).

194 Id. As an example, Families of September 11 is an organization that has met the Better Business Bureau “Seal Program” for meeting a number of accountability standards. Families of September 11, FOS11 Governance, http://www.fos11.org/governance.aspx (last visited Mar. 20, 2009).

195 Manne, supra note 9, at 254 (supporting the general proposition that a nonprofit’s reputation impacts fundraising and concluding that “a donative charity perceived as uncontrolled in the midst of well-controlled alternative charities will be at a competitive disadvantage for the scarce dollars given to nonprofits”); Sidel, supra note 142, at 809 (arguing that self-regulatory standards have two purposes: to improve the function of nonprofits and to elevate the credibility of nonprofits by comparing them to one another).
watchdog groups may not currently have.\textsuperscript{196} Time constraints might be overcome if a fast-track accreditation system is designed to assess and rate new disaster relief organizations. On balance, a self-regulatory rating system that verifies at least the existence of, or continuing improvements to, a financial oversight committee in new disaster relief organizations provides a much more expedient solution to enforcement than existing government channels.

3. Foundations

Foundations have the opportunity and responsibility to encourage the formation of a new financial oversight committee at new nonprofit disaster relief organizations.\textsuperscript{197} First, foundations are dramatically different from individual donors based on their expertise in how to direct funds after a disaster. Also, foundations may have expertise in good governance and financial accountability because they can carefully plan and spend their own funds in a manner that pleases their own donors.\textsuperscript{198} Foundations can provide grants to improve nonprofit governance where donors may not.\textsuperscript{199} While disasters stir emotions and lead to enormous and even historic levels of impulsive giving from many small-time donors,\textsuperscript{200} such donors lack disaster relief expertise, let alone knowledge of what governance structure will ensure that their donation is well spent after a disaster.

Finally, while foundations are limited in the extent to which they control what a nonprofit grant recipient does with its donation,\textsuperscript{201} they can condition grants after a disaster to new disaster relief organizations based on the formation of a financial oversight committee. Effectively, grants from foundations that implement such mandates lend legitimacy to a new organization. In contrast, self-regulatory watchdog groups lack the direct influence over a new disaster relief organization. Encouraging all foundations to condition grants on the formation of a financial oversight committee norm may be more effective than government

\textsuperscript{196} Aprill, supra note 71, at 789-90.
\textsuperscript{197} Sugin, supra note 77, at 893 (describing how increasingly “donors[.] . . . impose their vision on the organizations they support”); Vanderwarren, supra note 79, at 979 (“Donors have the power to withhold their contributions if they believe an organization is not being managed properly. Such donors include rank-and-file public donors, foundations, and even . . . governments in their capacity as ‘donors.’”).
\textsuperscript{198} Brakman Reiser, supra note 94, at 270.
\textsuperscript{199} Strom, supra note 134.
\textsuperscript{200} NETWORK FOR GOOD, THE YOUNG AND THE GENEROUS: A STUDY OF $100 MILLION IN ONLINE GIVING TO 23,000 CHARITIES 9, available at http://www.networkforgood.org/downloads/pdf/Whitepaper/20061009_young_and Generous.pdf (last visited Apr. 1, 2009) (“Disaster relief is the leading category of giving and ranks among top [online] searches . . . .”).
\textsuperscript{201} Manne, supra note 9, at 258 (“It is in the nature of nonprofits that nearly all donors (and many beneficiaries) are unable to control or even observe the disposition of the corporation’s income.”).
mandates and self-regulatory evaluation, though ideally, the three approaches should compliment one another after a disaster.

CONCLUSION

The potential for theft, fraud, and waste creates financial accountability issues in new disaster relief nonprofit organizations that jeopardize the effectiveness of disaster relief in general which, in turn, tarnishes the reputation of the nonprofit sector. Accordingly, this Note strives to add to nonprofit legal scholarship on accountability by addressing a risky context in which nonprofits operate without necessary governance mandates. Despite the criticism offered in this Note, new disaster relief organizations do have extraordinary opportunities to perform a useful role.202 Particularly in the wake of a disaster when public trust and faith in public institutions can be diminished, small or new disaster relief organizations can provide the necessary one-on-one interaction, especially with disenfranchised groups, that helps communities recover from a disaster.203 By improving the efforts of so many courageous people who endeavor to help disaster victims, the healing process will be enhanced. Therefore, society should embrace these nonprofit disaster relief “rookies”204 and their board members with higher expectations, as opposed to lower ones. The failures of accountability in some new disaster relief organizations to date should not preclude new organizations with good governance practices from continuing to offer vital responses to disaster victims.205

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202 DISASTER RELIEF AND RECOVERY, supra note 40, at 8 (arguing that newly formed organizations with “roots in the community” can be uniquely poised to “provide appropriate services”).
203 Id.
204 See supra note 50 and accompanying text.
205 Milton Cerny, Tsunami: NGO Response: Now and the Future, 47 EXEMPT ORG. TAX REV. 181, 187 (2005) ("[T]here should also be room for private citizens to form new organizations that contribute in new and innovative ways. To the extent that NGO[s] . . . discourage the formation of new organizations in response to new needs, they limit the diversity and vitality that are the hallmarks of a civil society.").
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