

Health Law Fellows Presentations

Center for Health, Science and Public Policy

Brooklyn Law School

Project Abstracts

Projects 2024

Organs for All: Improving Equitable Access to Transplants for People with Intellectual and Developmental Disabilities

Elisabeth Mayer '24

Abstract:

The ongoing need for healthy organs for transplantation in the United States is not matched by the available supply, despite national efforts to increase organ donations: seventeen people die each day waiting for an organ transplant. Given this extremely scarce resource, transplant centers are forced to prioritize certain individuals over others as transplant candidates, and as a result, some individuals are denied access to life-sustaining and life-saving medical interventions. While current allocation strategies focus on equitable distribution that ignores valuations of social worth, the contours of fair allocation remain controversial in the face of ongoing shortages. Individual and systemic inequality inevitably enters the process at various points and can limit marginalized people's opportunities for a transplant. Despite recognition of the value of the lives of people with intellectual and developmental disabilities (I/DD) among potential organ donors, these individuals are regularly deprioritized as candidates for transplant and are thus denied equitable access to the organ transplant system. This paper argues that patients with I/DD in need of organ transplants face discrimination that arises out of incorrect assumptions about the likelihood of successful outcomes and an ethical framework that places misguided weight on the relative value of lives lived with I/DD. While there has been recent legislative movement to eliminate discrimination against patients with I/DD in the transplant process, such efforts must be accompanied by broad changes that reduce a transplant team's ability to utilize I/DD (or proxies for I/DD) as criteria for exclusion, coupled with efforts to reduce structural impediments that prevent patients with I/DD from consistent access to needed medical procedures.

Culture Shift: From Fueling Gun Violence to Fueling Gun Safety: How the Spending Power Can Incentivize the Gun Industry to Change Their Role in the U.S. Gun Violence Epidemic

Sloane Forbush '24

Abstract:

The need for equitable, comprehensive, and intersectional gun safety policy is of the utmost urgency and a shift in U.S. gun culture is critical to accomplishing these goals. The Protection of Lawful Commerce in Arms Act (PLCAA) blocks access for those impacted by gun violence to hold the firearm industry accountable for their harmful business strategies. With the PLCAA and similar state laws in place, the gun industry has no financial incentive to advocate for gun safety. Political divides make repealing this immunity increasingly challenging. Efforts to shift gun culture through the gun industry should implement lessons from historic leveraging of another powerful industry – automobile manufacturers. This essay will argue the federal government has an opportunity to indirectly address the gun industry through the spending power and change their incentives to make it favorable to advocate for gun safety, as was done in the historic journey to U.S. adoption of mandatory seatbelt laws in the 1980s. The looming threat of litigation is intended to motivate the gun industry to change consumer messaging and lobby for gun violence prevention. These efforts have the power to foster a cultural shift towards gun safety and save lives for generations to come.

This project has been informed by my engagement with the gun violence prevention community in Michigan, including the University of Michigan Institute for Firearm Injury Prevention and the 2024 Michigan Gun Violence Prevention Summit.

Can Consolidation of an Industry Be a Good Thing?

Syed Zulqarnain Hussaini '24

Abstract:

Can consolidation of an industry be a good thing? The negative connotation associated with the consolidation of the health industry may be justified, but it fails to consider the benefit such consolidation brings to patient care, and to the health of the population overall. This article sheds light on some of the positive impacts such a market shift has had, while also addressing negative impacts, and lastly addresses how various administrative offices have dealt with these issues.

Increasing Psychiatric Advance Directives Awareness

Camille Tucker '24

Abstract:

Psychiatric Advance Directives (PADs) allow individuals with an episodic mental illness to state who they would like to make healthcare decisions for them and what forms of care they consent to before they experience a crisis. While these documents have several benefits—

including increasing engagement with mental health care and decreasing coercive treatment—they are not well known and are not always used by healthcare professionals when they exist. This project aimed to design a Psychiatric Advance Directives Facilitation Program for participants of the Brooklyn Mental Health Court. In addition, an empirical study was designed to determine the impact of psychiatric advance directives on patient satisfaction with crisis care and identify gaps in their use that detract from their effectiveness.

Third Time's the Charm: The Ongoing Journey for OMIG Audit Reform in New York

Imad Rafi '24

The New York State Office of Medicaid Inspector General (OMIG) has been a focal point of controversy since its establishment in 2006. This paper explores the historical context of the office and highlights legislative attempts at regulating and reigning in OMIG's audit practices, which have been criticized for being overly punitive and lacking in fairness, particularly in dealing with non-fraudulent technical errors made by healthcare providers. Despite repeated legislative efforts in 2011 and 2022 to reform these practices, both bills were vetoed by the sitting governors at the time, citing potential hindrances to fraud detection and financial concerns. In the current legislative session (2023-2024), another bill proposing significant reforms is pending, reflecting a continued push by healthcare providers for fairer audit practices that would allow for appeals and reduce the likelihood of reaudits, among other changes. This paper examines the specifics of the proposed reforms, the rationale behind the sustained advocacy, and the potential implications for New York's healthcare system should the reforms be enacted. It argues that adopting these reforms is crucial for ensuring a fair, effective, and just oversight mechanism that supports rather than penalizes healthcare providers operating in good faith.

Stamp of Approval: Why New York Executive Law 135-c Should Be Amended to Include Remote Ink Notarization

Megan Henley '24

Abstract:

During the onset of the COVID-19 pandemic, state governments had to act quickly by implementing lifesaving measures in every sphere, including legal processes. In New York, this took the form of Executive Order 207.7, an executive order signed by then-governor Andrew Cuomo; prior to this, New York notarization laws did not permit any. The order permitted notarization ceremonies to be conducted remotely over video call technology of the principal's choosing, with the signature notarized with wet ink on the same page the principal signed. This law helped countless New Yorkers continue to conduct legal transactions while staying secure and remote. When the legislature attempted in 2022 to permanently codify this executive order, the final bill, 135-c, came out with increased regulations that have had the opposite effect enjoyed by New Yorkers when the executive order was enacted.

My paper argues for an expansion of New York's current electronic notarization law. Its current form requires notary-specific electronic notaries to be registered with the state, use state-approved equipment to observe a notarization and signing ceremony, and use an electronic-only seal. 135-c is a step in the right direction, and currently 39 states that now have some form of electronic notarization legalized. Concerns about security are valid, but 135-c as it currently is written does not necessarily solve those. An expansion of 135-c combining the flexibility of the executive order's provisions, with the electronic notaries being an option, would be an effort granting those with disabilities and in hospice more autonomy and comfort as equal participants in legal processes.

Kava, Kratom, and the Law: Brewing up Legal Clarity in Substance Regulation

Anish Vaidya '25

Abstract:

Kava and kratom, both natural substances with deep-rooted traditional uses, have been steadily gaining popularity in the United States with bars and cafes dedicated to serving these psychoactive substances opening across the country. General knowledge of kava and kratom has not kept pace with their rising popularity, leaving uneducated consumers vulnerable to misleading marketing and serious potential health risks. While governmental agencies have taken note of kava and kratom, uncertainty surrounding the substances has hindered any significant strides towards formal regulation. Although scientific research on kava and kratom is limited, it is clear that any legal regulation or enforcement concerning these substances should take a balanced approach, considering their potential benefits and risks. As the rising popularity of kava and kratom poses a threat to public health, legal action on the matter will serve to protect the general population from potential harms.

Breaking Barriers; Transforming Gynecological Care for Intellectually Disabled People through the Law & Innovation Medical Education.

Sabrina Bernstein '24

Abstract:

The lack of adequate training and awareness among physicians in Intellectual and Developmental Disability (IDD) perpetuates discrimination and disparities in healthcare. Many individuals with IDD suffer forced sterilization, menstrual suppression, growth attenuating treatment (managing fertility), restrictive guardianship, and are frequently over-medicated. The lack of knowledge and understanding of I/DD leads to wrong or unnecessary treatments and, many times, invasive procedures based on ableist, racist, and classist biases. Therefore, it is critical that physicians in all areas of medicine are trained in the nature and

needs of people with I/DD. This paper will specifically look at gynecology as a case study to illustrate the importance of IDD training. Well into the 20th century, society forcibly prevented people with disabilities, particularly I/DD, from exercising their reproductive rights. Given this history, it is critical that doctors understand the impact of medical bias when treating people with disabilities. They must understand how to communicate and work with people with disabilities.

Currently, training on I/DD is piecemeal and not compulsory and lacks longitudinal learning opportunities and fails to integrate into formal curriculum. This falls far short of what people with I/DD need from their medical services providers. This paper argues that this violates New York State law and is in violation of the ADA and Public Health Laws because individuals with IDD are not receiving equal care under the law. Accordingly, far from being optional, this paper demonstrates that IDD training is a necessary component of current and continuing medical education, to prevent disability discrimination. This paper outlines essential components of training, including sessions working with caregivers and disabled patients, courses on communication with IDD patients, and information on accommodations for IDD patients. This training will be instrumental in improving a physician's knowledge, attitude, and quality of care delivery for this population.

Private Equity Investments in Medical Care: A Step Toward Improving the U.S. Health Care System or A Step Backward.

David Noh '24

Abstract:

The United States health care system remains largely complex, fragmented, and imperfect. Many policymakers are seeking ways to improve our health care system with three goals: controlling cost, increasing access, and enhancing quality. Against this backdrop, private equity firms have been rapidly acquiring hospitals and physician practices in record numbers. In fact, private equity firms' investment in health care reached \$750 billion dollars and is on track to reach the trillion-dollar mark in the coming years. Investments of this size necessarily demand exploring the impacts on our health care system. Accordingly, this paper seeks to provide a better understanding of how private equity firms operate in the health care space. Moreover, this paper will explore both the advantages and disadvantages of private investment as it affects cost, access, and quality of care. Lastly, the paper will highlight the challenges brought by private investments in health care and introduce certain measures that may lessen or eliminate harmful effects without completely discouraging private investment.

Projects 2023

Uphold the Lamp's Light

Kylie Bae '23

Abstract:

Florence Nightingale, known as the Lady with the Lamp, made her rounds at night during the Crimean War in the 1850s. Her iconic lamp light became a symbol that resonates with healthcare workers worldwide. During her time, the question of who should be responsible for individuals' health was not clearly answered – whether it was the duty of the individual, the wealthy class, churches, or the government, and at what level.

The public demanded systematic reforms when news of the horrific conditions faced by wounded soldiers spread through advancements in information technologies. The brutality of wars and the frequent targeting of hospitals and healthcare workers inspired the creation of the first Geneva Convention in 1864, which established rules for the protection of wounded soldiers and healthcare workers during armed conflicts. Despite these efforts, incidents of violence against healthcare workers and facilities persist globally.

Reflecting on Nightingale's legacy, roughly one hundred and fifty years later, healthcare workers worldwide continue to embody her visions and hopes for good health. Nightingale's establishment of a long tradition and codified right to health as international law should be respected. Ensuring the safety of healthcare workers is paramount in upholding the lamp's light -- a symbol of care, compassion, and the unwavering faith.

Shots in the Dark No Longer: How CDC Standards Can be Leveraged for State Immunization Systems' Improvement

Shoshana Finkel '23

Abstract:

Since the turn of the 21st century, immunization information systems have become one of the most important tools in how the medical community ensures broad protection from infectious diseases. These digital registries help individuals and communities stay on top of their vaccinations, while also collecting an unprecedented volume of data on how immunization campaigns can shape recovery from disease outbreaks. But without a centralized system for American vaccine records, we are left with a fragmented network of vaccine registries that are not interoperable and lack comparable data. The CDC has created functional standards which states are encouraged to meet and provides resources to help reach the federal goals for data, privacy, and equity. This paper suggest further steps Congress could take to codify the CDC Functional Standards for Immunization Information Systems to improve the quality of data produced on national immunity, especially among school-aged children.

The Sugar-Coated Chemicals Inside US: How the Atrophy of the FDA's Food Program is Sickening our Nation

Caitlyn Genovese '24

Abstract:

The progressing chronic disease epidemic within the United States strongly correlates to food intake and stresses the importance of optimal nutrition. So why do we allow food products with excessive unpronounceable ingredients on the market? After an infant formula crisis in 2022, an assessment of the Food and Drug Administration's (FDA) Human Foods Program demonstrated a need for reorganization, including a program focused on chronic diet-related disease. Notorious for their inability to meet deadlines or fully implement novel programs, the question is whether this reorganization will facilitate the necessary transformation.

This article discusses the FDA's neglect concerning the nation's cumulative health, tying chronic disease, and decreased nutrition to its regulatory failures. This failure is especially apparent in lower socioeconomic populations where consumers must often choose food sources with more affordable prices but more alarming ingredients. This article recommends that the FDA takes advantage of the Human Foods Program's critical restructuring to close the regulatory loopholes involving the Food Additives Amendment and substances "Generally Recognized as Safe" (GRAS). This reorganization is an ideal opportunity to create a new system that manages additives and scrutinizes their link to chronic disease. This article argues for a program that increases regulatory categories, requires pre- and post-market research, and establishes pipeline scientist training to investigate the long-term effects of additives. This article also addresses additional solutions involving a research system that encourages studying "natural" food's ability to exist and endure on the market. It's time the FDA alleviates the burden on consumers and create a more reliable food additive regulatory system.

Expanding Health Care Coverage to Undocumented Immigrants: A Policy Toolkit For New York State

Alyson Jenson '24

Abstract:

This policy toolkit will provide a synopsis of available policy options for New York state and local governments to expand health care access and coverage for undocumented immigrants. New York State has the fourth largest undocumented population in the United States, the vast majority of whom live in New York City. The NYC Mayor's Office of Immigrant Affairs estimates that nearly 476,000 immigrants living in NYC are undocumented, of which 46% are uninsured and largely ineligible for coverage. This toolkit will review a selection of policies and programs that New York state and local governments have implemented to provide health care coverage to undocumented immigrants, as well as provide suggestions for state and

local initiatives and policy opportunities to expand eligibility criteria for Medicaid programs and the Children's Health Insurance Program (CHIP).

Slay's Declassified Transgender Student Survival Guide

Slay Latham '23

Abstract:

Transgender and gender non-conforming people face various forms violent barriers as we attempt to access healthcare, housing, employment, and education which often feel insurmountable. For those of us whose identities do not fit into neat legal categories and whose existence ruptures the rigidity of the law, we are forced to carry the burden of our own liberation. This guide is informed by the lived experience of the author, a mixed South Asian non-binary first-generation lawyer. Created as a labor of love for every transgender and gender diverse member of the Brooklyn Law School Community this guide is designed to foster safety and inclusivity within the institution. This guide aims to alleviate harm inflicted by the unique barriers faced by Transgender and Gender Non-Conforming (TGNC) people in the legal profession. The guide functions to provide transgender students insight into their rights. Accordingly, the guide provides an overview of legal protections for transgender people at both the federal and state level. TGNC members of the Brooklyn Law School community should know how to identify and report harmful behavior. It follows, the guide explains what qualifies as misconduct and how to address harmful behavior in accordance with institutional misconduct reporting policies and practices. The guide contains an overview of the legal name change process and provides step-by-step guidance for requesting name and gender changes for BLS student records. The name change portion of the guide includes templates for students to use when notifying professors of name and pronoun changes. Additionally, the guide offers students a detailed roadmap for navigating the implications of a legal name change relating to the Bar exam and licensing.

My Body, My Data - A Proposal to Reclaim Privacy and Autonomy for Period Tracking Application Users

Carly Sternberg '23

Abstract:

With the recent overturning of Roe v Wade, period tracking apps have become a privacy concern for app users and reproductive and digital rights organizations. These apps collect personal information that could potentially be used against individuals seeking abortions in states with abortion bans and trigger laws. This paper first explores the legal framework that permits prosecutors to subpoena period tracking data from third-party entities and highlights the urgent need for app developers to minimize or eliminate dangerous features that could share data with third parties. The paper then suggests technical changes app creators should implement to protect users from potential criminal liability, such as keeping app data storage local, eliminating app location tracking, and using clear and user-friendly informed consent

provisions. Finally, the paper suggests taking specific actions to ensure the safety of users, including advocating for changes in legislation and regulations and utilizing social media to encourage users to move away from apps that don't prioritize privacy protection.

Out of Few, One: Addressing the Privacy Concerns for Cross-Border Data Sharing for Rare Disease Patients

Deanna Arpi Youssoufian '23

Abstract:

Previously excluded from the genomics revolution, rare disease patients are finally receiving their due attention from the scientific community, and specialized biobanks and infrastructures are being established around the world to promote rare disease research through cross-border data sharing. However, these patients, by virtue of being part of small and geographically dispersed populations, face a heightened concern of reidentification of their biospecimen and personal health data. This paper examines the data privacy laws of four representative jurisdictions—the United States, China, the United Kingdom, and the European Union. To address the concern of reidentification of rare disease patient data, this paper argues that international biobanks should adopt the privacy laws of the strictest member jurisdiction with respect to four regulated dimensions: (1) patient consent, (2) information privacy and security mechanisms, (3) jurisdictional standards for sharing data internationally, and (4) limitations on access. In doing so, biobanks can promote research initiatives, which are heavily dependent on cross-border data sharing, while significantly safeguarding the sensitive data of these vulnerable populations.

Projects 2022

Why Public and Private Universities Should Expand Their Medical Exemption Criteria to Include Disability Based Exemptions to the Covid-19 Vaccination Requirement

Caraline G. Mikkelsen '23

Abstract:

Many public and private institutions including, the top fourteen law schools, have adopted COVID-19 vaccination requirements and exemption policies to return to campus. Even though the Center for Disease Control and Prevention (CDC) allows discretion in terms of the medical exemption policy a public or private institution chooses to adopt, many public and private institutions apply the CDC's contraindication standard, which considers only very narrow physical aversions to the vaccine. As such, this paper examines why the contraindication standard is discriminatory against students with disabilities, particularly

those with psychiatric disabilities, and why this stringent application of the contraindication standard by public and private institutions is a violation of the Americans with Disabilities Act (ADA) based on disparate impact and reasonable accommodations grounds.

This paper also addresses defenses to bringing an ADA claim, namely by examining the accommodations already afforded to students with an approved medical exemption such as testing & masking requirements, and that making these same accommodations for students with psychiatric disabilities who are medically unable to take the vaccination, would not pose an undue hardship on the institution, nor a fundamental alternation of the educational service being offered by the institution. In addition, this paper addresses why the direct threat defense for bringing an ADA claim does not apply for students with disabilities in this context. This paper concludes by posing a solution of expanding the medical exemption criteria beyond the contraindication standard in public and private universities to consider disability-based exemptions to the COVID-19 vaccination requirement.

Towards Action and In Pursuit of Scofflaws: Shifting the Framework of Pandemic Public Health Punishment from Theory to Pragmatism

Michael L. Cederblom '22

Abstract:

The COVID-19 pandemic sparked a debate over whether public health interventions like mask mandates should be implemented and whether public health scofflaws should be punished. The result was a split largely across political lines; “permissive” jurisdictions promoted ideas of individual freedom and condemnation of government-imposed punishment while “restrictive” jurisdictions implemented a range of punishments attached to mask mandates. This political battle became one of stagnant theories and essentially fused considerations of public health and legal punishment. Bracketing political concerns, what philosophical theories fueled this divide? While public health generally employs a utilitarian framework limited by deontic constraints, permissive jurisdictions exuded a purer libertarian deontology and restrictive jurisdictions exhibited a retribution-laced utilitarianism.

Neither are sufficient to guide public health punishment during a pandemic based on their reliance on too pure a theory. Permissive jurisdictions promoted government inaction which is simply in contravention to public health principles during an emergency, and restrictive jurisdictions used overly harsh punishments that threatens equity. What is needed is pragmatic reconciliation: the decision-making framework guiding public health punishment during a pandemic must recognize the exigency of the crisis and shift the balance of values (like emergency medicine) to prioritize population health and equity. Lawmakers utilizing this more grounded approach which draws on foreign example will deliver a more practical public health response that delivers fairer outcomes, protects individual liberties, and reduces overall suffering.

Differences in COVID-19 Regulatory Guidance for Long-Term Care Facilities from State Intellectual and Developmental Disability Agencies

Shoshana Finkel '23

Abstract:

This paper addresses the differences in regulatory guidelines created during the COVID-19 pandemic by state agencies serving people with intellectual and developmental disabilities (I/DD). Since the beginning of the pandemic, much concern has been placed on the spread and severity of cases among vulnerable people in congregate care settings. The Centers for Medicare and Medicaid Services (CMS) issued a mandate in spring 2020 for nursing facilities to report and control COVID-19 cases and deaths among their patient populations. These guidelines, however, did not extend to long-term care facilities for people with intellectual and developmental disabilities, leaving the discretion up to states on how they would regulate infection control for these groups. While this omission of regulation may be telling of the lack of prioritization of care in the American medical system to people with ID/DD, some states outperformed others in the breadth of their guidelines created in this time. Earlier studies have done the diligent work of analyzing COVID-19 outcomes among people with intellectual and developmental disabilities, both those living in their own homes and those living in residential facilities. These studies have revealed not only disparities in disease infection, outcomes, and deaths between the general population and those with I/DD, but disparities between those in different care settings. This paper seeks to uncover links between the epidemiological data and the varied regulatory guidelines state health and social services departments issued for I/DD service providers.

Hacking the Data Bias: Policy Recommendations for Improving AI in Healthcare with Data from Underrepresented Groups

Hasan Tariq '22

Abstract:

Artificial Intelligence (AI) in healthcare has the potential to transform the healthcare system by enabling more accurate and efficient care. In theory this would solve some of the access, quality and safety problems that currently exist. However, AI in healthcare also presents risks that make it unsafe for some healthcare users. One of those risks is algorithmic bias attributable to datasets that are not representative of a broad spectrum of potential users. Although AI can adapt over time in response to real world data, machine learning AI will not overcome algorithmic bias without data from underrepresented groups. Acquiring data from underrepresented groups raises concerns around informed consent, privacy, and trust. This presentation examines existing policies around AI in healthcare and makes policy recommendations on how to promote the development of AI in Healthcare in ways that improve its accuracy and its potential benefits for minority and majority groups in terms of patient outcomes.

Disabled Students and Higher Education: How Can Law Schools Bridge the Gap

Leisa Rockelein '23

Abstract:

Nearly one in four Americans have a disability, yet only 2.5-3.5% of graduating law students identify as having a disability. Further, the ABA Commission on Disability Rights reported that around 6.87% of its members identified as having a disability and that 3.4% of law students were granted accommodations. All law schools must comply under Title III of the Americans with Disabilities Act, which prevents discrimination based on students' disability status, and Section 504 of the Rehabilitation Act of 1973, which grants students reasonable accommodations for their disabilities. Aside from these two laws, the process disabled students are faced with vary greatly from one law school to another. While almost all disabled law students will experience a process for being granted accommodations, some are significantly more cumbersome and less accommodating than others.

While student access to disability testing and diagnosis is imperative, this paper will focus on how law schools and the ABA can better meet disabled students' needs, with a focus on the process of receiving and implementing accommodations. Many students come into law school knowing they are disabled, and many students also discover their disability in law school given its rigorous nature, making accommodations essential to disabled students' success. This paper explores how the accommodation process could be made easier and faster, how accommodations could be expanded and tailored to better meet student needs, and how professors and faculty should be trained to best implement student accommodations.

Projects 2021

Resolving the Title X Circuit Split: Why the Supreme Court should find the Regulation is Arbitrary and Capricious and Contrary to Law

Sarah Colgan '21

Abstract:

Despite the fact that the right to have an abortion became the law of the land in Roe v. Wade, state legislatures and federal policies keep millions of women, especially low-income women, from accessing abortions. This paper focuses on those federal policies, specifically, the Title X Family Planning Program. Title X is a federal grant program that helps institutions provide family planning services to low-income patients. Under Title X, funds are prohibited from going to institutions "where abortion is a method of family planning". Since its enactment, the Department of Health and Human Services has repeatedly promulgated regulations implementing Title X. At issue in this paper is the 2019 Final Rule issued by the Trump Administration, which prohibits Title X providers from referring patients for abortion care and requires onerous physical and financial separation requirements for Title X funded institutions.

Currently, the 4th and 9th Circuits are split over the Final Rule's validity. The 9th Circuit upheld the Final Rule, finding it was neither arbitrary and capricious nor contrary to law, while the 4th Circuit reached the opposite conclusion. This paper analyzes that Circuit Split and argues that the Supreme Court should resolve the inter-circuit disagreement by finding that the Final Rule is arbitrary and capricious and contrary to law. The paper also discusses the likelihood that the Court will find that way, and the implications if the Court does not.

Do We Have To? An Examination of Vaccination Mandates

Marissa Wong '21

Abstract:

Vaccination mandates have long been a topic of debate. With COVID-19 vaccines becoming available to a large portion of the U.S. population, the idea of a COVID-19 vaccination mandate is not far-fetched. This project seeks to promote a better understanding of the background, history, current state, and future outlook on the possibility of a vaccination mandate. As the mechanism that can put an end to the COVID-19 pandemic and possibly allow the public to return to normalization, should the idea of vaccination mandates be re-examined?

This project addresses the idea of vaccination mandates across public and private sectors, employers and employees, the current guidance surrounding the topic, whether the unvaccinated population should be isolated, and legal complications that can arise.

Shadow Nursing Home Ownership: How A Failure in Government Oversight of For-Profit Nursing Homes in New York Has Allowed Profits to Balloon and Standard of Care to Plummet

Marissa Espinoza '23

Abstract:

This paper focuses on the oversight and regulation of for-profit nursing homes in New York State. The paper examines the various state and federal regulations governing nursing homes, a topic that has garnered significant attention following the many issues highlighted during the COVID-19 pandemic. The paper looks at the labyrinth of complex corporate structures that sophisticated for-profit nursing homeowners establish to evade liability and extract maximum profit from the facilities, an issue unique to for-profit nursing homes with an inherent profit motive in their business decisions. For-profit owners siphon profits from facilities, which simultaneously experience a decline in the quality of care afforded to residents. The paper offers several policy proposals, including a mandated minimum percentage of revenue that must be directed toward patient care, safe staffing levels, and stricter restrictions to prevent for-profit owners from directing unregulated amounts of funds to affiliated LLCs for various management and administrative consulting contracts.

Utilizing Citizen Science to Address Legal Remedies in New York City to Reduce Environmental Justice Disparities Regarding Adverse Health Outcomes from Air Pollution

Sydney Wolchok '22

Abstract:

Environmental Justice concerns are not adequately addressed and mitigated through policy initiatives. Despite recent efforts in legislation, across all levels of government, disparities still exist. Looking specifically at New York City, adverse environmental health impacts are disproportionately experienced in low-income communities and communities of color. Most of the environmental harms and hazards stem from air pollution from vehicle emissions, residual heating oil, and power plant emissions. Why haven't policy initiatives been successful in reducing environmental disparities? Is it the lack of acknowledgment of procedural rights and community members' abilities to participate in the decision-making process or the lack of legal remedies available? This paper and presentation will focus on citizen science and how it can be used as a tool to encourage public participation and pursue legal remedies. Utilizing citizen science in the decision-making process has the potential to highlight disparities that exist in communities most impacted by environmental harms and hazards from air pollution to effect real change.

The Patient Assistance Problem

Daniel Lichtenauer '22

Abstract:

Patient Assistance Programs offer Medicare beneficiaries the opportunity to take life-saving drugs they could otherwise not afford. While pharmaceutical donors insist this is their only goal in establishing such programs, the reality is that many of these programs offer a financial windfall for drug makers, helping funnel patients towards new pharmaceuticals with generic alternatives while collecting the drug's market price at the expense of taxpayers. This paper outlines the gaps in coverage experienced by Medicare Part D beneficiaries when they are in need of high-cost medication, examine the role that pharmaceutical companies have come to play in mitigating that cost via Patient Assistance Programs, and explain the failure of DOJ and OIG guidance to prevent litigation surrounding the administration of these programs. The paper further examines legislative proposals to reform Medicare, and why these proposals have failed. Finally, the paper argues for the creation of a central patient assistance fund administered by the Centers for Medicare & Medicaid Services (CMS) to take the place of current PAPs as a target for fair, honest pharmaceutical industry beneficence.

Due to the COVID-19 Pandemic the 2020 fellows were not able to prepare abstracts and give their fellowship presentations. Prior to the law school going remote, the fellows enjoyed a rich experience, made great progress on their projects, and made significant contributions to the health law program. They deserve recognition. The 2020 fellows were:

Kim Aquino '21

Cory Bernstein '20

Monica Beshay '20

Thomas Kelly '20

Celeste Russel '21

Projects 2019

Pharmaceutical Philanthropy or Resisting Regulations? Why Pharmaceutical Donations Do Not Violate the Anti-Kickback Statute

Tino Illiparambil '20

Abstract:

The government has acknowledged the dangerously excessive costs of health care. By discouraging pharmaceutical donors from absorbing costs through patient assistance programs (PAPs), however, claims of violating the Anti-Kickback Statute raise a greater public concern: access to affordable health care. The government should instead apply a direct causal link test when analyzing potential violations of the Anti-Kickback Statute and the False Claims Act due to the benefits that PAPs provide patients. The backbone of this argument rests on policy interests regarding the effects of restricting patient assistance programs. This paper will analyze the costs of the U.S. health care system, specifically looking at the Patient Protection and Affordable Care Act, as well as efforts to repeal it. This analysis will be used as evidence to support the health care industry's need for PAPs as a way to significantly reduce costs.

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Stop Letting Mothers Die: Advocating for Improved Maternal Mortality Policies and Procedures

Bailee Brown '19

Abstract:

The United States has the highest maternal mortality rate in the developed world, and nationally that number has been rising. However, that doesn't need to be the case. The CDC estimates that 60% of deaths during childbirth are preventable, and some states, like California, are implementing policies to prove that statistic is correct. Others, however, have been too slow to act. One such state is Indiana, which ranks third in the country for most maternal deaths. Building upon previous research, this project analyzes and compiles policies and procedures enacted or proposed in various localities and creates an advocacy one-pager for constituents in Indiana (and elsewhere) to utilize in contacting their local legislators and advocating for improved policies to help prevent mothers from dying during childbirth.

Ms. Brown is an Edward V. Sparer Public Interest Law Fellow, Brooklyn Law Students for the Public Interest Fellow, a Pro Bono Scholar, performing service at The Legal Aid Society's Exploitation Intervention Project, and an incoming New York State Excelsior Service Fellow.

Cyber Security and Privacy in the Healthcare Sector: How the Current Laws Fall Short

Hayley Bava '19

Abstract:

The Cybersecurity and Infrastructure Security Agency (CISA) works to identify and defend against cybersecurity threats that target critical infrastructure sectors within both the government and private sectors. Among the 16 critical infrastructure sectors identified by the U.S. government, the healthcare sector has been a target of more data breaches in recent years than any other critical infrastructure sector.

The healthcare sector is host to a variety of valuable information, which makes it an attractive target for cyberattacks. The healthcare sector's increase in cybersecurity attacks has been a result of both the quick advancements of the new digital age and insufficient cybersecurity protocols. These attacks both jeopardize patient health and safety and expose the affected healthcare entities to liability from a variety of adversaries. Aside from private actions, liability may arise from The Health Insurance Portability and Accountability Act (HIPPA) and the Federal Trade Commission (FTC) Act.

When dealing with cybersecurity, the healthcare sector must be able to identify threats, prepare for those threats, and be able to defend and respond to attacks. While current policies, procedures and laws provide some safety measure standards and some recourse in the event of a cybersecurity attack, they have not been able to keep up with advancements in technology enough to adequately protect patient information and health information systems. As a result, the healthcare industry needs new, more comprehensive laws and standards for IT system protection that addresses the changes of the new digital age.

The Appropriateness of Trademark Protection for Prescription Drugs and Pharmaceuticals

Matthew Gagliotti '19

Abstract:

Currently, the Lanham Act grants trademark protection to drug manufacturers, despite simultaneous patent protection on their medications. The legislative history of the Lanham Act emphasizes the source of a product, as this indicates distinctiveness to consumers. With most products, the differences are tangible. For example, an average consumer of a handbag can easily grasp most differences between methods of construction, materials, et cetera. In the pharmaceutical sector, the differences between branded drugs and their generic equivalents are more abstract, and not as obvious to the average consumer (i.e. vulnerable patients). In the United States, drugs are very highly regulated by the Food and Drug Administration (FDA). The FDA holds generic drugs to the standard of bioequivalence to its branded version before granting approval. Such strict regulation creates a market of uniformity. However, by permitting trademark law to govern medications while the FDA simultaneously holds generic drugs to the standard of bioequivalence, consumers are arguably deceived by an illusion of material differences between branded drugs and their generic equivalents. This is contrary to the intent of the Lanham Act, which presumes that brand identification is a factor of import to consumers because it conveys source and distinction amongst similar products to consumers. This raises the discussion of the appropriateness of trademark law in the pharmaceutical sector, and if there are other, more suitable forms of intellectual property protection that the law should adopt.

Criminal Law Should Mind Its Place in The Healthcare Sphere

Veronica Mishkind '19

Abstract:

Criminal prosecution of health care professionals for unintentional medical errors is exceptionally rare, however within the past few decades has increased. This type of prosecution has faced much criticism and opposition from the medical community including the Institute for Safe Medication Practices and the American Nurses Association. A primary argument against prosecution is that because medication errors occur with frequency, and they usually result in no harm to the patient, it is unjust to selectively prosecute those medical professionals whose patients happen to be harmed. Fear of prosecution can result in a chilling effect felt through the whole of the medical community including undermining the culture of safety and reducing open disclosure of errors, along with deterring potential practitioners from entering the healthcare field altogether, as well as stunting the growth of medical research and protocols.

While criminal prosecution of healthcare professionals is not without merit, it is essential for a bright line to be drawn between those actions warranting prosecution, and actions in which justice would better be served in civil court. Practitioners that have a guilty mind when committing their actions or have demonstrated a pattern of criminally negligent practice

should be criminally prosecuted, whereas practitioners who simply committed one medical error without the culpable mens rea should be exempt from criminal prosecution.

A Failed Drug: Expediting the Sluggish, Impossible, and Costly Drug Approval Process

Max Ezoory '19

Abstract:

Cancer has a significant impact in the United States, with an estimated 1,735,350 new cases being diagnosed in 2018. 609,640 will die because of the disease. To make matters worse, only one out of 5,000-10,000 researched drugs gain FDA approval, as the FDA has complete control in deciding which drugs will flow into the stream of commerce. Moreover, most drugs do not make it to clinical trials. Out of the drugs that actually make it through to clinical trials, only one in ten are ultimately approved,

which comes out to less than a .02% to a .01% chance of entering the market. Last, regulatory approval can take twelve to fifteen years with averaging costs in the billion- dollar range.

Over the past 30 years Congress and the FDA have been pressured from patient bodies, industry advocates and others to shorten the development and approval periods for life-saving treatments. As a result, the current administration is pushing ahead with plans for a more deregulated and faster drug approval system.

Future Public Health Threats from A Timeless Foe

Rashmini Sookraj '20

Abstract:

On or about July 10, 2016, the Government of the Cooperative Republic of Guyana entered into a contract with Exxon Mobil, CNOOC Nexen Energy, and HESS Corporation, granting these oil giants several Petroleum Prospecting Licenses and Petroleum Production Licenses to survey and conduct off-shore drilling along the coast of Guyana. This project seeks to promote a better understanding of the contract between the parties and will focus on an informative approach by considering what potential adverse health effects are likely to occur from an oil spill along the coast of Guyana. It also discusses measures currently in place to combat and effectively handle health impacts associated with an oil spill. It then details what legal remedies are available for potential victims.

Healthcare Inequity in Myanmar: Bridging the Gap

Madeline Huang '20

Abstract:

Following Myanmar's transition into a quasi-civilian government in 2011, the country's Ministry of Health (MoH) set off to revitalize the destroyed health system with the goal of providing Universal Health Coverage by 2030. But Myanmar is still far from reaching internationally accepted healthcare standards. This project examines the current scheme of public health in Myanmar and suggests that despite the country's current efforts at improvement, it fails to provide the equitable healthcare necessary for Universal Health Coverage. The objective is to analyze the current health environment in a manner that identifies its deficiencies but enables suggestions for potential policy reform. Myanmar's history is riddled with persistent ethnic armed conflicts that has led to the development of

two distinct health care systems along with a discriminatory legal system. Despite pressure from the international community, Myanmar continues to sustain laws that actively exclude ethnic minority populations from basic rights further widening health disparities, particularly between urban and rural regions. Recently, Myanmar has shown signs of improvement as ethnic and community-based health organizations (ECBHOs) and MoH staff have begun integrating their resources to reach vulnerable populations. But because the current government fails to enable a more effective collaboration between the two health care entities, Myanmar's health care still remains inadequate. Ultimately, the goal of achieving Universal Health Coverage remains distant as Myanmar's law continues to neglect its minority groups.

Dissecting the Opioid Crisis: Making Sense of Opioid Litigation

Reuben Gottlieb '20

Abstract:

This paper aims to examine the opioid crisis through the lens of litigation. While the opioid crisis is affecting millions of Americans every day, the law is unsettled with respect to who is legally accountable for its fallout. This paper discusses ongoing litigation between cities and counties throughout the United States, and pharmaceutical manufacturers, distributors, and pharmacies. This paper analyzes the court's new acknowledgment of the devastating role pharmaceutical manufacturers, distributors, and pharmacies have had in the opioid crisis.

Projects 2018

Utilizing the Canadian Approach to Safe Injection Facilities in the United States

Dana Vasers '18

Abstract:

In 2016, the United States Department of Health and Human Services reported that over 42,000 individuals died from opioid overdoses. While there have been many efforts by the

state and federal government to combat this epidemic, the rate of lethal overdoses has continuously increased in past years. In an attempt to mitigate the negative effects of injection drug use, many urban cities have looked into opening Safe Injection Facilities (SIFs). SIFs are locations that intravenous drug users can go to inject drugs under medical supervision with sterile equipment. There are currently no legally sanctioned SIFs in the US but 98 legal locations worldwide. Studies have shown that SIFs prevent the transmission of bloodborne diseases and lethal overdoses, reduce public drug use, and provide referrals for drug treatment programs. Even if a state or local municipality legalize a site, the federal Controlled Substances Act and the “Crack House Statute” 21 U.S.C. §856 expose operators and users of the sites to criminal liability.

The United States should use the Canadian approach to opening Safe Injection Facilities. In Canada, potential SIFs are required to submit an extensive application for exemption under federal criminal drug laws to show need and local support for such a site. Although it may be difficult to exempt sites under US federal law, this approach ensures that exempted SIFs are supported within the local and state community and free from prosecution under federal law.

Legality of Mandatory Flu Vaccination Among Children and Healthcare Workers

Xiaoliang Ma '18

Abstract:

Influenza (the flu) is a common contagious illness caused by flu viruses. Flu vaccines can help reduce the risk of infection. However, their effectiveness varies each year. The federal, state, and local governments have the legal authority to combat any public health emergency. As governments exercise their legal authorities, issues arise regarding testing, privacy, and the feasibility of mandating flu vaccines. Two groups have been at the center of public attention in recent flu outbreaks – school students and healthcare workers. Legal analysis of governmental response to a flu epidemic requires balancing those specific individuals' rights against the general public's interest.

Health Technology and the Lack of Health Privacy Regulations

Brittany Bell '18

Abstract:

The introduction of electronic data within the modern health information infrastructure could present significant benefits for medical providers, physicians, and patients, including public health surveillance, patient autonomy, and improved treatment. Despite these benefits, the new exchanges of personal health information have brought about many issues and debates about how these companies handle and distribute consumers' health information.

Many people believe that the data tracked and collected by health technologies are covered by HIPAA, but in fact, many are not. With health data being generated via non-covered entities and HIPAA only covering personally identifiable information from covered entities, individuals have found their personal health information being made public and/or collected by third-parties unbeknownst to them. My paper analyzes the fact that federal privacy law has fallen far behind personal-health technologies and proposes solutions to this issue.

Projects 2017

EMTALA

Marshal Nelson, MBA, LCSW '17

Abstract:

The Emergency Medical Treatment and Active Labor Act(EMTALA)was passed in 1986 to prevent hospital emergency rooms from refusing treatment based on foreseeable high costs or a patient's inability to pay. The law applies when a patient seeks treatment for an emergency medical condition and requires an Emergency Department to assess this condition by conducting a medical screening examination. Litigation since the law's inception has attempted to reduce some of the statute's ambiguity so that a hospital's responsibility towards treating these patients is more clearly defined. The impact of EMTALA is widespread, improving access to healthcare for the underserved while placing financial pressures on hospitals to care for this population largely without receiving any compensation for the services rendered.

Workplace Wellness Programs: Friend or Foe?

Jessica Cahill '16

Abstract:

From 2014-2015, Americans saw an average of 4% increase in insurance premiums. A continuing rise in the cost of health care has caused an increased financial burden placed on consumers in the form of insurance premiums and health plan designs requiring greater out-of-pocket contributions. Workplace wellness programs are one mechanism for offsetting these expenditures and placing a certain measure of control in the hands of health care consumers.

In the arena of employer-sponsored health care plans, companies are increasingly offering employees financial incentives for taking part in wellness programs and activities, and seeking preventive care measures such as an annual physical. The purpose of these incentives is two-fold: to help prevent certain health conditions caused by lifestyle factors such as stress, poor diet, and lack of exercise; and to detect existing health issues as early as possible. The ultimate goal is to save future health care costs by preventing and detecting health problems today.

Wellness programs have proven to lessen worker absenteeism and increase worker productivity but are frequently attacked as discriminatory and invasions of personal privacy. This project explores the legal framework surrounding wellness programs and aims to provide guidelines for creating a non-discriminatory and beneficial program.

The Medical Malpractice Crisis

Guy S. Regev, M.D. '16

Abstract:

Our healthcare system is in shambles due to the out-of-control medical malpractice system. Doctors can no longer practice medicine in much of the country. Defensive medicine results in billions of dollars in waste. Medical malpractice lawsuits are a sick joke by greedy lawyers who file frivolous lawsuits and ruin honest doctors' careers. "This is the medical malpractice myth," in Tom Baker's words.

Each of the above statements is unsupported by academic data on the topic. These are pure myths disseminated by big industry and misinformed healthcare providers with financial interests that are contrary to the average American's welfare. The occasional anecdotal story about such effects is completely unsupported by empirical evidence studied by independent experts on the topic. On the contrary, there is ample data showing the real crisis occurring in healthcare today is not too many medical malpractice lawsuits, but too much medical malpractice. Unfortunately, medicine today not only improves lives but may damage and destroy them. The Institute of Medicine back in the year 2000 estimated approximately 100,000 preventable deaths and 1 million injuries every year in the US alone are caused by errors. That is 1 injury per 30 seconds and 1 death every 5 minutes due to an error. In this talk, I will briefly review the available data, discuss the solutions reducing errors, as well as the role of litigation in medical malpractice.

Food Law: Awareness, Resources and Proposal

Dexin Deng '16

Abstract:

As a multi-doctrinal area of law, food law encompasses many important yet controversial issues. This 3-part project seeks to promote a better understanding of food law and to disseminate relevant student-oriented resources. This project is initiated by attending a national Student Food Law Leadership Summit organized by Harvard Food Law and Policy Clinic, followed by organizing a speech event featuring Professor Michael Reese, and completed by an article focused on a proposal to classify Genetically Engineered Food for labeling purposes.

The Price of Drugs is Too Damn High! How Good Lobbying Got It There

Naoufal Zouak '17

Abstract:

Price gouging is a very concerning trend in the pharmaceutical industry. It is a result of the monopolization of niche markets with high barriers to entry and the elimination of foreign competition with similarly effective pharmaceuticals produced by a very effective lobby. The pharmaceutical industry justifies their prices by focusing on the increases in life-expectancy from their products, their ability to incentivize more students to enter the field, and the rate at which they can create “wonder drugs.” Relative to EU firms, US firms are more profitable, earn higher stock returns and thus can spend more on R&D which supports the argument that their profits are well- deserved. Nonetheless, it is equally true that those innovations should not be made inaccessible to people based on profit preservation. This project aims to explore the reasons why the pharmaceutical industry has been so successful lobbying legislatures. It then draws on successful foreign regulation that keeps prices low and quality high and the economic theory of the FDA Export Reform and Enhancement Act which as potential solutions to this issue.

The Digital Life of Henrietta Lacks: Reforming The Regulation of Genetic Material

Kelsey Russo '17

Abstract:

The study of genetics has vastly contributed to the overall public good, but as the field progresses unprecedented questions concerning an individual right to genetic privacy have emerged. As research efforts grow genetic information is increasingly shared and published, making an individual's genetic data widely available. These scientific efforts have given rise to a new legal controversy: the impact of genetic discrimination. The family of Henrietta Lacks, a private citizen repeatedly thrust into public debates of research ethics, experienced the effects of genetic discrimination when her genome was made publicly available without their permission.

Genetic information and research is subject to inadequate regulations that are ill- equipped to address these superficially futuristic consequences of publicly available genetic data. The limitations and consequences the current regulatory structure highlight the need for a reformed system that effectively balances public and individual interests in genetic data. Henrietta Lacks lives on in the digital world: her family a reminder to the legal and scientific communities of the heavy burden they have in establishing privacy and sustainability in genetic research.

Opportunities for the Modern Lawyer at the Convergence of Healthcare and Technology

Judy Kim '17

Abstract:

The demand for better healthcare has driven startups to disrupt the digital healthcare landscape. A growing network of New York City based healthcare startups are making their impact to shake up the traditional worlds of insurance, consumer-facing platforms, data analytics, medical software, and more. This rapidly growing and changing landscape is testing the constraints of regulated healthcare law. As healthcare and technology continue to converge, technology companies and their investors are facing an increasing number of unique legal issues, enforced by regulators, including issues privacy of patient and physician information, consumer protection and patient safety. This presentation will explore the variety of legal issues that tech companies will be presented with as development in the healthcare sector expands and the opportunities that will be created for healthcare attorneys.

The Blocked Aetna/Humana Merger: A Different Way to Look at Antitrust Law in the Health Insurance Market

Daniel Weeks '18

Abstract:

On July 21st 2016 the Department of Justice (DOJ) sued to prevent Aetna's acquisition of Humana for \$37 billion alleging anticompetitive concerns. In response to the DOJ's actions, Aetna pulled out of two-thirds of the public exchanges in which it sold

individual insurance, removing key competition from the market. On January 23rd 2017, the United States District Court for the District of Columbia blocked the merger. Despite the concerns of the DOJ, provisions under the Affordable Care Act and individual state statutes give the government power to limit the price increases of insurance companies, making the insurance market different from the typical competitive free market which antitrust law is supposed to protect. In antitrust considerations in other highly regulated industries, the courts have developed the doctrines of Implied Immunity and State Action Immunity to reconcile traditional antitrust law with the regulatory powers already in place to limit anti-competitive behavior. This project will explore the regulatory powers already in place to limit insurance price increases, the development of the doctrines of Implied Immunity and State Action Immunity, and how the factors the courts consider in these doctrines are applicable to the unique regulatory environment of the health insurance industry.

The Corporate Practice of Medicine and Fee Splitting

Martha Pellicano '17

Abstract:

In an effort to ensure that the quality and safety of a patient's care is not compromised by improper profit incentives by health care providers, a significant number of states prohibit what is known as the "corporate practice of medicine" and "fee splitting". These doctrines

prohibit a wide range of activities involving the establishment of formal or informal business relationships between physicians, health care providers, and various health industry participants. As the health care industry and the “business” of health care have evolved in the last century, fee splitting, and particularly the corporate practice of medicine prohibitions, have come under review and scrutiny by relevant policy makers. This presentation will focus on the origins of the doctrines, their current status amongst the states, and how we might expect to see them evolve in the future.

Refusing Medical Attention in the Prehospital EMS Setting

Moshe Hoffman '17

Abstract:

Much literature has been published on the topic of patients' right to refuse medical care. However, much of what has been written is focused from the doctor's perspective, where the patient sought medical attention in the first place. In the prehospital setting, however, where bystanders and family members routinely call 911 for patients who do not want medical care, Emergency Medical Service providers, comprised of EMT's and Paramedics, face the dilemma of whether a patient has the capacity to refuse medical care (i.e. must he or she be taken to the hospital or can the patient stay at home). If EMS takes a patient against his or her will, they risk violating the patient's fundamental right to refuse care. However, if EMS allows the patient to refuse care and the patient suffers serious illness or perhaps death as a result, the EMS providers may get sued for medical malpractice. While there is no universal test EMS providers can use to determine if a patient has decisional capacity, there are certain criteria EMT's and Paramedics should use to help make the determination.

Projects 2016

Access to Medical Technologies: The Current Legal Framework

Julia Kuelzow '16

Abstract:

Blockbuster discoveries in the pharmaceutical sector and iterative improvements of medical technologies impinge on different innovation modalities. Accordingly, focus on access to medicines has been directed to market incentives (e.g., patent and regulatory exclusivities), while access to medical devices centers on transparent, practical regulation. Based on research at Médecins Sans Frontières/Doctors Without Borders and the World Health Organization, this presentation will sketch out the contours of relevant domestic and international legal frameworks governing the ultimate delivery of life-saving health technologies, highlighting recent developments in the field.

Do No Harm: High Risk Psychiatric Patients, Section 1983, and a New Type of Civil Rights Claim

Amanda Levine '16

Abstract:

One of the more pressing concerns in mental health care is the revolving door patient, a patient that exhibits a pattern of frequent readmission to inpatient psychiatric wards. In 2013, a New York psychiatric patient had a 19 percent chance of being readmitted within a month of discharge. Reformers have tried a variety of methods to solve the problem, including legislation such as Kendra's Law to force outpatient maintenance on the "frequent fliers." Despite these interventions, problems with these patients persist. In this project, I propose that a revolving door patient may be able to make a civil rights claim under Section 1983 as a result of a doctor's failure to properly discharge the patient. This "wrongful discharge" claim will fill the gap between patients who are covered by Kendra's law and patients who do not need the law's protections.

Incentivizing Consolidation and Preventing Efficiency: An Avoidable Contradiction

Benjamin Edlin '16

Abstract:

Hospitals in the 19th Century were originally founded as charitable institutions managed by religious organizations. These "voluntary" hospitals were funded mainly by charitable donations, and they were primarily designed and managed to provide societal welfare. However, by the 1920's these institutions had drastically transformed into business entities and focused on providing medical treatment for a fee in pursuit of a profit. Their emphasis shifted away from "patients and the poor" to "professionals and their patients."

This focus on profit resulted in a disproportionate increase in healthcare costs in America and soaring profits for American healthcare providers. In response, President Obama, through the Patient Protection and Affordable Care Act, attempted to rein in the excessive costs to give more Americans access to healthcare. Part of this cost-cutting regime created intrinsic incentives for individual hospitals to merge into massive healthcare systems. This move toward consolidation conflicted with the Federal Trade Commission's ("FTC") anti-trust goals, giving rise to litigation. While the FTC is trying to preserve fair competition in healthcare by preventing any one institution from acquiring excessive market power, healthcare institutions are consolidating in order to provide healthcare for Americans more efficiently and at a lower cost. Both the FTC and healthcare institutions have the ultimate goal of providing efficient productive care. This note argues that the legislature should adopt a mandatory mediation statute in all federal antitrust disputes involving healthcare consolidations. This will give courts the latitude to incentivize and consider alternative judicial remedies to allow healthcare institutions to consolidate while at the same time addressing the FTC's legitimate concerns.

Projects 2015

Right to Refuse: A Corporation's Right to Exercise Religious Freedom under the Patient Protection and Affordable Care Act

Kathleen D. Reilly '15

Abstract:

This project addresses how the First Amendment's free exercise provision applies to corporations with regard to the Patient Protection and Affordable Care Act's birth control mandate. Religious organizations, houses of worship, schools, and nonprofit organizations have the ability to be exempted, but for-profit corporations are in a more difficult position. When analyzing application of the birth control mandate, courts need to determine if an objecting corporation's free exercise right has been violated. The key is a corporation's standing to argue that its First Amendment right has been violated, and for the facts to be weighed by the court in their entirety.

This project first discusses the Patient Protection and Affordable Care Act and its contraceptive coverage. It provides an analysis of the issues and decisions surrounding the two main circuit cases, Hobby Lobby Stores, Inc. v. Sebelius and Conestoga Wood Specialties Corp. v. Sec'y of U.S. Dept. of Health & Human Services, explaining how the federal courts reached two entirely different decisions. Then, it analyzes how the First Amendment has been applied to corporations, focusing specifically on the support given to corporations for their freedom of speech. It then establishes that freedom of expression should be granted to corporations in light of case law supporting corporations' rights to the First Amendment, regardless of religious association. Finally, a constitutional analysis is applied to provide an outcome and a resolution for the circuit split, ultimately agreeing with the recent decision of the Supreme Court.

Intersex Children in Foster Care: Can the Government Elect Sex Assignment Surgery?

Ashley Huddleston '15

Abstract:

Between 1.7% and 4% of the population is born with an intersex condition. This means that an individual is born with a reproductive or sexual anatomy that does not fit the definition of a "normal" male or female. While this condition is hardly ever life-threatening, children are subjected to harmful sex assignment surgeries at a young age; before anyone knows which gender the child will identify as. Though it is usually the child's parents that authorize this life-altering surgery, in the case of M.C. v. Aaronson, it was the South Carolina Department of Social Services. This Note looks at the development of the current treatment of intersex children and questions whether the government may elect sex assignment surgery for a child in their care and custody. This Note argues that the government may not elect such a surgery under any circumstances. It then details some of the international responses to intersex

conditions and argues that the United States can emulate some of those measures to alleviate the pressure to subject an intersex child to sex assignment surgery. Finally, the Note concludes that the best thing the government can do in a situation like this is to do nothing—allow the child to develop without physically altering his or her natural body.

Electronic Health Records: How to Suture the Gap Between Privacy and Efficient Delivery of Healthcare

Mallory Turk '15

Abstract:

Electronic Health Records (EHRs) will likely become the norm in medical record storage and transmission in the near future. There are already regulations in place mandating different aspects of what must be included before a healthcare facility may set up and use EHRs for their patients. These regulations are relatively new, having only been adopted in 2012, so it is unclear how they will in practice protect patient privacy. In order to make an educated guess, I looked at credit card regulations, which are similar to EHR regulations, and concluded that mere certification is not enough. So, in order to better protect patient privacy, I conclude that there should be a civil monetary penalty imposed on the vendors – the people who create EHRs – if they fail to continuously comply with the regulations. As a society, we should encourage compliance with these regulations for fear of computer hackers stealing the information contained within EHRs, such as financial and medical information. Through imposing a civil monetary penalty as a deterrent, every party who has an interest in EHRs will be better protected.

Projects 2014

The Supreme Court Breaks its Silence in *US Airways, Inc. v. McCutchen*: ERISA Plan Terms Prevail but is it “Equitable”?

Jenny Chung '14

Abstract:

*This paper discusses the question of whether the equitable enforcement provision of ERISA Section 502(a)(3), which entitles plan administrators to seek reimbursement from a beneficiary on theories of equitable relief in certain scenarios, can also be used by beneficiaries to limit or prevent reimbursement. A majority of circuits favored the explicit terms of the plan and prohibited equitable defenses that would prevent reimbursement under the terms of the plan. On the other hand, a minority of circuits, including the United States Court of Appeals for the Third Circuit in *U.S. Airways*, allowed beneficiaries to raise equitable defenses in such circumstances. The United States Supreme Court’s opinion sides with the majority view, clarifying that the importance of giving consistent effect to plan*

language, provided that the plan language is clear, generally trump the role of equity in resolving actions under Section 502(a)(3) even if resulting in a seemingly unfair result for the beneficiary who has been harmed.

The paper agrees with the Supreme Court's in its applying the common fund doctrine to determine attorney's fees when a plan's terms is unclear. However, in order to avoid future confusion among the courts regarding ERISA subrogation claims, the paper concludes with recommendations for legislative enactments similar to the Medicare subrogation statute.

Outside of the Box: The Broader Public Health and Safety Costs Created by the Overuse of Solitary Confinement in New York Prisons

Melissa Lee '14

Abstract:

Through the lens of community health, this paper questions the overuse of solitary confinement practices and its most damaging aspects. Like prior studies examining the spread of infectious diseases among the prison populations and, consequently, the communities to which the inmates return, this paper seeks to raise awareness around the fact that our prisons do not operate in isolation, separate from our communities. Instead, the effects of what transpires within prison-life can have negative health impacts within the broader community. Here, where solitary confinement conditions have proven to have severe and lasting psychological effects, where nearly 2,000 inmates are released back into the community directly from "the Box" each year in New York alone, and where little to no mental health treatment and preparation for reentry is provided to these inmates, New York's solitary practices put our communities' health and safety at risk. This paper is still a work in progress but intends to make a number of proposals on ways to curb the health impacts of solitary confinement on the community. Ultimately, however, the paper questions whether the cost to the community outweighs the perceived usefulness of current solitary confinement policies within our prisons.

Between a Rock and a Hard Place; Federal Antitrust Guidance for Accountable Care Organizations

Veronica Jackson '14

Abstract:

This Note discusses the antitrust implications of Accountable Care Organizations (ACOs). One aspect of the Affordable Care Act aimed at combating rising health care costs is the incentivizing of ACOs through the Medicare Shared Savings Program. ACOs are "groups of providers of services and suppliers meeting criteria specified by the Secretary may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through

an [ACO].” There are potential advantages to integrating ACOs into the U.S. health care system, but there are also numerous financial and legal barriers to be faced by these new organizations. Federal antitrust laws that seem to directly contradict the structure of an ACO, pose real threats to the existence of these organizations. To solve this problem, federal agencies, such as the Department of Justice (DOJ) and the Federal Trade Commission (FTC), have released ACO antitrust guidelines that allow some flexibility for ACOs that fall within an antitrust “safety zone.” However, it could be difficult and burdensome for ACOs to remain in the safety zone, and falling outside that zone could lead to substantial financial and legal implications for participating physicians. This Note will discuss both the advantages and the legal and financial dangers that have been created for participating ACOs, and will propose that for physician-based ACOs to succeed and make an impact in our healthcare system, the FTC and DOJ need to either simplify and impose less complicated numerical oversight on ACOs, or discontinue their incentivizing and encouraging of physicians to create ACOs.

Disparate Treatment? Supported Decision-Making, Managed Long-Term Care, and the Looming Caregiver Crisis

Peter Travitsky '14

Abstract:

A growing and compelling academic discourse favors a shift from a best-interests model of guardianship to a supported decision-making model. The hope is to protect those who lack full capacity to make their own decisions, and who often lack involved family caregivers, while affirming their rights as citizens in the wake of an elder population boom. Current policymaking, however, is focused on cost-cutting, prompting states to move toward managed, coordinated-care models of service delivery. Although projections warn that the ratio of caregivers to care recipients will shrink significantly in the coming 30 years, little attention is being given to the imperative of helping seniors thrive in their communities amid the shift to managed care. Right here in New York, many of those who qualify for both Medicare and Medicaid and who require long term care are now mandated to enroll in Medicaid managed long term care plans (MLTCs). This project explores the modern-day role of nursing homes for this population, and highlights key points at which a senior citizen engages with institutional providers. People who lack caregivers in old age are often

at a representational disadvantage in care-planning, and, as a result, risk unnecessary institutional placement. The project concludes that the goals of managed care providers and advocates of supported decision-making are not incompatible, and have potential to generate savings for managed care organizations while supporting an aging population that has fewer caregivers.

Bloomberg’s Thirst Left Unquenched: Understanding the Unconstitutionality of the NYC Soda Ban

Rebecca Vainer '14

Abstract

*Americans consume 200-300 more calories daily than they did 30 years ago. The single largest increase can be attributed to sugary drinks. In response to this figure and data from other studies, former New York City Mayor Michael Bloomberg proposed a regulation to the New York City Board of Health, that would prohibit the sale of soda and sugary drinks greater than 16 ounces in street carts, movie theaters, stadiums, and restaurants. This paper examines the New York County Supreme Court's decision in *New York Statewide Coalition of Hispanic Chambers of Commerce v. New York City Department of Health and Mental Hygiene*, which suspended the Sugary Drinks Portion Cap Rule (Soda Ban) on March 11, 2013. This paper concludes by exploring how the Soda Ban, despite its judicial suspension, could represent a stepping-stone in combating the obesity epidemic.*

Increasing Public Health Engagement in Adopting Health Information Technology

Lara Glass '14

Abstract:

The field of Health Information Technology (Health IT) is going through a stage of significant change and rapid growth. Norms established now are likely to shape the future of not only healthcare, but also public health. The way health information is gathered, stored, and categorized could have a significant impact on the data that are available for public health professionals to analyze. Despite this, the public health profession has been significantly underrepresented in the discussions that inform federal Health IT policies.

This project explores potential strategies for increasing public health engagement in processes that lead to adopting Health IT. Two main obstacles standing in the way of public health involvement are a lack of public health funding and limited awareness in the public health community. To address the financial barriers concerns, the American Recovery and Reinvestment Act offers a possible funding source for public health to invest in Health IT infrastructure development. When considering awareness, it is

important to note that the US Department of Health and Human Services has created the Office of the National Coordinator for Health Information Technology (ONC) to coordinate Health IT work at the federal level. Professional communities of practice already developed by ONC could be leveraged to increase awareness among the target public health professionals. Through collaboration with ONC, this project involved creating appropriate materials for such an awareness-raising effort. One of the initial results of that ONC collaboration will be seen next month in a presentation at an upcoming national public health conference.

Projects 2013

Codifying Common Law: The Self-Critical Analysis Privilege and the New Jersey Patient Safety Act

Adam Blander '13

Abstract

This Note centers around the “self-critical analysis privilege.” I argue that self-critical analysis as codified in the New Jersey Patient Safety Act, deviated from its common law roots. The privilege under the common law, both in the federal system and in New Jersey, was traditionally malleable and “qualified” (in some ways akin to the work-product doctrine), and was applied infrequently and on an ad-hoc basis by trial judges in an attempt to balance competing public and private interests during the discovery process. In contrast, the PSA created a more crystallized, unbending and absolute privilege, which I suggest will produce more consistent, but perhaps less equitable results in future litigation against hospitals. I conclude by suggesting that the “subsequent remedial measure” evidentiary doctrine, embodied in F.R.E. 407, which would render self-critical material inadmissible but still discoverable, strikes a more appropriate balance as it would assure hospitals that their own safety-procedures will not expose them to liability while at the same time protect a patient’s right to all information concerning her treatment.

Published in the JOURNAL OF LAW & POLICY (Spring 2013).

Putting "Meaning" Back into "Meaningful Use": A Patient-Centric Model for EHR Adoption.

Rebecca Bernstein Ford '13

Abstract

There is little doubt that Electronic Health Records (“EHRs”) will eventually be fully adopted and will change how we experience health care. The road to full adoption has not been straight through and our short-term goals may need to be made more manageable in order to facilitate long-term adoption. Through HITECH the federal government set-up admirable goals for EHR adoption coupled with financial incentives, but the “meaningful use” metrics designed to measure success are daunting and stand in the way of adoption for many providers.

I argue that “meaningful use” should be redefined to focus on “meaningful patient use” since the base goal of our healthcare system is to help each individual patient meet their needs. By focusing on meaningful patient use we will be able to improve the quality of healthcare provided to each patient and lower risk for doctors and hospitals. The more informed a patient is, the more likely they will act as their own advocate and seek the best care possible.

Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access to Medicine Problem

Dina Halajian '13

Abstract

This Note aims to determine whether the Trade-Related Aspects of Intellectual Property Agreement (TRIPS) has been an effective tool to balance pharmaceutical patent rights with access to essential medicines in developing countries. The Note focuses primarily on Article 30 and 31 of TRIPS, namely compulsory licenses of patented medications during a public health emergency. The Note identifies and analyzes deficiencies in and obstacles to TRIPS. The Note also contains a discussion on the current shift in focus from infectious disease compulsory licensing to chronic disease compulsory licensing.

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Protecting the Patient: Private Rights of Action Under the Federal Nursing Home Amendments

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Abstract

This paper discusses whether patients in nursing facilities should be allowed to sue their nursing homes for violating standard of care benchmarks. The paper focuses on cases, one from the Third Circuit and a few others from various district courts, which take opposing views on this issue. The main dividing line centers around whether the amendments themselves give patients the power to sue under federal statute 42 U.S.C. § 1983, which imposes liability against those acting under state statutes that have violated a citizen's federal rights. The paper concludes by suggesting that patients should in fact have the right to sue if they are not receiving proper levels of care in these facilities, and that this view comports with sound public policy.

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Shaping Patent Law Through the Biotechnological and Pharmaceutical Research Process

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Abstract

The basis of the American patent system is found in Article I, Section 8 of the U.S. Constitution, which empowers Congress to “promote the Progress of Science and the useful Arts, by securing for limited Times to...Inventors the exclusive Right to their respective...discoveries.” Since the enactment of the first patent statute by Congress in 1790, the patent system has seen a number of changes to keep up with changes and advances in technologies. This paper explores the extent at which the biotechnology and pharmaceutical industries have shaped patent law in modern times.

The biotechnology and pharmaceutical industries are often seen as a product of the patent system. The patent system can encourage investment in an industry that requires an enormous amount of capital and possesses a high risk. As one of the driving forces of the U.S. economy, U.S. patent law has not only shaped the industry to allow the U.S. biotechnological and pharmaceutical industries to become world leaders, but the industries have also shaped the law. Technology and the development process have changed dramatically since the founding of the U.S. patent system. In order to continue the original policy goals of the patent system – to encourage innovation for the benefit of society – the law must be aware of the research processes for new technologies so it may adapt to better accomplish those goals. Awareness of the research process will allow courts to better understand the implications of the law on existing technologies as well as future technologies.

This research project explores the U.S. Court system’s awareness of the biotechnological and pharmaceutical research process and how this awareness has shaped the current patent system. Specifically, long standing patent tests for utility, non-obviousness and patentable subject matter have recently been scrutinized by courts that have become increasingly aware of these tests’ effects on innovative and complex biotechnological research.