



The Petrie Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School

*Annual Report, Fiscal Year 2018
July 2017–June 2018*

Executive Summary

Fiscal Year 2018 was a year of exciting transitions and changes for the Petrie-Flom Center, in terms of leadership, project focus, types of events, and staffing. FY18 marked the first year of **Carmel Shachar**'s tenure as Executive Director. During this year the Center also launched two new initiatives and largely completed work on a third. In FY18 we also made some changes to the types of events hosted, choosing to shift to larger scale events with new partners and collaborators. We also changed our staffing, bringing in a Communications Manager with significant experience in digital media to replace our previous Project Coordinator, in part to reflect our re-commitment to a strong digital presence.

In FY18 the Center expanded its work on health law policy issues and sought to build deeper connections with health law practitioners. For example, this year marked our first event co-hosted with a law firm, Will Value-Based Care Save the Health Care System? Our partner, Ropes & Gray LLP, was integral in procuring high level industry speakers such as the Chief Medical Officer of Harvard Pilgrim Health Care and the General Counsel of Fresenius Health Care. The event brought close to two hundred scholars and health law practitioners to campus and sparked a dialog between industry and thought leaders. We hope that this event will be the first of many in which the Center facilitates a dialog between practitioners and scholars. We also anticipate that these events can serve to strengthen the ties between HLS alumni working in health law and the HLS community, especially students. Carmel is currently working to launch our Health Care General Counsel Roundtable, a forum for ten to fifteen leading health lawyers to come together for peer conversations and education. Again, the Center hopes that the Roundtable will build a bridge between the HLS campus, including students, and leaders in our field.

Carmel continues to work closely with Faculty Director Professor **I. Glenn Cohen** to promote our many ongoing initiatives and launch new projects at the intersection of health law policy, biotechnology, and bioethics. This task keeps them busy, as our sponsored research portfolio is



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also in an exciting state of flux. Most notably, this year we launched our Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL), a five-year project funded by the University of Copenhagen's CeBIL, the Collaborative Research Program in Biomedical Innovation Law. PMAIL seeks to understand the frontiers of big data in health care diagnostics through interdisciplinary analysis of important health law and policy issues. By the end of PMAIL, our goal is to produce a comparative analysis of “black box” personalized medicine, explaining the shortcomings of the current innovation policy landscape in Europe and the US and providing a comprehensive examination of various policy options to better align incentives. Artificial intelligence is increasingly becoming a high-profile topic in legal and ethical work, so we are thrilled to be diving deeply into this work. Our focus for PMAIL in FY18 was hiring a Research Fellow for Precision Medicine, Sara Gerke, who will join us for three years starting in August 2018.

We also launched the Innovative Funding Models in Translational Research Project, led by Senior Fellow Douglas Eby, to explore the regulatory and ethical challenges around the increase of for-profit funding in early stage medical and scientific research. This Project will bring representatives of leading research institutions such as the Broad Institute and the Dana-Farber Cancer Institute to campus in October 2018 for a sophisticated discussion of problems and opportunities created by the influx of for-profit funding and corresponding decrease of governmental funding for research. Both projects launched in FY18 reflect the Center's strong and unique positioning in the health law policy and bioethics landscape. Because of our close ties to the medical research community, particularly at the Longwood Medical Area, we are well placed to identify areas of legal and ethical ferment as they initially present themselves.

Our existing research projects also had a strong year. Our collaboration with the Regulatory Foundations, Ethics, and Law Program of Harvard Catalyst was very productive, generating guidance and several articles, including a New England Journal of Medicine article, on the complicated issue of compensating research subjects. Through this project we also continued to publish work on social media as a research recruitment tool and prioritizing study recruitment. And our work on the Patient-Centered Outcomes Research Oversight Study mostly finished by the end of FY18, culminating in a Delphi panel to establish consensus among expert stakeholders on key recommendations for the oversight of Patient-Centered outcomes research. The results will be published in the Annals of Internal Medicine. Both of these projects reflect our commitment to supporting ethical research, including supporting the work of researchers and the voices of research subjects.

Our more policy-oriented projects also had busy years, especially in regard to events hosted on campus. Our Project on Law and Applied Neuroscience wrapped up its fourth year with a workshop cosponsored by the Federal Judicial Center on “Tailoring Justice: Science-Informed Decision Making,” which was designed to help federal criminal justice practitioners develop improved collaborative responses to individuals with mental health and substance use disorders. Our FY18 Senior Fellow on the Project, Francis X. Shen, organized a large conference on law and dementia. Considering the aging demographic of the United States, it is important to encourage legal practitioners to better understand current medical and neuroscience frameworks when it comes to capacity to consent, aging, and dementia. The Center's strong ties in the legal and medical fields positions us to be an important leader in this field and to help influence policy to better



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reflect the experience of older Americans. We hope to continue to grow our law and dementia work in the coming year. Our Project on Advanced Care and Health Policy has helped contribute to the regulatory framework around advanced care and illness. The project released a whitepaper on critical pathways to improved care for serious illness that came out of a conference hosted in FY17. We also hosted a well-attended conference one on shared decision-making for advanced care that we are translating into a whitepaper and several academic articles, to reach as wide an audience as possible. One of our next goals to continue to grow this project will be to create a fellowship to bring young leaders in the field of advanced care to Harvard, both from the federal and state level. Senior Fellow Mark Sterling will continue in his inaugural role for another year.

We had an extremely busy year in term of events: we hosted eleven conferences and a number of smaller panel events, as well as providing support for events hosted by partners at Harvard Law School, Harvard Medical School, and elsewhere. The topics addressed covered the gamut of health law policy and bioethical issues: Patient-Centered outcomes research, economic ordeals in health care, dementia in our elected officials and judiciary, the cost of drugs in America, and crimes of passion among other topics. A highlight of the year was our event at HLS | 200, New Technologies, New Dilemmas, featuring Atul Gawande, Eric Lander, and Judith Edersheim along with our Faculty Director I. Glenn Cohen, to discuss the impact that breakthroughs in science have, should have, and will have on our legal and regulatory systems. As mentioned above, this year we began to strengthen our offerings for the health law practitioner community, especially HLS alumni, when we had our first collaborative event with a law firm. We collaborated with the Center for Bioethics at Harvard Medical School on a number of conferences and events, including the year-long health policy and bioethics consortium and a conference on access to care in the American prison system. We also collaborated with our friends at the Berkman-Klein Center for Internet and Society at Harvard University to continue the Digital Health @ Harvard series, which we hope to build into a larger collaboration. We hosted our 6th Annual Health Law Year in P/Review, which featured panels recapping an eventful year in health care reform with perspectives from both conservative and liberal advocates from Washington D.C. This year's annual conference, hosted in collaboration with the Harvard Law School Project on Disability, explored the framing of disability in the medical and legal fields.

This year we have also been very busy in the scholarship department, publishing an array of articles in legal, medical, and bioethics journals, including in the *New England Journal of Medicine*. Additionally, this was a full year for our edited volumes, as we released:

- LAW, RELIGION, AND HEALTH IN THE UNITED STATES (Cambridge University Press, July 2017),
- SPECIMEN SCIENCE: ETHICS AND POLICY IMPLICATIONS (MIT Press, October 2017), and
- BIG DATA, HEALTH LAW, AND BIOETHICS (Cambridge University Press, March 2018).

We have also just submitted the final manuscript for TRANSPARENCY IN HEALTH AND HEALTH CARE, stemming from our 2017 annual conference, which will be released in the coming year. We are excited to see where our scholarship goes next, especially with our new focus on artificial intelligence in health care.



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Our excellent Student Fellows joined the Center from across campus and pursued projects related to the perspectives of mental health providers on mental health apps, bioethics in the Islamic tradition, the regulation and theology of Christian health care ministries, and the rights of the fetus in Irish law. Our Bill of Health blog continues to be a leading forum for health law policy and bioethical perspectives from thought leaders across the country and in Europe. In particular, entries relating to the opioid epidemic and vaccine policy have recently sparked conversations and debate. Although it is very popular, with over 970,000 unique users visiting since 2012 and 17,000 page views per month, we are in the midst of planning a major relaunch for the blog, to be supported by our new Communications Manager. We anticipate that Bill of Health will continue to host insightful analysis from contributors at Harvard and beyond, but will build its reputation in the wider digital landscape. This refresh reflects our commitment to expanding our online presence, to allow more people to engage with us than ever before.

We believe great things are in store for the Center in Fiscal Year 2019. We are well positioned to be thought leaders on an increasingly high-profile topic, the use of big data and artificial intelligence in health care, and hope to use that project as a springboard to work more in the field of digital health. We also are looking to launch the Center's work in several important health law policy areas, including the treatment of aging individuals with dementia and the impact of the opioid epidemic. We are excited about a potential collaboration on the topic of value-based health care with our colleagues at Harvard Business School. We are working to build connections between legal scholars and health law practitioners, both at Harvard and beyond, through our event programming and our Health Care General Counsel Roundtable. Our commitment to serving a broad audience is also reflected in our soon-to-be launched refresh of our successful blog, Bill of Health, which we believe will help amplify the work of Center staff and students. To support all of these projects and programming, and to secure the future of the Center, we hope to have a successful year in fundraising. The Center's work remains strong and we are looking forward to sharing it widely through these initiatives.

With sincere thanks to everyone who supports our work,

I. Glenn Cohen

A handwritten signature in blue ink that reads "I. Glenn Cohen".

Faculty Director & James A.
Attwood and Leslie Williams
Professor of Law, HLS

Carmel Shachar

A handwritten signature in blue ink that reads "Carmel Shachar".

Executive Director



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2017–18 Report of Activities

(Fiscal Year 2018: July 2017–June 2018)

Areas of Inquiry

The Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School was founded in 2005 through a generous gift from Joseph H. Flom and the Carroll and Milton Petrie Foundation. The Center's founding mission was to promote interdisciplinary analysis and legal scholarship in these fields. Today, the Center has grown into a leading research program dedicated to the unbiased legal and ethical analysis of pressing questions facing health policymakers, medical professionals, patients, families, and others who influence and are influenced by health care and the health care system. To achieve this goal, the Center fosters a community of leading intellectuals, practitioners, and policymakers from a variety of backgrounds at all stages in their careers, across Harvard University and the world.

The Center's work generally falls into the following categories:

- (1) ***Public engagement***, including frequent conferences and other events; extensive media commentary; our popular health policy and bioethics blog, Bill of Health, boasting an average of around 15,000 unique monthly users; and our website featuring Center news, scholarship, and events, as well as health law policy and bioethics opportunities and other resources for the public.
- (2) ***Academic programs***, including programs for visitors and senior scholars; a range of curricular contributions, most notably the Health Law, Policy, Bioethics, and Biotechnology Workshop; and various mentorship and writing opportunities for Harvard students, including a coveted graduate fellowship.
- (3) ***Sponsored research*** collaborations across the university and its affiliated hospitals, and elsewhere, with projects addressing the use of big data in health care diagnostics, innovative funding models in translational research, human subjects research regulation and ethics, Patient-Centered outcomes research, and more, alongside additional collaborations covering law and neuroscience and care for advanced illness.
- (4) ***Independent scholarship*** and publications by our affiliates, including the peer-reviewed, open-access Journal of Law and the Biosciences with partners at Stanford and Duke universities, and several books on cutting edge topics in health policy and bioethics.

Typically, our work spans the entire range of issues at the intersection of law and health policy, biotechnology, and bioethics. Among the many issues the Center's work has covered are health care reform and economics, human subjects research regulation, medical



tourism, the fragmentation of American health care, conflicts of interest in medicine, religion and health policy, reproductive technology, law and neuroscience, health law and behavioral economics, pharmaceutical and device regulation, and more.

Leadership

During FY18, the Center was led by Faculty Director Professor **I. Glenn Cohen** and Executive Director **Carmel Shachar**, who joined the Center as Executive Director in June 2017.

Research, Project Activities, and Scholarship

The Petrie-Flom Center has developed a strong reputation for leading scholarship at the forefront of health law policy, biotechnology, and bioethics. This year our affiliates again published top-rate scholarship and served as commentators for major media outlets, as well as invited lecturers, panelists, and presenters at a wide variety of events. We continued several sponsored research projects and other collaborations and also took steps in some new directions. These accomplishments are described in more detail below.

Sponsored Research

The Center was engaged in several sponsored research projects in FY18, one of which, the Patient-Centered Outcomes Research Oversight Study (PCOROS), will close shortly after the end of FY18. We also launched a new sponsored research project, the Project on Precision Medicine, Artificial Intelligence, and the Law. We continue to seek additional funding opportunities, and submitted several letters of interest, proposals, and applications for additional funding.

The Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL)

The Petrie-Flom Center, along with several former Academic Fellows and current Center affiliates, joined former Visiting Scholar **Timo Minssen**'s innovative and expansive application to the Novo Nordisk Foundation to establish the Center for Advanced Studies in Biomedical Innovation Law (CeBIL), an international and interdisciplinary research program centered around various aspects of biomedical innovation law. The Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL) is the Center's segment of the collaboration. We were notified at the end of FY17 that the project was approved, and PMAIL launched in January 2018. The Project will run until the end of December 2022.



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PMAIL will provide a comparative analysis of the law and ethics of black-box precision medicine, explaining the shortcomings of the current innovation policy landscape in Europe and the US and providing a comprehensive examination of various policy options to better harness the potential of black-box medicine. PMAIL seeks to answer important health technology questions, such as:

- What exactly are – or will be – the distinguishing features and added benefits of black-box medicine in comparison to traditional personalized medicine?
- What are the concrete scientific and legal hurdles to the further development of black-box medicine?
- How does the legal framework differ in the US and Europe and what could each learn from the other?
- How much control should patients have over how their data is used to produce personalized medicine models and the use of these models in their health care?

PMAIL seeks to answer these questions by:

- reviewing biomedical literature in order to get a basic understanding of the most important technologies for the development of precision medicine;
- investigating the landscape of intellectual property incentives commonly used to support the development of the technology that is most relevant to precision medicine;
- analyzing the implications of recent intellectual property case law in the US and the E.U. on black-box personalized medicine; and
- assessing and evaluating the nature, source(s), and extent of the incentive gap for developing precision medicine and the feasibility, efficacy, and lawfulness of proposed legal policy solutions.

PMAIL is led by **I. Glenn Cohen**, with support from **Carmel Shachar**, and contributions from **Timo Minssen** and former Academic Fellow **Nicholson Price**. The focus of PMAIL in FY18 was finding the Research Fellow for Precision Medicine to join the Project. **Sara Gerke**, a former visiting researcher, will join in August 2018 as the Research Fellow for Precision Medicine.

Harvard Catalyst
Regulatory Foundations, Ethics, and Law Program

Harvard Catalyst | The Harvard Clinical and Translational Science Center at Harvard Medical School was established in 2008 to improve human health by enabling collaboration and providing tools, training, and technologies to clinical and translational investigators. It is funded by the National Institutes of Health (NIH)



Clinical and Translational Science Award (CTSA) program (grant 1UL1 TR001102-01), and by contributions from a number of Harvard schools and affiliated institutions.

The Petrie-Flom Center has collaborated with Harvard Catalyst's Regulatory Foundations, Ethics, and Law Program since December 2013, and has continued into the beginning of FY19. Our work may continue, pending the reorganization and reprioritization of Harvard Catalyst after their successful renewal of the CTSA for another 5-year term.

The Center's work on this project has been co-led by **I. Glenn Cohen** and **Carmel Shachar**. **Luke Gelinas** joined the program in August 2015 as the Petrie Flom-Harvard Catalyst Fellow in Clinical Research Ethics, undertaking primary responsibility for advancing the various projects on a day-to-day basis. As of July 2017, Luke's title shifted to Senior Researcher to reflect his work on other sponsored research projects at the Center. He remained involved in the project until Spring 2018, when he transitioned away from full time work at the Petrie-Flom Center to serve as the Chairperson at Advarra IRB.

The Center's main focus for this collaboration has traditionally been to develop practical solutions to key legal and ethical barriers affecting participant recruitment to and retention in clinical research studies.

Projects

Using Social Media as a Research Recruitment Tool

Social media is emerging as a promising research recruitment tool. Despite this, there is no specific regulatory guidance and very little in the bioethics literature to help investigators and IRBs navigate this potentially unfamiliar terrain. This project develops a methodology for assessing social media recruitment techniques, analyzes and applies key norms of privacy and investigator transparency, and uses detailed case studies to shed light on relevant aspects of social media recruitment. The primary deliverable, completed in FY16, is a guidance document outlining numerous concrete recommendations for investigators and IRBs. This year, we continued to disseminate and promote this work, contributing a book chapter titled *Social Media and Pediatric Research Recruitment* to an edited volume by Oxford University Press (ETHICS AND RESEARCH WITH CHILDREN, in press), and by way of presentations at the National Cancer Institute and a national webinar.

Evaluating Offers of Payment to Research Participants

Institutional Review Boards (IRBs) responsible for overseeing research with human subjects and investigators conducting such research express confusion and uncertainty over key regulatory concepts applicable to offers of payment to research participants, as well as the ethical boundaries that should be used in evaluating such



offers. The result is substantial conservatism, spurred by fear that offers of payment are too high. This project aims to clarify the definitions of key terms such as “undue influence,” “coercion,” and “exploitation,” and to draw attention to the overlooked problems associated with paying research participants too little. We published an article directed at helping IRBs and investigators promote “fair” payment, *Paying Research Participants: The Outsized Influence of Undue Influence*, in *IRB: Ethics & Human Research* (Jul-Aug 2017). A guidance document offering definitions and an ethical framework for paying research participants was completed in Summer 2017, and a companion article titled *A Framework for Ethical Payment to Research Participants* was published in the *New England Journal of Medicine* in Winter 2018. In Spring of 2018, we published two additional articles on related topics: *Truth in Advertising: Disclosure of Participant Payment in Research Recruitment Materials* in *Therapeutic Innovation & Regulatory Science*, and *Mutual Obligations in Research and Withholding Payment From Deceptive Participants* in the *American Journal of Bioethics*. Additionally, we have continued to disseminate this work through a national webinar and invited presentations.

When Clinical Trials Compete: Prioritizing Study Recruitment

It is not uncommon for multiple trials at the same institution to recruit concurrently from the same population. When the relevant pool of participants is limited, as it often is, trials essentially compete for them. There is evidence that such competition is a predictor of low study accrual, but there is no consensus on what steps, if any, institutions should take to manage this issue. One approach is for institutions to minimize competition between trials by prioritizing between them, allowing some studies to recruit eligible participants ahead of others. In this project we examine prioritization as a means of addressing the challenges of competing studies and address the ethical and practical issues involved with implementing institutional prioritization models. This year, we published an article, *On Scarcity and the Value of Clinical Trials*, in the *American Journal of Bioethics* and gave a presentation to a national audience on this topic.

Educational Initiatives

The Center’s affiliates working on this project have also been involved in various educational initiatives, including lectures for Harvard Catalyst training programs, and invited presentations and webinars for various organizations, including Public Responsibility in Medicine and Research (PRIM&R) and various IRBs.

The Patient-Centered Outcomes Research Oversight Study (PCOROS)

Since September 2015, the Petrie-Flom Center has been part of a collaborative project funded by the *Patient-Centered Outcomes Research Institute (PCORI)* called the “Patient-Centered Outcomes Research Oversight Study,” or PCOROS, led by Principal Investigator *Joel Weissman*. The Petrie-Flom Center’s work on PCOROS has been led



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by I. Glenn Cohen. In March 2017, Luke Gelinas joined the project as Research Associate, splitting his time between PCOROS and work for Harvard Catalyst. He remains associated with this project until its close in early FY19 as a Senior Researcher at the Center.

The primary focus of this project is to identify and address any novel or prevalent ethical and regulatory challenges posed by Patient-Centered outcomes research (PCOR) as relevant to human subjects protection and oversight. The goal is to engage with institutional review boards (IRBs), investigators, patients, and other stakeholders to better understand the practical realities of PCOR oversight: what are the barriers, ethical decision points, regulatory challenges, and outstanding questions calling for resolution?

The first phase of the project was a qualitative research study (including interviews, focus groups, and case studies) to catalogue the practical and ethical challenges encountered by IRB members, patient research partners, and other stakeholders dealing with PCOR. A publication summarizing the findings of this research, *Patient-Centered Outcomes Research: Stakeholder Perspectives and Ethical and Regulatory Oversight Issues*, has been published in IRB: Ethics & Human Research.

The second phase of this project was a national survey of IRB members on PCOR and human subjects protection and oversight. The results have been published as *IRB Oversight of Patient-Centered Outcomes Research: A National Survey of IRB Chairpersons* in the Journal of Empirical Research on Human Research Ethics. In Spring 2018 we completed the third and final phase of the project, consisting in a Delphi panel that established consensus among expert stakeholders on key recommendations for oversight of PCOR. An article containing the recommendations and further analysis, *Oversight of Patient-Centered Outcomes Research: Recommendations from a Delphi Panel*, has been accepted for publication in Annals of Internal Medicine. The work from this project was further disseminated at a national PRIM&R presentation and at a symposium entitled *Putting Patients at the Center of Research: Opportunities and Challenges for Ethical and Regulatory Oversight*, hosted by the Petrie-Flom Center in June 2018, which brought together a diverse group of patients and community members, policymakers, bioethicists, and regulatory officials to address oversight challenges with PCOR.



Additional Efforts

In FY18, we submitted five applications for sponsored research projects, one of which was successful and one of which is still outstanding. This reflects a fairly typical return on competitive research funding applications. We also explored potential projects relating to topics such as the medicalization of the social determinants of health and the regulation of digital health, although we have not yet submitted grant applications for those projects.

Greenwall Foundation Law and Bioethics Seminar Series

This grant submission proposed to develop a seminar series aimed at enabling scholars to become better consumers of legal materials, “issue spot” legal questions in their research where they need help, understand the way in which existing law may constrain their projects, and better translate their recommendations into policy change through legal means. The seminar series will combine two half-day in-person sessions with online sessions and be offered to Greenwall Foundation Faculty Scholars. I. Glenn Cohen will create and teach the seminar series, with a couple of sessions taught by others who have participated in Center events. This proposal was successful.

CIFAR

Solving the “Many-Hands Problem”: Towards Global and National Regulatory Mechanisms for Artificial Intelligence and Big Data in Health Care

This grant submission sought funding for an international workshop to explore the “Many-Hands” problem in the context of the development of artificial intelligence. The “Many-Hands Problem” is when responsibility cannot be attributed to a single individual or entity and it is difficult to determine who is liable for an incident and to what extent. During this workshop, we would examine the Many-Hands Problem of the AI community, with the aim of proposing recommendations for both AI developers and policymakers while also exploring governance mechanisms currently in development. I. Glenn Cohen, and Visiting Researcher Jean-Christophe Belisle-Pipon would lead the efforts of the Center, along with collaborators Timo Minszen and Effy Vayena. We are currently awaiting a decision.

Greenwall Foundation Making a Difference in Real-World Bioethics Dilemmas Grants Program

Gatekeeping Sex: Clinician and Caregiver Roles in Assessing Sexual Consent Capacity for People with Intellectual Disabilities

This grant submission proposed to develop workable, stakeholder-informed standards that demystify sexual consent capacity for people with intellectual disabilities and strike an informed ethical balance between sexual autonomy and



freedom from abuse. We proposed a two-year project to address this need by providing a sustained analysis of the standards for sexual consent capacity determinations currently in use and developing actionable guidance for improving practices. I. Glenn Cohen, Carmel Shachar, and Luke Gelinis would have collaborated with Michael Ashley Stein and Matthew “Hezzy” Smith of the Harvard Law School Project on Disability. Although we were invited to submit a full proposal on the basis of our Letter of Intent, the proposal was ultimately not selected for funding. We are currently exploring alternative avenues for funding.

**Robert Wood Johnson Foundation Policies for Action
Dual Stigma: Understanding the Challenges of Providing Substance Use
Treatment to Undocumented Patients**

This grant submission sought to address the knowledge gap in the medical community regarding treatment of undocumented patients with substance use disorder by performing a survey of existing policies, practices, and attitudes among health care providers in the New England region that will lead to best practices guidance for medical providers and policymakers. We proposed a two-year project to investigate policy and practice at the health care systems level, identifying gaps in knowledge, as well as identifying key outcome measures and best practices for substance use treatment for undocumented persons. Carmel Shachar and Center for Bioethics at Harvard Medical School Fellow Stephen Wood would have led this project. Our Letter of Intent was not selected to move forward to the proposal phase, but we are considering alternative avenues for funding.

**Harvard Global Institute
Global Technologies, Global Regulations, Global Ethics: A Study of National
Regulations and International Responses to Cutting Edge Genomic and
Reproductive Technologies**

This grant submission sought to examine the intersection of health care globalization, including medical tourism, and explosion of genomic and reproductive technologies. The project would have tried to answer the question of how countries can better regulate global reproductive and genomic technologies. The team, led by I. Glenn Cohen, would have included scholars from Harvard such as Tarun Khanna of Harvard Business School and Amitabh Chandra of Harvard Kennedy School. The team would have also included scholars in India and China, such as Wang Chenguang of the School of Law at Tsinghua University. The project would have produced a survey of the regulations and norms around these technologies in India, China, and the US along with a report outlining opportunities for global regulation and harmonization. Our Letter of Intent was not selected to move forward to the proposal phase.



Project Activities

In addition to sponsored research, the Petrie-Flom Center is involved in a number of projects that seek to advance cutting-edge scholarship and policymaking in our fields, including a collaborative, peer-reviewed journal that offers a unique opportunity outside of traditional law reviews for publications at the intersection of law and the biosciences, as well as programs on law and neuroscience and law and advanced care planning.

Journal of Law and the Biosciences

The Journal of Law and the Biosciences (JLB) is a collaboration between the Petrie-Flom Center and colleagues at Duke and Stanford Universities, published by Oxford University Press. **I. Glenn Cohen** serves as co-Editor-in-Chief, alongside **Nita Farahany** (Duke) and **Hank Greely** (Stanford). In FY18 visiting researcher **Jean-Christophe Belisle Pipon** has taken over managing editor duties on behalf of the Center. JLB is now in its fifth volume.

JLB is the first fully Open Access peer-reviewed legal journal focused on advances at the intersection of law and the biosciences. An online, interdisciplinary academic journal, JLB publishes cutting-edge scholarship, including original and response articles, essays, and commentaries on a wide range of topics, including bioethics, neuroethics, genetics, reproductive technologies, stem cells, enhancement, patent law, and food and drug regulation.

The journal is freely available to readers and without publication fees to authors, making it one of the most accessible journals in the field. The journal continues to experience extraordinary growth.

Project on Law and Applied Neuroscience

Since Fall 2014, the Petrie-Flom Center has hosted the Project on Law and Applied Neuroscience, a collaboration with the Massachusetts General Hospital Center for Law, Brain and Behavior (CLBB). The collaboration has included a Senior Fellow in residence at the Petrie-Flom Center, public symposia at Harvard Law School, and a Law and Neuroscience Seminar (taught by Petrie-Flom Center Faculty Affiliate **Hon. Nancy Gertner**).

In Fall 2017, **Francis X. Shen** became the third Senior Fellow in Law and Neuroscience. Francis is currently an Associate Professor and McKnight Presidential Fellow at the University of Minnesota; faculty at the Center for Law, Brain and Behavior at Massachusetts General Hospital; and Executive Director of Education and Outreach for the MacArthur Foundation Research Network on Law and Neuroscience. During his fellowship, he pursued original research, mentoring, and public engagement related to issues of neuroscience, law, and the aging brain. This



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included expert symposia and public events, notably the April 27, 2018, day-long conference “Our Aging Brains: Decision-making, Fraud, and Undue Influence,” which explored how new neuroscience might aid law in its determinations of capacity and competence for older adults. The conference led to the creation of a working group, which is now exploring publication and research opportunities. During the fellowship year, Francis also was a frequent guest lecturer of the Law and Neuroscience seminar, including organizing the joint seminar and public event “Addiction, Neuroscience, and the Law: *Commonwealth v. Julie Aldred.*”

During the fellowship, Francis developed three writing projects in collaboration with the Petrie-Flom Center and CLBB. The first, titled *Aging Judges*, explores how advances in neuroscience may allow for better and earlier detection of decision-making deficits in older judges. Building on our November 15, 2017, event, “Dementia and Democracy: America’s Aging Judges and Politicians,” Francis used his time as the Senior Fellow to develop an article proposing a new solution to the challenge of aging judges. In the federal judiciary, there is no mandatory retirement, and dementia on the bench is handled through informal policing mechanisms. This may result in judges serving even though they do not have the requisite capacity to judge. On the other hand, at the state level, a majority of states have adopted mandatory judicial retirement ages. By contrast to the federal system, the states’ mandatory retirement age approach may result in highly skilled and capable judges being removed even though their decision-making capacity is not diminished. Shen argues that a middle-path is optimal: harnessing scientific advances to better distinguish between those judges whose capacity remains sufficient, and those judges whose decision-making is no longer sufficient to stay on the bench. The initial article will be published in 2019, followed by work to put the ideas into practice.

The second project, *Neuroscientific Evidence of Dementia in the Court Room*, is a collaborative project building on the success of our April 27, 2018, conference, “Our Aging Brains: Decision-making, Fraud, and Undue Influence.” Led by Francis, with several scientists and legal scholars co-authoring, this publication will delineate the principles by which new neuroscientific technology should, and should not, be used as courtroom evidence. The core ideas for the article were explored in a closed working group session held after the public *Our Aging Brain* event, and the article is expected to be completed in 2019.

The third project is a *Judicial Bench Card* for judges, providing updated information related to scientific evidence of dementia. The bench card will be a two-page summary document, which briefly touches upon best practices for assessing legal capacity in older adults, appropriate uses of neuroscientific evidence in capacity assessments, and further resources for evaluating evidence of dementia. The bench card is expected to be completed in 2019.



Events

The Project on Law and Applied Neuroscience hosted the following events this year:

The Neurolaw Revolution: A Lecture by Francis Shen

September 13, 2017

Dementia and Democracy: America's Aging Judges and Politicians

November 15, 2017

Addiction, Neuroscience, and the Criminal Law: Commonwealth vs. Julie Eldred

February 29, 2018

Crimes of Passion: New Neuroscience vs. Old Doctrine

April 9, 2018

How to Fix Youth Sports Concussion Laws: Neuroscientific Perspectives

April 11, 2018

Our Aging Brains: Decision-Making, Fraud, and Undue Influence

April 27, 2018

Federal Judicial Center-Harvard Law School Workshop: Science-Informed Decision Making

May 2–4, 2018

Cosponsored by the Federal Judicial Center.

Project on Advanced Care and Health Policy

In March 2016, the Petrie-Flom Center launched a collaboration with the Coalition to Transform Advanced Care (C-TAC). C-TAC is a non-partisan, non-profit alliance of over 130 national organizations dedicated to being a catalyst to change the health delivery system, empower consumers, enhance provider capacity, and improve public and private policies in advanced illness care.

Recognizing that current health care policy and regulation, developed largely in a fee-for-service environment with siloed providers, creates barriers that may impede widespread adoption of improved models of care for those with advanced illness, our joint Project on Advanced Care and Health Policy seeks to study and foster development of improved models of care for individuals with serious advanced illness nearing end-of-life, and to apply interdisciplinary analysis to important health law and policy issues raised by the adoption of new person-centered approaches to care for this



growing population. It includes a Senior Fellowship, public symposia and events, and policy and research projects. Additional information is available on our [website](#).

Senior Fellow

The role of the Senior Fellow is to advance the work of the Project, develop a policy/research agenda, plan symposia and panel discussions, and be available as a resource for interested members of the Harvard community.

Mark Sterling, MPP, JD, is the Project's inaugural Senior Fellow in Advanced Care and Health Policy. For over 35 years, Mark has been an advisor to mission-driven health care organizations. His experience includes serving as partner in a leading global law firm, as general counsel and chief strategy officer of a leading health care services organization providing end-of-life care, and as a member of nonprofit Boards of Directors serving frail elderly and terminally ill individuals. He is a senior strategic advisor to C-TAC, and recently was a Senior Fellow at Harvard University's Advanced Leadership Initiative.

Over three decades, Mark has worked to structure, develop, and expand innovative programs serving the elderly and terminally ill, including PACE, home care, and hospice programs. He has served as President (Board Chair) of Hospice Care of the District of Columbia, and as a Board member of Comprehensive Care Management Corporation (now CenterLight Health care System), which operates PACE programs in New York City.

Symposia and Events

The Project regularly hosts public events and workshops with business leaders, policymakers, and legal scholars. In FY18 we focused on translating the conversations had at our events into whitepapers and journal articles.

In April 2018, we hosted a conference titled, "The Development and Certification of Decision Aids: Promoting Shared Decision-Making for Patients with Serious Illness." Speakers included federal and state policymakers, leaders of organizations developing certified decision aids and implementing shared decision-making in health care systems, and other experts. Executive Director **Carmel Shachar** and Senior Fellow **Mark Sterling** introduced the conference.

Shared decision-making is recognized as critical to ensuring the delivery of value-based, person-centered care. Decision aids offer people needed tools to engage in their care as fully-informed and active participants. The conference featured an in-depth examination of the successes and challenges experienced by Washington State, which established a process to certify decision aids. Discussions centered on the Washington State experience and implications for other states and national efforts to adopt similar programs.



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A white paper based on the conference is expected to be released later this year. The white paper proposes policy solutions to overcome barriers impeding widespread use of decision aids to promote person-centered care for patients with serious illness. Petrie-Flom Center Student Fellow **Gali Katznelson** is assisting in the preparation of the white paper. Funding for the event and white paper was provided by Cambia Health Foundation, Kaiser Permanente, the Milbank Memorial Fund, and C-TAC. To draw attention to the white paper Executive Director **Carmel Shachar** and Senior Fellow **Mark Sterling** will write several related academic articles.

In August 2017, based on two roundtable events hosted by our Project, a 92-page report was issued, "Toward a Serious Illness Program Design and Implementation Framework," to help providers develop, replicate, and scale programs across a variety of serious illness populations and settings. The report's framework provides steps to allow health care organizations to assess evidence-based options for each facet of care model design and implementation. As noted in the report, the framework is designed to:

- Inform serious illness program development, replication, and scaling
- Integrate with care model payment design
- Inform care model and pro forma simulator development
- Inform other aspects of design and development such as policy, standardized measurement, and regulatory analysis.

The framework incorporates a variety of business models, target populations, and packages of services, and notes the importance of tailoring the program to fit the local context. It also identifies and highlights keys to success, such as leveraging existing resources, recruiting the right program leadership and clinicians, establishing multidisciplinary care teams with strong relationships among team members and with patients and caregivers, and creating processes for evaluation and quality improvement.

The full report is available on the [C-TAC website](#).

The report is based upon two related meetings hosted by our Project on Advanced Care and Health Policy in March and June 2017, both titled "Critical Pathways to Improved Care for Serious Illness." These roundtable meetings were part of an initiative, funded by the Gordon and Betty Moore Foundation, to develop a guiding framework for providing improved community-based care for people with serious illness. Both meetings included panels of health care executives and experts, policymakers, and other thought leaders. The roundtables reviewed and reported on innovations to test and replicate new ways of delivering high quality care for serious chronic illness, especially for an aging population with declining function and complex care needs.



Policy and Research Projects

Current regulatory frameworks can impose obstacles to adoption of innovative models of caring for those with advanced illness. As the Project moves forward, it will continue to engage in policy and research projects that identify and analyze these obstacles, and propose policy solutions that promote development and scaling of successful programs. This may entail developing proposed regulatory approaches or a model regulatory framework for an advanced care delivery model that could be adopted by policymakers. It also could explore potential payment methodologies for this model of care.

Additional Collaboration

Since the Project launched, it has (through the stewardship of Senior Fellow Mark Sterling) become a member of the Massachusetts Coalition on Serious Illness Care. The Coalition has 90 members (led by Blue Cross Blue Shield of Massachusetts) with a goal of ensuring that all Massachusetts residents receive care that is in accordance with their goals, values, and preferences.

As a result of the Project, Muriel Gillick, M.D., became a panelist and an important contributor to the work, funded by the Gordon and Betty Moore Foundation, to develop a guiding framework for improved community-based care for serious illness. Dr. Gillick is Director, Program in Aging, Harvard Pilgrim Health Care Institute, and Professor of Population Medicine at Harvard Medical School.

Innovative Funding Models in Translational Research Project

Launched in early 2018, the Innovative Funding Models in Translational Research Project explores the bioethical, legal, and risk management challenges of translational research in the context of a shift from governmental funding to private funding for cutting edge biomedical research. The purpose of the Project is to investigate the ethical safeguards necessary to accelerate the development and application of new health care technologies through intelligent and thoughtful private for-profit investment and support. The goal of the Project is to articulate the best ethical practices for for-profit involvement in early stage health care startups and translational research.

Senior Fellow

Leading the Innovative Funding Models Project for the Center is inaugural Senior Fellow, Douglas Eby. Doug's role will be to advance the work of the Project by developing a policy/research agenda for the Project, planning the convening of the working group, co-authoring a report on the group's findings, and being available as a resource for interested members of the Harvard community. As a 2017 Fellow in Harvard University's Advanced Leadership Initiative, Doug's



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efforts have been focused on innovative financing models to meet the unprecedented gap that currently exists in translational research. His work at Harvard led to the formation of Cambridge Science Corporation, where Doug serves as the Chief Executive Officer. Cambridge Science Corporation's mission is to improve global health by accelerating the pace of medical technology innovation.

Prior to founding Cambridge Science, Doug worked in the investment management industry. He has extensive experience in the health care sector as an institutional investor across all stages of the capital continuum: public, private equity, venture capital, and angel startup financings. Most recently, Doug was the President and Portfolio Manager for an investment advisor managing institutional assets for clients in the US equity markets deploying a long-term value based strategy. Doug has served as a director of several NYSE listed public companies including the Markel Corporation, Level 3 Communications, and CBRE Realty Finance, and as an advisory director of the Student Loan Marketing Association (Sallie Mae). He has served on the boards of numerous nonprofits including Suburban Hospital-Johns Hopkins Medicine, where he was chairman of the hospital's investment committee, and the Boys and Girls Clubs of Greater Washington, DC, where he served as chairman of the board.

Steering Committee

The Project is led by Executive Director **Carmel Shachar** and the Senior Fellow. The Project is guided by a steering committee of thought leaders in this area, including:

- **Irit Ben-Chelouche**, Executive Director, Harvard University Office of Technology Development
- **Susan Korsmeyer**, Senior Managing Director for Institutional Management, The Whitehead Institute
- **Adam Landman**, Chief Information Office, Brigham and Women's Hospital
- **Lesley Millar-Nicholson**, Director, MIT Technology Licensing Office
- **Scott Orchard**, Senior Counsel, Johnson & Johnson Innovation
- **Gregory Raskin**, Vice President of Technology Development, Memorial Sloan Kettering Cancer Center
- **Issi Rozen**, Chief Business Officer, The Broad Institute

Events

The initial phase of the Project (FY18–19) will focus on facilitating conversations with key stakeholders about the scope of the regulatory and ethical questions raised by the trend to innovative funding models for translational research. The Petrie-Flom Center, led by the Senior Fellow, will convene a working group in October



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2018 to articulate concerns around innovative funding models in this space. The focus of the Project's efforts in FY18 were to organize this working group event.

In FY19 the Center, again led by the Senior Fellow, will produce a report evaluating the extent to which utilizing non-governmental sources of funding for translational research, especially in the early stages, raises legal and ethical questions distinct from government-funded clinical and translational research. This report is intended to be a road map for ethicists and other scholars working in this area. The report will draw heavily upon the conversations hosted at the working group event.



Scholarship

One of the central missions of the Petrie-Flom Center is to support emerging, transitioning, and senior scholars making critical contributions to the ways in which the law can and should shape health law and policy, biotechnology, and bioethics.

Academic Fellows

Although the Academic (post-doctoral) Fellowship has been a cornerstone of the Center since its inception in 2006, we have temporarily discontinued the program as we pursue new funding opportunities and Topical Programs. We hope to reinstate the Academic Fellowship as soon as possible.

Visitors

Although the Center does not actively solicit applications for Visiting Scholars, it is a sign of our national and international influence that we receive a number of requests to visit with us each year. We welcome Visitors to our Center who have demonstrated academic success in our areas of interest, have a current project that would benefit from collaboration with our affiliates, and have a perspective that may be of value to our students, fellows, and faculty.

Visiting Scholars are expected to pursue their own independent academic projects related to our areas of focus, attend any Center events that take place during their visit, and share their expertise with students and colleagues. We sometimes invite Visitors to present on the topic of their research at a public lecture and/or blog about their work at Bill of Health.

We hosted several outstanding visitors whose terms extended into FY18:

Jean-Christophe Belisle Pilon, September 2017–October 2020

Jean-Christophe Belisle Pilon completed his PhD in Bioethics at the University of Montreal in Fall 2017. He is supported as a Visiting Researcher at the Petrie-Flom Center with funding from the Canadian Institutes of Health Research. During his three years at the Center, Jean-Christophe will pursue independent research on issues surrounding direct-to-consumer marketing in the pharmaceutical industry. He will also serve as managing editor of the Journal of Law and the Biosciences on behalf of the Center, and will collaborate with Faculty Director **I. Glenn Cohen** and Executive Director **Carmel Shachar** in the development and execution of research that falls within his areas of expertise.



Belinda Bennett, October–November 2017

Belinda Bennett is Professor of Health Law and New Technologies in the Faculty of Law at Queensland University of Technology in Brisbane, Australia. She joined QUT in 2014 as part of QUT’s research capacity building program. Prior to joining QUT Belinda worked at Sydney Law School, University of Sydney for many years, most recently as Professor of Health and Medical Law. In November 2011 she was the Smith Visiting Professor at Maurer School of Law, Indiana University, Bloomington, Indiana USA and in May 2014 she was a Plumer Visiting Research Fellow at St Anne’s College, Oxford, UK. Belinda leads the Governance and Regulation of Health Care program within the Australian Centre for Health Law Research at QUT. Her research addresses health law and globalization, and global public health.

During her visit at the Petrie-Flom Center, she pursued research on the legal and ethical challenges associated with regulation of new technologies. During her visit Belinda’s work included work on a co-authored paper on whether rights should be recognized for artificial intelligence. She also gave a presentation on October 23, 2018, to the Health Law, Policy, Bioethics, and Biotechnology Workshop titled “Law, Transformative Technologies and the Automation Age: Lessons from the Past for a High-Tech Future.” She is currently engaged in the application for Fulbright funding that would support her in a return visit in 2019 to pursue a project entitled, “The Automated Self: Law, Ethics and Robotics.”

Avishalom Westreich, October–November 2017

Avishalom Westreich is a Senior Lecturer (the equivalent of an Associate Professor in the United States) at the Law School of the College of Law and Business in Ramat Gan, Israel, and a Research Fellow at the Kogod Research Center for Contemporary Jewish Thought, Shalom Hartman Institute, Jerusalem. He holds degrees in Hermeneutic Studies (MA Summa Cum Laude), Law (LLB), Talmud (BA), and Jewish History (BA Summa Cum Laude), and completed his PhD at Bar-Ilan University in the President’s Program for Outstanding Doctoral Candidates (2007).

Avishalom’s research deals primarily with the dramatic changes in the family during the second half of the twentieth and the beginning of the twenty-first centuries and the ways in which Jewish law decisors face new kinds of dilemmas. Accordingly, he examines the changes in the structure of the Jewish family as reflected in the *agunah* problem, and explores this problem’s main civil and religious aspects. He examines how Jewish law decisors engage in metalegal deliberations on family concepts (such as fatherhood, motherhood, and parenthood), how they interact with civil law, and, accompanying all, how they discuss, from a formal halakhic viewpoint, the role of Jewish law in changing social, legal, and cultural environments. During his visit at the Petrie-Flom Center



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Avishalom pursued research on assisted reproductive technologies in halakhic law, as well as a project entitled “Family Dichotomies and Their Moderation: Comparative Religious Perspectives.”

During his stay, Avishalom worked on the following research projects:

- “Assisted Reproduction in Israel: Law, Religion, and Culture” (monograph, Brill Research Perspectives Series, 2018);
- “Present-Day Postmortem Sperm Retrieval and Traditional Levirate Marriage: Two Types of Interaction” (submitted article).

Avishalom also gave three academic lectures:

- “Why Are Fallen Soldiers Different from Others? Two Concepts of Posthumous Procreation,” Seminar, the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Harvard Law School
- “Assisted Reproduction in Jewish Law,” an invited lecture at the Seminar on Faith, Morality, and Law, Boston College Law School; and
- “Law, Religion, and State in Israel: The Vexed Issue of the Chained Wife (*agunah*) for Contemporary Jews,” an invited lecture at the Jewish Studies Program, Northeastern University.

Jennifer Drobac, December 2017–April 2018

Jennifer Drobac is the R. Bruce Townsend Professor of Law at the Indiana University Robert H. McKinney School of Law. During the 2016–2017 academic year she was a Visiting Fellow at Clare Hall, Cambridge University. Her scholarly work has been published in a variety of law reviews and journals. She is the author of “Sexual Harassment Law: History, Cases and Theory (2004) and Sexual Exploitation of Teenagers: Adolescent Development, Discrimination, and Consent Law” (2016).

During her time at the Petrie-Flom Center, Jennifer worked on a project entitled “Myth of Consent: How Brain Sciences Debunk the Myth of the Rational Legal Actor and How Society Should Respond.” In the context of this project, Jennifer worked closely during her time at the Center with the Project on Law and Applied Neuroscience under the 2017–2018 Senior Fellow, **Francis Shen**. Her involvement with this project culminated in her participation in the private working group that met in conjunction with the April 28, 2018, conference “Our Aging Brains: Decision-Making, Fraud, and Undue Influence.”



Sara Gerke, April–July 2018

Sara Gerke joined the Petrie-Flom Center as a Visiting Researcher after submitting her doctoral thesis, a comparative legal analysis of stem cell regulations in German and UK law, in Spring 2018. She was previously the General Manager of the Institute for German, European and International Medical Law, Public Health Law and Bioethics of the Universities of Heidelberg and Mannheim, Germany. She is also the Co-Investigator of the interdisciplinary project “ClinhiPS: A Scientific, Ethical and Comparative Legal Analysis of the Clinical Application of Human Induced Pluripotent Stem Cells in Germany and Austria,” sponsored by the German Federal Ministry of Education and Research.

From July 2015 to March 2016, Sara attended Durham Law School, England, as a visiting PhD student to undertake research under the supervision of Professor Shaun D Pattinson. For this purpose, she was awarded a scholarship from the German Academic Exchange Service (DAAD). Prior to this, Sara studied law at the Universities of Passau and Augsburg, Germany, graduating with distinction from the University of Augsburg, Germany, in July 2012 (First State Examination in Law). In addition, she holds a Master degree in Medical Ethics and Law from King’s College London (12/2013).

During her time at the Petrie-Flom Center, Sara pursued research on reproductive and regenerative medicine from a comparative legal perspective (i.e., US, EU, German and UK law). She also networked extensively with scholars in her field(s), including participating in the Health and Wellbeing Working Group at the Berkman Klein Center for Internet and Society at Harvard.

We are pleased that after an extensive search in the spring – completely independent of her previously planned term as a Visiting Researcher – Sara was selected to join us in August 2018 for a three-year term as Research Fellow for Precision Medicine working with I. Glenn Cohen on the Center’s research project on Precision Medicine, Artificial Intelligence, and Law.



Faculty Summer Research Support

The Center contributes summer support for HLS faculty research projects related to our areas of interest. In Summer 2017, we supported the following:

I. Glenn Cohen worked on several books, articles, and book chapters including:

Artificial Wombs and Abortion Rights, HASTINGS CTR. REP. (July 27, 2017).

SPECIMEN SCIENCE: ETHICS AND POLICY IMPLICATIONS (Sept. 2017) (co-edited with Holly Fernandez Lynch, Barbara E. Bierer & Suzanne M. Rivera).

Religion and Reproductive Technology, in **LAW, RELIGION, AND HEALTH IN THE UNITED STATES** (Holly Fernandez Lynch, I. Glenn Cohen, and Elizabeth Sepper eds., Cambridge University Press, 2017).

Preventing Mitochondrial Disease: A Path Forward, 131 OBSTETRICS & GYNECOLOGY 553-56 (Mar. 2018) (co-authored with Eli Y. Adashi).

Personhood Seeking New Life with Republican Control, 93 INDIANA L. J. _ (forthcoming) (co-authored with Jonathan Will and Eli Adashi)

TRANSPARENCY IN HEALTH AND HEALTH CARE (forthcoming 2019) (co-edited with Holly Fernandez Lynch, Barbara J. Evans & Carmel Shachar).

Einer Elhauge, the Petrie-Flom Center's founding faculty director, continued work on an ongoing project titled **A LITTLE LOWER THAN GOD: REDESIGNING HUMANS – WHAT LIMITS?** He also engaged in additional work on antitrust and economic topics.

2017–2018 Affiliate Scholarship

The Petrie-Flom Center's leadership, fellows, and other affiliates have once again enjoyed a prolific year, producing cutting-edge scholarship in the areas of human subjects research, football player health, religion and health, reproductive technologies, and more. These publications (some of which remain pending) have generated academic conversation, invitations to events, inquiries from the press, and a great deal of positive attention to our Center.



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Publications from Center faculty, staff, fellows, and visitors are listed below. The work of Student Fellows is discussed in the section of this report on the Student Fellowship Program.

Publications from Sponsored Research

The Football Players Health Study (FPHS)

Adam M. Finkel, Chris Deubert, Orly Lobel, I. Glenn Cohen, & Holly Fernandez Lynch, *The NFL as a Workplace: The Prospect of Applying Occupational Health and Safety Law to Protect NFL Workers*, 60 ARIZONA L. REV. 291 (April 17, 2018), also published in University of San Diego School of Law Legal Studies Research Paper Series.

Harvard Catalyst

Luke Gelinias, Holly Fernandez Lynch, Barbara Bierer & I. Glenn Cohen, *When Clinical Trials Compete: Prioritising Study Recruitment*, 43 J. MED. ETHICS 803 (2017).

Luke Gelinias, Emily A. Largent, Susan Kornetsky, Barbara E. Bierer & Holly Fernandez Lynch, *A Framework for Ethical Payment to Research Participants*, 378 NEW ENG. J. MED. 766-71 (Feb. 22, 2018).

Luke Gelinias, Holly Fernandez Lynch, Emily Largent, I. Glenn Cohen & Barbara Bierer, *Truth in Advertising, Disclosure of Participant Payment in Research Recruitment Materials*, 52 THERAPEUTIC INNOVATION & REGULATORY SCI. 268-74 (April 8, 2018).

Holly Fernandez Lynch, Luke Gelinias & Emily Largent, *Mutual Obligations in Research and Withholding Payment From Deceptive Participants*, 4 THE AM. J. OF BIOETHICS 85-7 (April 5, 2018).

Luke Gelinias, Holly Fernandez Lynch, Barbara E. Bierer & I. Glenn Cohen, *On Scarcity and the Values of Clinical Trials*, 4 THE AM. J. OF BIOETHICS 71-3 (April 5, 2018).

Patient-Centered Outcomes Research Oversight Study (PCOROS)

Emily A. Largent, Joel S. Weissman, Avni Gupta, Melissa Abraham, Ronen Rozenblum, Holly Fernandez Lynch & I. Glenn Cohen, *Patient-Centered Outcomes Research: Stakeholder Perspectives and Ethical and Regulatory Oversight Issues*, 40 HASTINGS CTR. REP. (January-February, 2018).



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Joel S. Weissman, Eric G. Campbell, I. Glenn Cohen, Holly Fernandez Lynch, Emily A. Largent, Avni Gupta, Ronen Rozenblum, Melissa Abraham, Karen Spikes, Maureen Fagan & Martie Carnie, **IRB Oversight of Patient-Centered Outcomes Research: A National Survey of IRB Chairpersons**, JOURNAL OF EMPIRICAL RESEARCH ON HUMAN RESEARCH ETHICS (June 14, 2018).

Luke Gelinas, Joel S. Weissman, Holly Fernandez Lynch, Avni Gupta, Ronen Rozenblum, Emily Largent, I. Glenn Cohen, **Oversight of Patient-Centered Outcomes Research: Recommendations from a Delphi Panel**. ANNALS OF INTERNAL MEDICINE (in press).

Center-Edited Volumes

Holly Fernandez Lynch, I. Glenn Cohen, & Elizabeth Sepper, **LAW, RELIGION, AND HEALTH IN THE UNITED STATES** (July 2017).

Holly Fernandez Lynch, Barbara E. Bierer, I. Glenn Cohen, & Suzanne M. Rivera, eds., **SPECIMEN SCIENCE: ETHICS AND POLICY IMPLICATIONS** (Sept. 2017).

I. Glenn Cohen, Holly Fernandez Lynch, Effy Vayena, & Urs Gasser, **BIG DATA, HEALTH LAW, AND BIOETHICS** (March 2018).

Holly Fernandez Lynch, I. Glenn Cohen, Barbara J. Evans, & Carmel Shachar, **TRANSPARENCY IN HEALTH AND HEALTH CARE** (forthcoming 2019).

I. Glenn Cohen, Michael Stein, Anita Silvers, and Carmel Shachar, **BEYOND DISADVANTAGE: DISABILITY, LAW, AND BIOETHICS** (under review).



Affiliate Scholarship¹

I. Glenn Cohen

Books

HEALTH CARE LAW AND ETHICS (Wolters Kluwer, 9th ed. 2018) (co-author with Mark A. Hall, David Orentlicher, Mary Anne Bobinski, and Nicholas Bagley).

BIOETHICS AND PUBLIC HEALTH LAW (Wolters Kluwer, 4th ed. 2018) (co-author with Mary Anne Bobinski, David Orentlicher, and Mark A. Hall).

MEDICAL LIABILITY AND TREATMENT RELATIONSHIPS (Wolters Kluwer, 4th ed. 2018) (co-author with Mark A. Hall, David Orentlicher, Mary Anne Bobinski, and Nicholas Bagley).

Chapters and Articles

Religion and Reproductive Technology, in **LAW, RELIGION, AND HEALTH IN THE UNITED STATES** (Holly Fernandez Lynch, I. Glenn Cohen, and Elizabeth Sepper eds., Cambridge University Press, 2017).

Artificial Wombs and Abortion Rights, HASTINGS CTR. REP. (July 27, 2017).

Germ-Line Gene Editing and Congressional Reaction in Context: Learning From Almost 50 Years of Congressional Reactions to Biomedical Breakthroughs, 30 J. L. & HEALTH (Aug. 24, 2017) (co-authored with Russell A. Spivak & Eli Y. Adashi).

Influence, Integrity, and the FDA: An Ethical Framework, 357 SCI. 876-77 (Sept. 1, 2017) (co-authored with Spencer Phillips Hey, Eli Y. Adashi, & Aaron S. Kesselheim).

Your Money or Your Patient's Life? Ransomware and Electronic Health Records, 167 ANNALS OF INTERNAL MED. 587-88 (Oct. 17, 2017) (co-authored with Sharona Hoffman, & Eli Y. Adashi).

Cops, Docs, and Code: A Dialogue Between Big Data in HealthCare and Predictive Policing, 51 U.C. DAVIS L. REV. 437-74 (Jan. 2, 2018) (co-authored with Harry Graver).

¹ Publications included above under sponsored research or edited volumes are not repeated for each individual affiliate.



Preventing Mitochondrial Disease: A Path Forward, 131 *OBSTETRICS & GYNECOLOGY* 553–56 (Mar. 2018) (co-authored with Eli Y. Adashi).

Is There a Duty to Share Health Care Data?, in *BIG DATA, HEALTH LAW, AND BIOETHICS* (I. Glenn Cohen, Holly Fernandez Lynch, Effy Vayena, and Urs Gasser eds., Cambridge University Press 2018).

Preventing Mitochondrial Diseases: Embryo-Sparing Donor-Independent Options, 24 *TRENDS IN MOLECULAR MED.* 449–57 (May 2018) (co-authored with Eli Y. Adashi).

Circumvention Medical Tourism and Cutting Edge Medicine: The Case of Mitochondrial Replacement Therapy, 25 *INDIANA J. OF GLOBAL LEGAL STUD.* (May 24, 2018).

HIPAA and Protecting Health Information in the 21st Century, 320 *J. AM. MED. ASS'N* 231–32 (July 17, 2018) (co-authored with Michelle Mello).

Building Capacity for a Global Genome Editing Observatory: Institutional Design, 36 *TRENDS IN BIOTECHNOLOGY* 639–41 (June 8, 2018) (co-authored with Krishanu Saha et al.).

Personhood and the Three Branches of Government, 378 *NEW ENG. J. MED.* 2453–55 (June 28, 2018) (co-authored with Eli Y. Adashi).

On the Human Right to Health: Statistical Lives, Contingent Persons, and Other Difficult Questions, in *HUMAN RIGHTS, DEMOCRACY, AND LEGITIMACY IN A WORLD OF DISORDER* (Silja Voenekey & Gerald Neuman eds., Cambridge University Press, forthcoming Sept. 2018).

Regulation of Stem Cell Therapy Travel, I. Glenn Cohen, I. & Simana, S. *CURR STEM CELL REP* (forthcoming 2018).

Personhood Seeking New Life with Republican Control, 93 *INDIANA L. J.* _ (forthcoming, 2018) (co-authored with Jonathan Will and Eli Adashi).

Luke Gelinas

Pediatric Social Media Recruitment, in *ETHICS AND RESEARCH WITH CHILDREN: A CASE-BASED APPROACH*, Eric Kodish, Ed. (2nd ed. forthcoming 2018) (with Jennifer C. Kesselheim).



Francis X. Shen

How Dangerous. are Youth Sports for the Brain?: A Comprehensive Review of the Evidence, BERKELEY JOURNAL OF ENTERTAINMENT & SPORTS LAW (forthcoming 2018) (co-authored with Carly Rasmussen, Sydney Diekmann, Christine Egan & Tyler Johnson).

Are Youth Sports Concussion Statutes Working?, 56 DUQUESNE UNIV. LAW REVIEW 7 (2018) (Symposium issue: Traumatic Brain Injury and Law).

Decoding Guilty Minds: How Jurors Attribute Knowledge and Guilt, 71 VANDERBILT L. REV. 241 (2018) (co-authored with Matthew R. Ginther, Richard J. Bonnie, Morris B. Hoffman, Owen D. Jones, René Marois & Kenneth W. Simons).

Avishalom Weistreich

ASSISTED REPRODUCTION IN ISRAEL: LAW, RELIGION, AND CULTURE, Brill Research Perspectives Series (2018).

Present-Day Postmortem Sperm Retrieval and Traditional Levirate Marriage: Two Types of Interaction (forthcoming).

Sara Gerke

ELSA: Eine neue Fachgruppe des GSCN, ELSA: A New Working Group of the GSCN, ZUKUNFT DER STAMMZELLFORSCHUNG: JAHRESMAGAZIN DES GERMAN STEM CELL NETWORK (GSCN)// FUTURE OF STEM CELL RESEARCH: ANNUAL MAGAZINE OF THE GERMAN STEM CELL NETWORK (2017/18) (co-authored with Tobias Cantz).

Informed Consent Sample Text for the Donation of Somatic Cells for Human Induced Pluripotent Stem Cell (hiPSC) Research, GSCN (GERMAN STEM CELL NETWORK). (With the ELSA workgroup and the PluriCore Network).

Jean-Christophe Bélisle-Pipon

'What Is PER?' Patient Engagement in Research as a Hit, 1 CANADIAN JOURNAL OF BIOETHICS 2, 59–62 (2018).



Early-Career Researchers' Views on Ethical Dimensions of Patient Engagement in Research, BMC MEDICAL ETHICS (2018) (co-authored with Geneviève Rouleau & Stanislav Birko).

Survey on Ethics Teaching in Public Health Schools and Programs in Canada: Preliminary Results, MONTRÉAL, QUÉBEC: NATIONAL COLLABORATING CENTRE FOR HEALTHY PUBLIC POLICY (2018) (co-authored with Michael Keeling, Louise Ringuette, Olivier Bellefleur, Bryn Williams-Jones, Victoria Doudenkova, Vardit Ravitsky, Stanislav Birko & Hazar Haidar).

Survey to Identify the Public Health Ethics Needs of Public Health Practitioners in Canada: Preliminary Results, MONTRÉAL, QUÉBEC: NATIONAL COLLABORATING CENTRE FOR HEALTHY PUBLIC POLICY (2018) (co-authored with Michael Keeling, Louise Ringuette, Olivier Bellefleur, Bryn Williams-Jones, Vardit Ravitsky, Victoria Doudenkova, Mylène Maguire & Marie-Christine Roy).

Merging Arts and Bioethics: An Interdisciplinary Experiment in Cultural and Scientific Mediation, BIOETHICS (2017) (co-authored with Couture, Cloutier & Barnabé).



2017–2018 Affiliate Commentary

Our affiliates are highly sought after for their expert opinions on a number of pressing news items, including issues related to health reform, football player health, reproductive technology, human subjects (and biospecimens) research, organ transplantation, intellectual property, and more. Center affiliates also authored editorial pieces and gave extended interviews, and several are also regular bloggers at the Petrie-Flom Center’s collaborative blog, [Bill of Health](#), as well as other high-profile blogs, including Health Affairs. These contributions to the media, lay press, and more informal online outlets help advance the Center’s goal of reaching beyond academic circles on critical policy issues.

A full list of our extensive media commentary can be found [here](#), covering the gamut of leading press outlets, including ABC News, CNN, NPR, NBC, PBS, Business Insider, the BBC, Bloomberg, Forbes, Salon, Health Affairs, the New York Times, Politico, Reuters, STAT, US News & World Report, the Washington Post, Vox, and more. Selected highlights in which Center affiliates authored commentary or were extensively interviewed are featured below:

1. Glenn Cohen

Questions About the FDA’s New Framework For Digital Health, HEALTH AFFAIRS BLOG (August 16, 2017) (co-authored with Nathan G. Cortez, Nicolas Terry).

Interview: *How Gene Cloning in Pigs Could Help Humans Fight Disease*, WGBH (Aug. 15, 2017).

James F. Childress, reviewing report co-authored by I. Glenn Cohen, *Organ Donor Research: Overcoming Challenges, Increasing Opportunities*, 318 J. AM. MED ASS’N 2177-78 (October 10, 2017).

Opportunities for Organ Donor Intervention Research: Saving Lives by Improving the Quality and Quantity of Organs for Transplantation, THE NAT’L ACADEMIC PRESS (October 10, 2017) (I. Glenn Cohen and members of the Committee on Issues in Organ Donor Intervention Research).

Presentation: *Are There Non-human Persons? Are There Non-person Humans?* TEDX Cambridge (October 12, 2017).

Interview: *FDA-Approved Digital Pill CaU.S.es Concerns*, KJZZ RADIO (November 28, 2017).



2017's Word of The Year In Health Law And Bioethics: Uncertainty, HEALTH AFFAIRS BLOG (December 8, 2017) (co-authored with Carmel Shachar).

Interview: Ann-Derrick Gaillot, *Four Ethicists Walk into a Super Bowl Party*, THE OUTLINE (February 1, 2018).

Francis X. Shen

You Can Love the Brain and Football Too, MINNEAPOLIS STAR-TRIBUNE (January 31, 2018).

Jean-Christophe Bélisle Pipon

What your government can't tell you about drug prices, CBC NEWS (April 28, 2018).

Interview: *Vaccine against Meningitis: Quebec Pays Twice As Much As United Kingdom* (*Québec paie deux fois plus cher que le Royaume-Uni*), LA PRESSE (April 25, 2018).

Interview: *The Price of Vaccines Must Be Disclosed, Orders the Court* (*Le prix des vaccins doit être dévoilé, ordonne un tribunal*), LA PRESSE (April 19, 2018).



Public Events Programming and Conferences

In addition to a variety of invited presentations given by Center affiliates around the world, the Petrie-Flom Center hosted a number of fantastic events again this year. It was a very busy year, with eleven conferences and multiple panel events organized by the Center. We also provided support for a range of events hosted by partners at Harvard Law School, Harvard Medical School, and elsewhere.

Reflecting the change in Executive Directors for FY18, the Center shifted its focus away from panel events to larger, often cosponsored conference events. This change enabled the Center to build relationships with law firms, government agencies, and scholarly centers within and outside of Harvard. An important focus was a diversity in topics and intended audiences. For example, this year the Center partnered both with a leading health law firm to host a conference that would be of interest to legal practitioners and health care companies and with an institute of the National Academies of Sciences to hold a workshop on the regulation of animal research subjects relevant to research administration professionals and scientists. Our continued goal is to raise the profile of the Center with leading scholars, policymakers, and practitioners while delivering quality programming to the Harvard community.

We continue to draw large audiences to these events from around Harvard's campus and beyond, with our average attendance continuing to increase this year, and to expand our reach by posting video and speakers' slide presentations whenever possible. Our programming allows the Center to form partnerships with and to learn from other research programs, to offer students and other interested participants direct contact with key opinion leaders and exposure to cutting-edge issues in health policy and bioethics, and to bring our scholarship to life through in-person discussion and debate. In many ways, these events are the backbone of the Center and we look forward to continuing to prioritize this service in the coming years.

Below is a condensed list of our events from the past year, with hyperlinks for additional information regarding topic descriptions and speakers:

Major Events/Conferences

Behind Bars: Ethics and Human Rights in U. S. Prisons **November 30–December 1, 2017**

Cosponsored by the Center for Bioethics at Harvard Medical School and the Human Rights Program at Harvard Law School, with support from the Oswald DeN. Cammann Fund at Harvard University.



Sixth Annual Health Law Year in P/Review

December 12, 2017

Cosponsored by Health Affairs, the Center for Health Policy and Law at Northeastern University School of Law, Harvard Health Publications at Harvard Medical School, the Program On Regulation, Therapeutics, And Law (PORTAL) in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital, and the Center for Bioethics at Harvard Medical School, with support from the Oswald DeN. Cammann Fund at Harvard University.

Future Directions for Laboratory Animal Law in the United States: Pre-Workshop Webcast and Workshop

January 26, 2018

Cosponsored by the Institute for Laboratory Animal Research in the National Academies of Sciences, Engineering, and Medicine and the Animal Law & Policy Program at Harvard Law School, with support from the Oswald DeN. Cammann Fund at Harvard University.

Will Value-based Care Save the Health Care System?

March 2, 2018

With support from the Oswald DeN. Cammann Fund and Ropes & Gray LLP.

Harvard Medical School Center for Bioethics Annual Conference

Beecher, Brain Death, & the Future of Organ Transplantation:

A Celebration of the 50th Anniversary of the Harvard Report

April 12–13, 2018

Hosted and organized by the Center for Bioethics at Harvard Medical School and cosponsored by the Hastings Center and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, with support from the Oswald DeN. Cammann Fund at Harvard University.

The Development and Certification of Decision Aids: Promoting Shared Decision-Making for Patients with Serious Illness

April 18, 2018

Part of the Project for Advanced Care and Health Policy, a collaboration between the Petrie-Flom Center and the Coalition to Transform Advanced Care (C-TAC), a non-partisan, non-profit alliance of over 130 national organizations dedicated to being a catalyst to change the health delivery system, empower consumers, enhance provider capacity and improve public and private policies in advanced illness care.

Funding was provided by Cambia Health Foundation, Kaiser Permanente, the Milbank Memorial Fund, and the Coalition to Transform Advanced Care (C-TAC).

Our Aging Brains: Decision-Making, Fraud, and Undue Influence

April 27, 2018

Part of the Project on Law and Applied Neuroscience, a collaboration between the Center for Law, Brain and Behavior at MGH and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.



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Federal Judicial Center-Harvard Law School Workshop: Science-Informed Decision Making

May 2–4, 2018

Cosponsored by the Federal Judicial Center and the Center for Law, Brain and Behavior at MGH.

Ordeals in Health Care: Ethics and Efficient Delivery

May 10–11, 2018

Cosponsored by the Edmond J. Safra Center for Ethics at Harvard University and the Mossavar-Rahmani Center for Business and Government at the Harvard Kennedy School of Government, with support from the Oswald DeN. Cammann Fund at Harvard University.

2018 Petrie-Flom Center Annual Conference

Beyond Disadvantage: Disability, Law, and Bioethics

June 1, 2018

In collaboration with the Harvard Law School Project on Disability, and with support from the Oswald DeN. Cammann Fund at Harvard University.

The Networking Exchange at the Broad Institute

June 3, 2018

This event was hosted by the Broad Institute of MIT and Harvard. For a full list of cosponsors, visit the website.

Putting Patients at the Center of Research: Opportunities and Challenges for Ethical and Regulatory Oversight

June 29, 2018

Part of the Patient-Centered Outcomes Research Oversight Study (PCOROS), a collaborative project funded by the Patient-Centered Outcomes Research Institute (PCORI) and led by Principal Investigator Joel Weissman at Brigham and Women's Hospital.

Lectures, Panels, and Other Events

The Neurolaw Revolution: A Lecture by Francis Shen

September 13, 2017

Part of the Project on Law and Applied Neuroscience, a collaboration between the Center for Law, Brain and Behavior at MGH and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

2017 Petrie-Flom Center Open House

September 13, 2017

Cosponsored by the Center for Bioethics at Harvard Medical School, with support from the Oswald DeN. Cammann Fund.

Book Launch: Law, Religion, and Health in the United States

September 27, 2017

Cosponsored by the Harvard Law School Library.



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What's Next for the ACA? A Lecture by Larry Levitt

October 3, 2017

Cosponsored by the Center for Health Law Policy and Innovation and the Harvard Health Law Society at Harvard Law School.

The Cost of Medications: Current Realities and the Future of Pharmaceutical Pricing in the United States

October 4, 2017

With support from the Oswald DeN. Cammann Fund at Harvard University.

Research with Biospecimens: Balancing Individual Interests and Social Goods

October 21, 2017

Panel session at the American Society for Bioethics and Humanities national meeting.

HLS in the World: New Technologies, New Dilemmas

Part of the HLS|200 Bicentennial Celebration

October 27, 2017

Sponsored by Harvard Law School as part of the HLS / 200 bicentennial celebrations.

Book Launch: Specimen Science: Ethics and Policy Implications

November 9, 2017

Cosponsored by the Harvard Law School Library, the Francis A. Countway Library of Medicine at Harvard Medical School, and the Center for Bioethics at Harvard Medical School, with support from the Oswald DeN. Cammann Fund at Harvard University.

Dementia and Democracy: America's Aging Judges and Politicians

November 15, 2017

Part of the Project on Law and Applied Neuroscience, a collaboration between the Center for Law, Brain and Behavior at MGH and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

Digital Health @ Harvard Series: Health Care Costs and Transparency

Lecture by Dr. John Freedman, Freedman Health care

February 6, 2018

Part of the Digital Health @ Harvard Series, cosponsored by the Berkman Klein Center for Internet and Society at Harvard University.

Addiction, Neuroscience, and the Criminal Law: Commonwealth vs. Julie Eldred

February 29, 2018

Part of the Project on Law and Applied Neuroscience, a collaboration between the Center for Law, Brain and Behavior at MGH and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

Health Law and Public Service

March 23, 2018

Cosponsored by the Harvard Health Law Society and the Center for Health Law and Policy Innovation at Harvard Law School and the Massachusetts Bar Association.



Health in the Headlines: Reporting on Health Care in the Trump Era

April 4, 2018

Cosponsored by the Center for Health Law and Policy Innovation at Harvard Law School; the Shorenstein Center on Media, Politics and Public Policy at the Harvard Kennedy School of Government; the Harvard PhD Program in Health Policy; the Harvard T. H. Chan Student Association (HCSA) at the Harvard T. H. Chan School of Public Health; and the Harvard Health Law Society at Harvard Law School.

Crimes of Passion: New Neuroscience vs. Old Doctrine

April 9, 2018

Part of the Project on Law and Applied Neuroscience, a collaboration between the Center for Law, Brain and Behavior at MGH and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

Health Law in the Private Sector: A Panel Discussion with Law Firm Partners and In-House GCs

April 10, 2018

Cosponsored by the Harvard Health Law Society and the Office of Career Services at Harvard Law School.

How to Fix Youth Sports Concussion Laws: Neuroscientific Perspectives

April 11, 2018

Part of the Project on Law and Applied Neuroscience, a collaboration between the Center for Law, Brain and Behavior at MGH and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

Health Policy and Bioethics Consortia

The Health Policy and Bioethics Consortia is a monthly series that convenes two international experts from different fields or vantage points to discuss how biomedical innovation and health care delivery are affected by various ethical norms, laws, and regulations. They are organized by the Center for Bioethics at Harvard Medical School and the Program On Regulation, Therapeutics, And Law (PORTAL) at Brigham and Women's Hospital, in collaboration with the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School. Support for the Consortia is provided by the Oswald DeN. Cammann Fund at Harvard University. While most of the sessions were hosted on the Harvard Medical School campus, on February 9, 2018, the Petrie-Flom Center hosted a session at Harvard Law School on **“The Conduct of Clinical Trials of Treatments during Public Health Emergencies.”**

For a full listing of consortium topics, visit the [website](#).



Additional Events with Petrie-Flom Co-Sponsorship and/or Participation

In addition to events the Petrie-Flom Center played a leading role in organizing, we also collaborated on several other events organized by our Harvard colleagues:

Fourth Annual Harvard-UCLA Food Law and Policy Conference: Food Innovation and the Law: Navigating the Next Frontier

October 13, 2017

Sponsored by the Food Law Lab at Harvard Law School and the Resnick Program for Food Law & Policy at UCLA School of Law, with support from the Animal Law & Policy Program at Harvard Law School, the Harvard Food Law and Policy Clinic at Harvard Law School, and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

National Summit on Advanced Illness Care

November 27–29, 2017

Washington, DC

Convened by the Center to Transform Advanced Care. For a full list of sponsors, please visit the [website](#).

Punishing Disease: HIV and the Criminalization of Sickness

Book Talk by Trevor Hoppe

January 29, 2018

Part of the Human Rights Program's year-long speaker series examining the criminalization of human rights concerning gender, sexuality, and reproduction. Cosponsored by the Petrie-Flom Center for Health Law, Policy, Biotechnology and Bioethics, the Criminal Justice Policy Program, and the Center for Health Law Policy Innovation at Harvard Law School.

HIV Criminalization: Creating a Viral Underclass in the Law

A Lecture by Sean Strub, Founder of POZ Magazine

March 1, 2018

Cosponsored by HLS Lambda, the Petrie-Flom Center for Health Law, Policy, Biotechnology and Bioethics, the Criminal Justice Policy Program, and the Center for Health Law Policy Innovation at Harvard Law School.

Criminal Abortion in the United States

March 1, 2018

Cosponsored by the Human Rights Program, the Criminal Justice Policy Program, and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School; and the HLS Students for Reproductive Justice.

Enabling Disability Rights in the U.S. and around the World

March 19, 2018

Cosponsored by the American Constitution Society; the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics; and the Center for Health Law and Policy Innovation at Harvard Law School.



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**The Future of the Affordable Care Act Following the Elimination of Cost-Sharing
Reduction Payments**

March 21, 2018

Cosponsored by the American Constitution Society, the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, and the Center for Health Law and Policy Innovation at Harvard Law School.

Annual Health Law Conference: Diseases of Despair: The Role of Policy and Law
April 12–13, 2018

This conference was sponsored by the Northeastern University School of Law Center for Health Policy and Law. For a full list of cosponsors, visit the website.



Contributions to the HLS Teaching Program

Petrie-Flom Center affiliates make substantial contributions to the university's health law curriculum through various courses and frequent guest lectures. Of particular note this year, **Luke Gelinas** lectured at a number of Catalyst course offerings related to the regulation and ethical oversight of human subjects research.

In addition to contributions to regular university courses, **I. Glenn Cohen** launched a new HarvardX course in fall 2016, "**Bioethics: The Law, Medicine, and Ethics of Reproductive Technologies and Genetics.**" The class has run several times as a self-paced course since April 2016, with the most recent session launching on June 4, 2018. Over the life of the course nearly 30,000 learners have enrolled, with almost 800 paying associated fees to receive a verified certificate of completion. He also lectured online and in person in other offerings around Harvard University, including "**Implementation Research in Health and Healthcare**" at the Harvard T.H. Chan School of Public Health.

This year, Petrie-Flom affiliates also offered the following full courses for credit:

Health Law, Policy, Bioethics, and Biotechnology Workshop

I. Glenn Cohen

Fall 2017

The Health Law, Policy, Bioethics, and Biotechnology Workshop is offered annually at HLS for enrollment by graduate students from across the university, and is a required course for Petrie-Flom Center Student Fellows. However, attendance is open to all interested parties, and the workshop audience often includes faculty, fellows, and students from across Harvard and surrounding universities, as well as local practitioners and the general public.

The workshop – the content of which varies every year – has become one of the preeminent venues for leading scholars in health law, biotechnology, and bioethics to launch, discuss, and improve their newest ideas. During two-hour sessions that take place over the course of the full academic year, presenters engage in extensive Q&A with the audience, and students enrolled in the course also offer written suggestions and responses. Workshop presentations are usually followed by a small dinner in which Harvard students, fellows, and faculty continue the discussion and have the opportunity to engage more closely with the speaker.



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The 2017–2018 workshop welcomed the following scholars:

- **Aziza Ahmed**, Professor of Law, Northeastern University School of Law (Petrie-Flom Visiting Scholar, 2014)
“Dead But Not Disabled”: A Feminist Legal Struggle for Recognition
- **Belinda Bennett**, Professor of Health Law and New Technologies, School of Law, and head, Governance and Regulation of Health Care program, Australian Centre for Health Law Research, Queensland University of Technology (Petrie-Flom Visiting Scholar, Fall 2017)
Law, Transformative Technologies, and the Automation Age: Lessons from the Past for a High-Tech Future
- **I. Glenn Cohen**, James A. Attwood and Leslie Williams Professor of Law and Faculty Director, Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Harvard Law School
Cops, Docs, and Code: A Dialogue Between Big Data in Health Care and Predictive Policing
- **Allison K. Hoffman**, Professor of Law, University of Pennsylvania Law School (Petrie-Flom Academic Fellow, 2008–2010)
Health Care’s Market Bureaucracy
- **Jody Madeira**, Professor of Law and Louis F. Niezer Faculty Fellow at the Indiana University Maurer School of Law
Terminating the Paper Trail: Evaluating the Efficacy of a Multimedia Informed Consent Application in Reproductive Medicine
- **Thaddeus Pope**, Professor of Law and Director of the Health Law Institute, Mitchell Hamline School of Law
From Informed Consent to Shared Decision Making: How Patient Decision Aids Can Improve Patient Safety and Reduce Medical Liability Risk
- **Vardit Ravitsky**, Associate Professor in Bioethics Programs, Department of Social and Preventive Medicine, University of Montreal School of Public Health
The Shifting Landscape of Prenatal Testing: Between Reproductive Autonomy and Public Health
- **Rachel E. Sachs**, Associate Professor of Law, Washington University School of Law (St. Louis) (Petrie-Flom Academic Fellow, 2014–2016)
Delinking Reimbursement
- **William Sage**, James R. Dougherty Chair for Faculty Excellence, University of Texas-Austin Law School and Professor, Department of Surgery and Perioperative Care, Dell Medical School, University of Texas at Austin
Fracking Health Care: The Need to Safely De-Medicalize America and Recover Trapped Value for Its People
- **Francis X. Shen**, Associate Professor, University of Minnesota Law School (Petrie-Flom Senior Fellow in Law and Applied Neuroscience, 2017–2018)
How Dangerous are Youth Sports for the Brain? A Review of the Evidence



- **David M. Studdert**, Professor of Medicine and Professor of Law, Stanford University
Once Ticketed, Twice Shy? Specific Deterrence from Road Traffic Laws
- **Alicia Ely Yamin**, Program Director, Health and Human Rights Initiative and Visiting Professor, Georgetown University Law Center; Adjunct lecturer on Law and Global Health, Harvard T. H. Chan School of Public Health; Global Fellow, Center on Law and Social Transformation (Norway) (Joseph H. Flom Global Health and Human Rights Initiative Fellow at Petrie-Flom, 2006–2007)
Democracy, Health Systems and the Right to Health: Narratives of Charity, Markets and Citizenship

Law and Neuroscience

Nancy Gertner

Spring 2018

With guest lectures and contributions to classroom discussion from Senior Fellow **Francis X. Shen**, this course was offered as part of the Project on Law and Applied Neuroscience. The course examined cutting edge and controversial linkages between law and neuroscience. It sought to highlight neuroscientific bases for behavior patterns with legal implications, including how neuroscience intersects with criminal law, its normative assumptions and criminal punishment, evidentiary rules, memory bias and enhancement, lie and deception detection, adolescent brains and juvenile law. It looked critically at efforts to use neuroimaging in court in connection with in the prediction of criminality and predispositions towards mental illness and addiction, as well as efforts to identify neurobiological influences on the brain. Is there such a thing as a criminally “violent brain”? Does it make sense to speak of the “neurobiology of violence” or the psychopathology of crime, and how are (or should) such concepts translated into criminal law. The seminar considered the relationship between law and science, more generally, and neuroscience in particular. Speakers provided insights into their work and research.

Health Care Rights in the Twenty-First Century

Kevin Costello and Carmel Shachar

Spring 2018

Underlying the current health care debate engulfing Washington is the fundamental question whether Americans enjoy a basic entitlement to health care. This course briefly traced the history of the American conception of health care rights through the last half-century of administrative and political cycles, contrasting a diverse array of ideological perspectives over this progression to understand the context of the current climate.



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Building on this background, the course considered a broad range of rights-affording sources across the landscape of the modern American health care system: Federal civil rights statutes; the laws and agreements that govern public and private health insurance arrangements; data privacy and ownership rights; and other state and federal statutes that govern health care consumers, insurers, institutions and spending. It also considered negative rights in the context of the Affordable Care Act's individual mandate and the relevant Religious Freedom Restoration Act developments. Building from this context, the course placed congressional and common law health care rights provisions in the broader context of civil rights jurisprudence, including anti-discrimination regimes. Applying a lens of civil rights and enforcement to these sources of law, the course considered differing avenues available to achieve enforcement of health care rights, including through administrative and policy-based advocacy, as well as more formalized litigation.

The seminar was designed to be limited lecture, incorporating debates, role-plays, and other interactive sessions. It culminated in a student-chosen project arising from the course materials – students wrote rights-enforcing instruments, which could include an administrative filing, a federal court complaint, or a regulatory comment. Students had the option of further honing their health care rights skills by participating in the Health Law and Policy Clinic in conjunction with this seminar.

The seminar appeals to law students interested in working across the spectrum of the health care field generally, to those interested in the intersection between law and health care, and to those who aspire to be civil rights lawyers.

Redesigning Humans: What Limits?

Einer Elhauge

Spring 2018

Modern technology is increasingly making it possible to enhance human biology through medical, genetic, and biomechanical means. What regulatory limits should be imposed on such efforts? This seminar covered a range of literature on that topic.



Participation of HLS Students in Program Activities

Student engagement is a key component of the Center's academic focus, which we achieve through our programming (often in collaboration with student groups), curricular offerings, research assistantships on the individual scholarship of Center affiliates as well as the Center's sponsored research and book projects, availability of affiliates for mentoring and professional advice, and, most importantly, our Student Fellowships.

Student Fellowship Program

The Petrie-Flom Center's Student Fellowship program is an integral component of our contribution to student development. Open to any graduate student at Harvard, the fellowship is designed to support mentored scholarship in health law policy, biotechnology, and bioethics.

Under the substantial guidance of Petrie-Flom affiliates, Student Fellows conduct independent research projects designed to lead to publishable articles, and are expected to produce at least one such paper by the end of the academic year. They are also expected to attend Center events and are required to enroll in the Health Law, Policy, Bioethics, and Biotechnology Workshop, which is intended to provide Student Fellows with opportunities to interact with leading scholars and Academic Fellows in the fields of health law and bioethics, with the expectation that these interactions will further enhance and inform their research and academic development. Finally, Student Fellows regularly blog at Bill of Health.

In addition to strong mentoring relationships, Student Fellows receive either a small stipend or writing credit upon successful completion of their written work, depending on arrangements with their home school. They also may be eligible to request additional funding to cover reasonable costs associated with their research projects and related opportunities.

The Center's 2017–2018 Student Fellows and projects were as follows:

Aobo Dong

Harvard Divinity School, MTS '18

Paper: "Insured by Faith: Legal and Ethical Ambiguities in Health Care Sharing Ministries"

Gali Katznelson

Harvard Medical School, MBioethics '18

Paper: "Exploring the Wild West: Smartphone Mental Health Apps in Clinical Settings"



Yusuf Lenfest

Harvard Divinity School, MTS '18

Paper: “Keeping God in Mind: Metaphysics, Ethics, and Psychiatry in the Islamic Tradition”

Clíodhna Ní Chéileachair

Harvard Law School, LLM '18

Paper: “Ask Any Happily Expectant Parent’: The Right to Refuse Medical Intervention in Pregnancy under the Eighth Amendment to the Irish Constitution”

Research Assistants

Petrie-Flom affiliates routinely work directly with Harvard graduate students as Research Assistants (RAs) on particular projects. We have engaged RAs to help identify topics, develop book proposals, and edit manuscripts for our conference volumes; conduct literature reviews and draft memos; prepare for media interviews; assist with development and submission of research protocols to Institutional Review Boards; and collaborate on empirical research projects.

In particular, we enjoyed the excellent work of the following students this year:

Patient-Centered Outcomes Research Oversight Study (PCOROS)

- Katherine Kwong, HLS '17 (via the HLS Cyberlaw Clinic)

Transparency in Health and Health Law

- John Hylton, HLS '20
- Gali Katznelson, HMS '18
- Rohit Rajan, HLS '18
- Joe Ruckert, HLS '19
- Nate Szyman, HLS '18
- Grace Wallack, HLS '19

Advanced Care and Health Policy

- Gali Katznelson, HMS '18

Other Petrie-Flom Projects

- John Hylton, HLS '20
- Lauren Tonti, HSPH '18



Student Bloggers

In addition to our Student Fellows, Bill of Health is home to a number of graduate student bloggers from HLS and around Harvard. We anticipate that this number will only grow as we relaunch the blog in FY19.

Student Interns

Our student internship program employs paid interns (undergraduates at Harvard and elsewhere, as well as high school students hired through the Cambridge Housing Authority's WorkForce program) who assist with various Center projects while gaining experience with the work of the Center. Intern projects this year included:

- Developing our biweekly newsletter;
- Updating the website and social media as needed;
- Developing Harvard health law/bioethics curriculum lists for the website;
- Advertising and preparing materials for Petrie-Flom events;
- Collecting and formatting material for drafts of Center reports;
- Research projects as assigned.

Our 2017–2018 interns were:

- Emily Jung, Harvard COL '18
- Megha Majumder, UC Berkeley '18
- Sabira Uddin, Cambridge Rindge and Latin, '21



Faculty Participation

As noted throughout this report, HLS faculty participation in the Petrie-Flom Center is both strong and essential. In addition to the clear investment by Faculty Director **I. Glenn Cohen** and Founding Director **Einer Elhauge**, **Hon. Nancy Gertner**, Lecturer on Law, has continued to support our collaborative Program on Law and Applied Neuroscience; **Michael Stein** of the Harvard Law School Project on Disability co-organized the 2018 Petrie-Flom Center Annual Conference, “Beyond Disadvantage: Disability, Law, and Bioethics”; and we have continued to collaborate regularly on events with our colleagues at the Animal Law and Policy Program. Under new Executive Director **Carmel Shachar** – an alumna of the Center for Health Law Policy and Innovation – we expanded our relationships with **Robert Greenwald** and **Emily Broad Leib**. Finally, **Urs Gasser** was a key collaborator for our 2016 annual conference and the resulting edited volume, BIG DATA, HEALTH LAW, AND BIOETHICS, published in Spring 2018. This year we worked with Urs and **Terry Fisher** of the Berkman Klein Center for Internet and Society to explore new avenues for collaboration.

Other faculty members from around the university have been involved in Petrie-Flom events and research, including:

- **Danielle Allen**, University Professor and Edmond J. Safra Center for Ethics
- **William P. Alford**, HLS
- **Jerry Avorn**, HMS
- **Till Bärnighausen**, HSPH
- **Peter Berman**, HSPH
- **Barbara E. Bierer**, HMS
- **Richard Born**, HMS
- **J. Wesley Boyd**, HMS
- **Rebecca Brendel**, HMS
- **Joshua W. Buckholtz**, FAS
- **Eric Campbell**, HMS
- **George Church**, HMS
- **Jessica Cohen**, HSPH
- **Kevin Costello**, HLS
- **Gregory Curfman**, HMS
- **Leemore Dafny**, HBS
- **George Q. Daley**, HMS
- **Jonathan Darrow**, HMS
- **Brad Dickerson**, HMS
- **Eric Drogin**, HMS
- **Judith G. Edersheim**, HMS
- **Nir Eyal**, HMS
- **Austin Frakt**, HSPH



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- Charles Fried, HLS
- Atul Gawande, HMS
- Jacob Gersen, HLS
- Jeannie Suk Gersen, HLS
- Joseph T. Giacino, HMS
- James Hammitt, HSPH
- Omar Sultan Haque, HMS
- Spencer Hey, HMS
- Nien-hê Hsieh, HBS
- Robert S. Kaplan, HBS
- Aaron S. Kesselheim, HMS
- Louise P. King, HMS
- Eric Lander, Broad Institute
- Timothy Layton, HMS
- Meira Levinson, GSE
- Margaret McConnell, HSPH
- John McDonough, HSPH
- Paul McLean, BCH
- Bill Meehan, BCH
- Christine Mitchell, HMS
- Diane L. Moore, HDS
- Ben Moulton, HSPH
- Jennifer A. Moye, HMS
- Lee Nadler, HMS
- Steven M. Niemi, FAS
- Andrew Nierenberg, MGH
- Bruce H. Price, HMS
- Intisar A. Rabb, HLS
- Meredith Rosenthal, HSPH
- James Sabin, HMS
- Ameet Sarpatwari, HMS
- Benjamin Sommers, HSPH
- Lucas Stanczyk, FAS
- Robert D. Truog, HMS
- Joel Weissman, HMS
- Daniel Wikler, HSPH
- Richard Zeckhauser, HKS

Harvard faculty are also less formally involved with the Center through attendance and participation in the Center's Health Law, Policy, Bioethics, and Biotechnology Workshop and other programmed events.



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Several faculty members are also involved with our blog, [Bill of Health](#):

- [Gregory Curfman](#), HMS
- [Jonathan Darrow](#), HMS
- [Nir Eyal](#), HMS
- [Aaron S. Kesselheim](#), HMS
- [Ameet Sarpatwari](#), HMS

We continue to actively develop faculty involvement to help offer a centralized location within the university for faculty sharing a collective interest in our fields.



Connections to the Community and Professions

The Center's regular programming focuses on policy issues of interest to both academic and lay communities, and is almost always free and open to the public. Nearly all of our events are also video-recorded in full and posted online with links on our website, thereby permitting the broader community the opportunity to take advantage of our offerings.

Affiliate Engagement

In addition, our affiliates are regularly sought after to provide media commentary on news stories in our fields, to serve as expert witnesses and legal consultants, and perform other types of public service, such as committee membership, amicus curiae briefs, peer review for academic publications, and the like. Representative examples of such engagement are included below:

I. Glenn Cohen

Faculty Director **I. Glenn Cohen** served as a member of the Standing Committee on Ethics of CIHR (Canadian Institute for Health Research; the Canadian equivalent to NIH) until his term on the committee expired during this past fiscal year. Since 2016, has served on the National Academy of Sciences committee on Issues in Organ Donor Intervention Research. He also serves on the Ethics Committee for the American Congress of Obstetricians and Gynecologists (ACOG). He has also recently joined the Research Oversight Committee of Genome British Columbia.

Carmel Shachar

Executive Director **Carmel Shachar** serves as a board member for the Fishing Partnership Support Services, a non-profit organization devoted to improving the health, well-being, and safety of fishing communities of New England. She also serves on the leadership team for the recently launched Scientific Citizenship Initiative at Harvard Medical School.

Luke Gelinas

Senior Researcher **Luke Gelinas** served for most of FY18 as a board member of the Schulman Associates IRB, where he is responsible for reviewing proposals for clinical trials and other types of research to ensure that they meet pertinent regulatory and ethical requirements. This involves reviewing scientific protocols to evaluate the design of clinical research studies and ensuring that consent documents clearly communicate risks and other key information to prospective study participants.



Francis Shen

Senior Fellow in Law and Applied Neuroscience **Francis Shen** has been named to the Neuroethics Subgroup of the National Institutes of Health Advisory Committee to the Director BRAIN Initiative Working Group. He also served on the Minnesota Bar Association Commission on Juvenile Sentencing for Heinous Crimes.

Francis also delivered numerous public presentations related to his work with the Project on Law and Applied Neuroscience to audiences that included undergraduate student organizations, legal and medical practitioners, judges, and international legal and medical scholars. Selected presentations include:

Emerging Issues in Sports Concussion and the Law, ANNUAL LEADERSHIP MEETING OF THE AMERICAN ORTHOPEDIC ASSOCIATION (Boston, MA) (2018).

Neuroscience and the Law: A Brief Introduction, DUKE LAW JUDGES SEMINAR (Durham, NC) (2018).

Lie Detection in the Courtroom, BOSTON SOCIETY OF NEUROLOGY AND PSYCHIATRY (Boston, MA) (2018).

Confinement Companions: Can AI Address The Solitary Confinement Crisis?, WE ROBOT AT STANFORD LAW SCHOOL (Palo Alto, CA) (2018).

Law and the Aging Brain: From Clinic to Courtroom, PSYCHIATRY GRAND ROUNDS, MASSACHUSETTS GENERAL HOSPITAL (Boston, MA) (2018).

National Security Implications of Neurolaw, 2018 U.S. SPECIAL OPERATIONS COMMAND LEGAL CONFERENCE (Tampa, FL) (2018).

Blueprint for a Neurolaw Clinic, BIOLAWPALOOZA AT STANFORD LAW SCHOOL (Palo Alto, CA) (2018).

The Future of Neuropsychiatry and the Law: Promise and Peril, ANNUAL MEETING OF THE AMERICAN NEUROPSYCHIATRIC ASSOCIATION (Boston, MA) (2018).

Neuroscience and the Rules of Evidence, NATIONAL ACADEMIES OF SCIENCES (Washington, DC) (2018).

Dementia and the Law, Remarks at Harvard Law School Petrie-Flom Center Annual Year in P/Review 2017-18, (2017).

Neuroscience and the Law: What Judges Need to Know, 2017 MINNESOTA ANNUAL CONFERENCE OF JUDGES (Bloomington, MN) (2017).



Law and Neuroscience 2.0, LAW AND MIND CONFERENCE AT JAGIELLONIAN UNIVERSITY (Krakow, Poland) (2017).

Every Story is a Brain Story: The Future of Neuroscience and Law, VIRGINIA TECH NEUROSCIENCE CLUB (Blacksburg, VA) (2017)

Law and Neuroscience (multiple presentations), NEUROSCIENCE SCHOOL OF ADVANCED STUDIES, CERTOSA DI PONTIGNANO (Siena, Italy) (2017).

The Roles of Science in Society: Research, Education and Practice, MAYO SPORTS MEDICINE CLINIC ICE HOCKEY SUMMIT III: ACTION ON CONCUSSION (Rochester, MN) (2017).

Mark Sterling

Along with a team at the Coalition to Transform Advanced Care (C-TAC), Mark Sterling provides consulting services and strategic advice to health systems and others seeking to implement an advanced care model. As noted below, Senior Fellow Mark Sterling served on the planning committee for a proposal by C-TAC submitted to the Physician-focused Payment Technical Advisory Committee (PTAC), a panel of experts convened by HHS. C-TAC's proposal was favorably recommended by P-TAC to the Secretary of the Department of Health & Human Services.



Sponsored and Other Research

The Center's sponsored research and other projects described above have direct policy implications for the broader community. For example:

- Through our work with Harvard Catalyst, we are directly engaging with researchers, institutional policymakers, industry leaders, regulators, patients, and others to advance clinical and translational research through improved recruitment to clinical trials.
- Our work on the Patient-Centered Outcomes Research Oversight Study (PCOROS) seeks to identify and address any novel or prevalent ethical and regulatory challenges posed by Patient-Centered outcomes research (PCOR) as relevant to human subjects protection and oversight.
- Our edited volume, SPECIMEN SCIENCE: ETHICS AND POLICY IMPLICATIONS, which was showcased in several public events in Fall 2017, will help pave the way forward for medical advancement via biospecimen research in light of the federal government's recently updated relevant regulations.
- Our edited volume, LAW, RELIGION, AND HEALTH IN THE UNITED STATES, examines the role of law in creating or mediating conflict between religion and health care, and explores potential policy and legal solutions to allow religion and health care to simultaneously flourish in a culturally diverse nation.
- Our Project on Law and Applied Neuroscience is devoted to bringing together the professions of law and neuroscience so that each discipline can inform the other.
- The Project on Advanced Care and Health Policy seeks to implement policy change to improve decision-making and care at the end of life, issues of dramatic importance to patients and their families.
- The Project on Precision Medicine, Artificial Intelligence, and the Law is already garnering significant interest from thought leaders, despite being only recently launched. PMAIL will provide a comparative analysis of the law and ethics of black-box precision medicine, explaining the shortcomings of the current innovation policy landscape in Europe and the US, and providing a comprehensive examination of various policy options to better harness the potential of black-box medicine.
- The Innovative Funding Models in Translational Research is gathering the leaders in the medical and scientific research community to articulate the challenges around for-profit funding of early stage research. We anticipate that this work will lead to significant policy recommendations in the area.
- Finally, the Journal of Law and the Biosciences is an open-access online journal freely available to anyone with an interest in its contents, providing an important resource to both professional and lay communities.



Communications

Website and Social Media

The Petrie-Flom Center's [website](#) is a critical component of promoting our public-facing work, offering users easy access to a wide array of information about the Center's [events](#), [research](#), [affiliate scholarship](#), [fellowships](#), and other activities, as well as more general information about [news](#), [opportunities](#), and [resources](#) in the Center's major research areas at the intersection of health law and policy, biotechnology, and bioethics.

The website is maintained by Center staff, who update it daily with new opportunities, breaking news, scholarship by our affiliates, and other resources. The website is a central hub for all information related to the Center's work, that of our larger community, and the broader fields of health law policy and bioethics.

In the past year we have seen tremendous results from efforts to increase engagement on social media and drive traffic to the site. Overall traffic has increased across all platforms and, crucially, we have continued to see a steady flow of requests by partners to be included in our resource listings (e.g., opportunities and partner events), as well as strong attendance at our own events.

The Center's [website](#) averaged roughly 5,000 unique visitors per month, with usage spiking during the academic year to nearly 7,000 visitors in some months. Visitors to the site came from over 170 countries.

We continue to use our web presence to share our [events](#), in particular, with a much broader community. Our [Vimeo account](#), where we host videos of panels and lectures from our events, saw more than 5,000 plays this year, while our [slide-sharing site](#) received an average of over 1,500 views per month. Both of these are a significant increase year-over-year.

Our social media properties continue to grow, helping us reach new audiences. Our [Facebook](#) following nearly doubled this year, and our [Twitter](#) following has grown by a third, with our monthly impressions reaching into the hundreds of thousands. We continue to be a leading source for health law news, opportunities, and community on social media.

We circulate a [biweekly email newsletter](#) that gives our subscribers information about upcoming events, commentary from the [Bill of Health](#), affiliate news and scholarship, opportunities at the Petrie-Flom Center, across Harvard, and elsewhere, as well as other information relevant to our community. Our subscribers list continues to grow, with almost 6,000 members in July 2018.



These numbers exhibit the ways we are effectively employing a variety of digital media products to engage our community and position the Center as a leader in the field, within the academy and beyond.

In the coming year, Communications Manager **Alex Pearlman** will spearhead communications strategy and digital development. We are looking forward to the results of Alex’s work in growing our reach and expanding to new outlets.

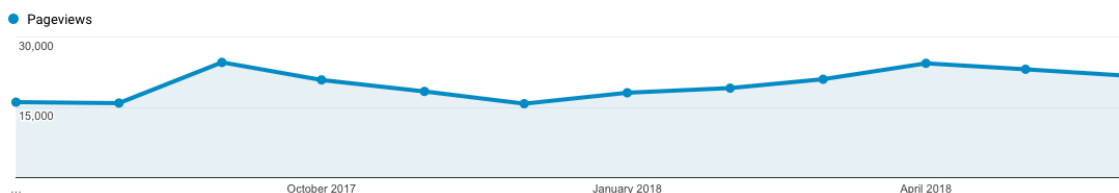
Bill of Health

Bill of Health, our blog on health law policy, biotechnology, and bioethics, edited by our new Communications Manager **Alex Pearlman** since May, continues to be a resounding success.

Our bloggers are leading health law scholars and bioethicists at universities around the country and the world. The community remains heavily active, with new bloggers joining us regularly. We publish one or two new posts every day, and have hosted a number of successful blog symposia in conjunction with the many topical conferences the Center hosts over the course of the year. Our blog has also become a recognized outlet for other health law programs and centers, such as programs from Temple University, Northeastern University, and the University of Minnesota, who regularly ask us to host symposia on their events and research.

We consistently see Bill of Health content shared across social media. Users have increased 13 percent in the last year, up to over 153,000 unique readers and 239,000 pageviews in FY18. Engagement is also very high, and Bill of Health readers see an average of two pages per visit where they remain for over three minutes – significantly longer than industry average. Our colleagues and collaborators in the field have helped make Bill of Health a go-to destination for high caliber, original health law analysis and commentary.

Pageviews ? ↓	Unique Pageviews ?	Avg. Time on Page ?
239,016	210,668	00:03:13



The most popular articles we published this year spanned subjects across the health law and bioethics spectrum, and demonstrate how Bill of Health is a home for thought leaders throughout this incredibly important niche.



Some of our most popular articles included:

- [Be Very, Very Concerned About What Allergan Just Did](#)
- [Orphan Drugs Designations and Approvals have Something to Say about Risks](#)
- [More on the ECJ Vaccine Liability Decision](#)
- [Long Overdue: Check Out the Vaccine Resources Library for Expert Witnesses](#)
- [Why Are So Many American Women Dying in Childbirth?](#)
- [What can an 11th century Islamic philosopher teach us about 21st century neuroscience?](#)

We have also increased our focus on the opioid epidemic in America, creating a new category of coverage and regularly publishing expert views from practitioners, legal experts, and other stakeholders.

In the coming year, we will continue to grow the Bill of Health brand through a redesign, strategic publishing partnerships with mainstream outlets, and a recruitment effort to reinvigorate the community of writers and readers. Our goals are to be a leading forum for innovative ideas in the field, to expand and diversify our contributor base, to serve as a conduit between mainstream outlets and scholars, to improve our conversion of first-time readers into returning users, as well as to increase engagement with our newsletters and social media presence.



Events with Industry Participation

As noted above, the Petrie-Flom Center hosted several events this academic year with participants from the health care and pharmaceutical industries. This reflects our renewed commitment in FY18 to build our relationships and reputations with the health law practitioner community and other relevant industries. To meet our goals of increased engagement with industry, we sought out collaborations and events to host with industry leadership. We hope in the coming years to further build upon our commitment to foster closer ties between scholarship and practice by continuing to involve a range of practitioners and industry leaders in our events, projects, and other initiatives. We believe this commitment to industry relationships is crucial to expose students to real-world issues and maintain connections with practical challenges arising in our fields of inquiry:

Putting Patients at the Center of Research: Opportunities and Challenges for Ethical Oversight

June 29, 2018

This conference was the culmination of our three-year collaborative Patient-Centered Outcomes Research Oversight Study (PCOROS), led by Principal Investigator Joel Weissman of Brigham and Women's Hospital. The conference was grounded in recent efforts to place the patient at the center of medical research, spurred by the Affordable Care Act's founding of the Patient-Centered Outcomes Research Institute, that have begun to change the way clinical research is conceptualized and conducted. Such efforts hold great promise, but also raise potential challenges for ethical oversight. How should oversight bodies approach the presence of patients in potentially unfamiliar research roles, such as investigator? What forms of patient involvement in research, if any, warrant increased scrutiny from oversight bodies? How do we keep the patient voice from being 'captured' by special interest groups? This symposium brought together a diverse group of patients and community members, policymakers, bioethicists, and regulatory officials to address these and other issues.

Industry Participants:

- **Martha Carnie**, Senior Patient Advisor, Brigham and Women's Hospital
- **Luke Gelinas**, Chairperson, Advarra IRB and Senior Researcher, Petrie-Flom Center
- **Paul McLean**, ethics associate, Boston Children's Hospital; social media coordinator, Community Ethics Committee; patient/family co-investigator, governance of learning activities in learning health care systems (PCORI)
- **Megan Morash**, IRB Chair, Partners Human Research Committee
- **Jane Perlmutter**, Cancer Survivor and Patient Advocate
- **Joe Selby**, Executive Director, Patient-Centered Outcomes Research Institute (PCORI)



The Networking Exchange at the Broad Institute

June 3, 2018

This event, hosted by the Broad Institute, was cosponsored by the Petrie-Flom Center. Faculty Director **I. Glenn Cohen** moderated a public “Life Sciences Ethics Discussion,” and Executive Director **Carmel Shachar** hosted a table featuring information on the Center’s work and events. The event provided Petrie-Flom Center directors with a range of opportunities to engage with members of life science technologies community, including Boston-area universities, research institutions, and hospitals throughout Massachusetts, as well as Massachusetts technology licensing offices. Participating organizations included Boston Children’s Hospital, Brandeis University, the Broad Institute of MIT and Harvard, Dana-Farber Cancer Institute, Harvard University, the Massachusetts General Hospital Research Institute, the Massachusetts Institute of Technology, and the University of Massachusetts.

2018 Petrie-Flom Center Annual Conference:

Beyond Disadvantage: Disability, Law, and Bioethics

June 1, 2018

In collaboration with the Harvard Law School Project on Disability and cosponsored by the Center for Bioethics at Harvard Medical School, with support from the Oswald DeN. Cammann Fund at Harvard University.

The aim of this year’s annual conference, organized in collaboration with the Harvard Law School Project on Disability, was to construct a twenty-first century conception of disablement that resolves the tension about whether being disabled is merely neutral or must be bad, examines and articulates the clinical, philosophical, and practical implications of that determination, and attempts to integrate these conclusions into medical and legal practices. We received a number of paper proposals from patient advocates working this space, and were thrilled to welcome Harvard Law School alumnus and former Petrie-Flom Student Fellow **Nathaniel Counts**, now Senior Policy Director at Mental Health America, as a presenter. (Nathaniel’s paper was coauthored with **C. Taylor Poor**, **Julie Erickson**, **Thomas Hart**, and **Kelly A. Davis**, also of Mental Health America.)



Workshop on Science-Informed Decision Making May 2–4, 2018

Sponsored by the Federal Judicial Center, with support from the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and the Center for Law, Brain and Behavior at Massachusetts General Hospital.

This workshop was designed to help federal criminal justice practitioners develop improved collaborative responses to individuals with mental health and substance use disorders. The workshop brought together federal court stakeholders engaged in different phases of the criminal case process to learn from scholars and clinicians about how scientific research can be translated into practical district-level applications at key criminal case decision points including initial appearance, violation hearings, presentence investigation, and sentencing.

Industry participants:

- **Anthony Castellano**, Chief Probation Officer, N.D. of Florida
- **Kate Desmond**, Community Justice Manager, Adult Services Division, Multnomah County, Oregon
- **Hon. Esther Salas**, U.S. District Judge, D. of New Jersey
- **Cassandra Snyder**, Federal Judicial Center

Our Aging Brains: Decision-Making, Fraud, and Undue Influence April 28, 2018

This conference, organized by Senior Fellow in the Project on Law and Applied Neuroscience **Francis Shen**, explored the neuroscience, psychology, and legal doctrine of financial decision-making in older adults. How does the aging brain make financial decisions, and when is it uniquely susceptible? How can courts best use science to improve their adjudication of disputes over “competency,” “capacity,” and “undue influence”? Is novel neuroimaging evidence of dementia ready for courtroom use? This conference brought together experts in medicine, science, and law to explore these important questions and chart a path forward for dementia and the law.

Industry Participants:

- **Shelly L. Jackson, PhD**, Office for Victims of Crime Visiting Fellow, Elder Justice Initiative, U.S. Department of Justice
- **Nicholas Losurdo, JD**, Counsel, Goodwin Procter LLP
- **Ana Maiques**, Chief Executive Officer, Neuroelectrics
- **Andy Mao, JD**, Deputy Director (Fraud Section) and Coordinator of the Elder Justice Initiative, U.S. Department of Justice
- **Phillip Marshall, PhD**, Elder Justice Advocate and Founder, *Beyond Brooke*
- **Erica Wood, JD**, Chief Counsel, ABA Commission on Law and Aging



The Development and Certification of Decision Aids: Promoting Shared Decision Making for Patients with Serious Illness

April 18, 2018

Part of the Project for Advanced Care and Health Policy, a collaboration between the Petrie-Flom Center and the Coalition to Transform Advanced Care (C-TAC). Funding for this event was provided by Cambia Health Foundation, Kaiser Permanente, the Milbank Memorial Fund, and the Coalition to Transform Advanced Care (C-TAC).

Decision aids can be highly-effective tools to promote shared decision making and support patients in becoming engaged participants in their health care. Join us for the first-ever convening with leaders behind a Washington experiment in certifying decision aids, as state officials, health systems, and on-the-ground implementation experts share lessons learned and discuss policy recommendations for national or statewide approaches to decision aid certification.

Industry Participants:

- **Linda Briggs**, Director of Program Development & Research, Respecting Choices, a division of C-TAC Innovations
- **Dominick Frosch**, Palo Alto Medical Foundation Research Institute
- **Matt Handley**, Senior Medical Director for Quality and Safety, Kaiser Permanente of Washington
- **Christopher F. Koller**, President, Milbank Memorial Fund
- **Jennifer Lippy**, Health Insurance Specialist and Project Officer, Medicare Care Choices Model
- **Karen Merrikin**, Project Consultant, Washington State Health Care Authority
- **Laura Pennington**, Practice Transformation Manager, Washington State Health Care Authority
- **Sandra Schellinger**, Senior Faculty and Consultant, Respecting Choices, a division of C-TAC Innovations

Health Law in the Private Sector: A Panel Discussion with Law Firm Partners and In-House GCs

April 10, 2018

This panel discussion, cosponsored by the Harvard Health Law Society and the Office of Career Services at HLS, brought together partners in law firms and in-house general counsels focused on health law to discuss the breadth of career options available to attorneys interested in the intersection of health and law.

Industry Participants:

- **Stephen Bernstein** global head, Health Practice and co-chair, Life Sciences Practice, McDermott Will & Emery
- **Chris Kirby**, Deputy General Counsel, Boston Children's Hospital
- **Jennifer Zachary**, general counsel, Merck & Co.



Health in the Headlines: Reporting on Health Policy in the Trump Era

April 4, 2018

Sponsored by the Center for Health Law and Policy Innovation at Harvard Law School; the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School; the Shorenstein Center on Media, Politics and Public Policy at the Harvard Kennedy School of Government; the Harvard PhD Program in Health Policy; the Harvard T. H. Chan Student Association (HCSA) at the Harvard T. H. Chan School of Public Health; and the Harvard Health Law Society at Harvard Law School.

This panel session brought together leading health care journalists to talk about the rapidly shifting health policy landscape in Washington DC. Panelists discussed the high drama of a tumultuous year in health policy that has seen repeated congressional attempts to repeal the Affordable Care Act, the resignation of a cabinet secretary amidst scandal, and a steady effort to undermine Obama-era priorities. Further, the panel explored the role of journalism in modern policy-making, and how social media impacts the dialogue.

Industry Participants:

- **Julie Rovner**, Chief Washington Correspondent, Kaiser Health News
- **Margot Sanger-Katz**, domestic correspondent, *New York Times*
- **Rachana Pradhan**, health care reporter, *POLITICO*

Health Law and Public Service

March 23, 2018

This panel discussion, cosponsored by the Harvard Health Law Society, the Center for Health Law and Policy Innovation at Harvard Law School and the Massachusetts Bar Association, brought together advocates and practitioners to discuss careers focused on health law.

Industry Participants:

- **Lauren Birchfield Kennedy** (HLS '09), co-founder, Neighborhood Villages; previously Director of Health Policy, National Partnership for Women & Families, Washington, D.C.
- **Jenny Williams**, attorney, U.S. Department of Health and Human Services, Office of the General Counsel, Region I
- **Sandra Ullman Wolitzky** (HLS '12), Assistant Attorney General, Health Care Division, Office of the Attorney General of Massachusetts



Will Value-based Care Save the Health Care System?

March 2, 2018

With support from the Oswald DeN. Cammann Fund at Harvard University and Ropes & Gray LLP.

The Center collaborated with Ropes & Gray LLP to host a one-day conference on value-based health care. This event brought together scholars, health law practitioners, and health care entities to evaluate the impact of value-based health care on the American health care system, with a focus on the pressing need to evaluate the implementation of these initiatives thus far and to discuss the direction that American health care financing will take in the coming years.

Industry Participants:

- **Thomas Bulleit**, Partner, Ropes & Gray
- **Deborah Gersh**, Partner, Ropes & Gray
- **Karen Gledhill**, Senior Vice President and General Counsel, Fresenius Medical Care North America
- **Ira Klein**, Senior Director of Quality, Strategic Customer Group, Janssen Pharmaceutical Companies of Johnson & Johnson
- **Thomas Lee**, Chief Medical Officer, Press Ganey Associates
- **Timothy McCrystal**, Partner, Ropes & Gray
- **David Peloquin**, Associate, Ropes & Gray
- **Lee Sacks**, Executive Vice President and Chief Medical Officer, Advocate Health Care and Chief Executive Officer of Advocate Physician Partners
- **Josh Seidman**, Senior Vice President, Avalere Health
- **Michael Sherman**, Senior Vice President and Chief Medical Officer, Health Services, Harvard Pilgrim Health Care
- **Betsy Van Hecke**, Vice President, Legal, Cardiac and Vascular Group, Medtronic

Addiction, Neuroscience, and the Criminal Law: Commonwealth vs. Julie Eldred

February 28, 2018

Organized as part of the Project on Law and Applied Neuroscience, this panel discussion featured key legal and scientific experts involved in the potentially landmark case *Commonwealth vs. Julie Eldred*, in which the Massachusetts Supreme Judicial Court had to decide if it is constitutional for the criminal justice system to require addicted offenders to remain drug free. (The court ruled in July 2018 that judges can require drug users on probation to remain drug free.)

Industry Participants:

- **Lisa Newman-Polk**, defense attorney



Digital Health @ Harvard Series: Health Care Costs and Transparency

February 6, 2018

This session of the Digital Health @ Harvard series, started in Fall 2016 by the Petrie-Flom Center and the Berkman-Klein Center for Internet and Society at Harvard University, focused on what is driving health care costs up, who is benefiting, and how data is harnessed to study problems and remedy them.

Industry Participants:

- **John Freedman**, Founder of Freedman Health care

Future Directions for Laboratory Animal Law in the United States: Pre-Workshop Webcast and Workshop

January 26, 2018

Sponsored by the Roundtable on Science and Welfare in Laboratory Animal Use of the Institute for Laboratory Animal Research, the Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics, and the Animal Law and Policy Program of Harvard Law School, with support from the Oswald DeN. Cammann Fund at Harvard University.

Industry Participants:

- **Lida Anestidou**, Institute for Laboratory Animal Research, National Academies of Sciences, Engineering and Medicine
- **Anne DesChamps**, Federation of American Societies for Experimental Biology
- **Nathan W. Herschler**, New England Anti-Vivisection Society
- **Bernadette Juarez**, US Department of Agriculture - Animal and Plant Health Inspection Services
- **Lisa Moses**, Angell Animal Medical Center & Harvard Medical School
- **Delcianna J. Winders**, PETA Foundation & Elisabeth Haub School of Law at Pace University



Sixth Annual Health Law Year in P/Review

December 12, 2017

Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, Health Affairs, the Center for Health Policy and Law at Northeastern University School of Law, Harvard Health Publications at Harvard Medical School, the Program On Regulation, Therapeutics, And Law (PORTAL) in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital, and the Center for Bioethics at Harvard Medical School, with support from the Oswald DeN. Cammann Fund at Harvard University.

The Sixth Annual Health Law Year in P/Review symposium featured leading experts discussing major developments during 2017 and what to watch out for in 2018. The discussion at this day-long event covered hot topics in such areas as health policy under the Trump administration, law at the end of life, patient rights and advocacy, pharmaceutical policy, reproductive health, and public health law. To present a comprehensive view of developments in federal health care policy, we brought both conservative and liberal D.C. health care thought leaders to campus.

Industry Participants:

- **Joseph Antos**, Resident Scholar and Wilson H. Taylor Scholar in Health Care and Retirement Policy, American Enterprise Institute
- **Audrey Morse Gasteier**, Chief of Policy & Strategy, Massachusetts Health Connector
- **Michael B. Lampert**, Partner, Ropes & Gray LLP
- **Claire Laporte**, Partner, Foley Hoag LLP (through June 2018)
- **Judith Solomon**, Vice President for Health Policy, Center on Budget and Policy Priorities

Behind Bars: Ethics and Human Rights in U.S. Prisons

November 29–December 1, 2017

Cosponsored by the Human Rights Program at Harvard Law School, the Center for Bioethics at Harvard Medical School, and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, with support from the Oswald DeN. Cammann Fund at Harvard University.

This conference examined various aspects of human rights and health issues in our prisons. In collaboration with educators, health professionals, and those involved in the criminal justice system – including former inmates, advocates, and law enforcement – the conference sought to clarify the issues, explore possible policy and educational responses, and establish avenues for action.

Industry participants:

- **Mary Baxter**, Inaugural Fellow, Right of Return Fellowship Program
- **J. Wesley Boyd**, Associate Professor in Psychiatry and faculty member in the Center for Bioethics, Harvard Medical School; staff psychiatrist at Cambridge Health Alliance (CHA); and founder and co-director, Human Rights and Asylum Clinic at CHA



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- **Kathleen Dennehy**, The Heller School for Social Policy and Management, Brandeis University, and former Commissioner of the Massachusetts Department of Corrections
- **Louie Diaz**, substance abuse counselor and re-entry specialist, Middlesex County Sheriff's Office
- **Stuart Grassian**, Psychiatrist, Author of *Psychopathological Effects of Solitary Confinement*
- **Rahsaan D. Hall**, Director, Racial Justice Program, American Civil Liberties Union of Massachusetts
- **Mik Kinkead**, Staff Attorney and Prison Justice Project Director, Sylvia Rivera Law Project
- **Robert P. Marlin**, Director, Coordinated Care Program for Political Violence Survivors and Attending Physician, Cambridge Health Alliance; Instructor in Medicine, Harvard Medical School
- **Fatimah Loren Muhammad**, Director, Trauma Advocacy Initiative, Equal Justice USA
- **Jenny Phillips**, Producer/Director, *Beyond the Wall*
- **George Powell**, Author and Screenwriter
- **Stefanie Rivera**, Director of Client Services, Sylvia Rivera Law Project
- **Joli Sparkman**, Reentry Coordinator, Bethany House Ministries, Inc.
- **Marc Stern**, Affiliate Assistant Professor, Health Services, University of Washington School of Public Health and Former Health Services Director, Washington State Department of Corrections
- **Homer Venters**, Director of Programs, Physicians for Human Rights; Clinical Associate Professor, Department of Population Health and Clinical Associate Professor, Department of Medicine, NYU

Book Launch: Specimen Science: Ethics and Policy Implications

November 9, 2017

Sponsored by the Harvard Law School Library, the Francis A. Countway Library of Medicine at Harvard Medical School, and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, with support from the Oswald DeN. Cammann Fund at Harvard University.

Industry Participants:

- **Jane Perlmutter**, Cancer Survivor and Patient Advocate



The Cost of Medications: Current Realities and the Future of Pharmaceutical Pricing Regulations in the United States

October 4, 2017

Cosponsored by the Center for Bioethics at Harvard Medical School, with support from the Oswald DeN. Cammann Fund at Harvard University.

This panel of experts discussed current laws and regulations governing pharmaceutical pricing in the United States, the impact of breakthrough therapeutics on drug pricing, and the future of drug pricing policy in the United States.

Industry Participants:

- **Jorge Lopez**, General Counsel, Memorial Sloan Kettering Cancer Center
- **Sabrina Yohai**, Vice President, Policy, Access & Value, Vertex Pharmaceuticals

What's Next for the ACA?: A Lecture by Larry Levitt

October 3, 2017

Sponsored by the Center for Health Law Policy and Innovation, the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, and the Harvard Health Law Society, all at Harvard Law School.

Industry Participants:

- **Larry Levitt**, Senior Vice President for Special Initiatives, Kaiser Family Foundation



Collaborations

As described throughout this report, the Petrie-Flom Center actively seeks out collaborators both within and beyond Harvard in order to extend our influence and capitalize on the expertise of others. We cosponsor events, work with affiliated faculty, co-teach classes, and participate in joint projects wherever appropriate.

This year, our major collaborative efforts included:

- Our blog, Bill of Health
- Our sponsored research project primarily based at Harvard Medical School, Harvard Catalyst (with collaborators at various Harvard-affiliated medical centers and colleagues at Emory University)
- The Patient-Centered Outcomes Research Oversight Study (PCOROS), based out of Brigham and Women's Hospital
- Our new sponsored research project on Precision Medicine, Artificial Intelligence, and the Law, in collaboration with colleagues at the University of Michigan School of Law, under the leadership of the Center for Advanced Studies in Biomedical Innovation Law at the University of Copenhagen
- Our new project on Innovative Funding Models in Translational Research includes a steering committee of representatives from the Broad Institute, the Whitehead Institute, Partners Health care, the Dana-Farber Cancer Institute, and Johnson & Johnson Innovation.
- Our Project on Law and Applied Neuroscience with the Center for Law, Brain, and Behavior at Massachusetts General Hospital
- A major conference, co-organized as part of the Project on Law and Applied Neuroscience, sponsored by the Federal Judicial Center in Washington, D.C.
- Our Project on Advanced Care and Health Policy, with the Coalition to Transform Advanced Care (C-TAC)
- Work on the Journal of Law and the Biosciences with colleagues at Duke and Stanford
- Participation on the leadership team of the Scientific Citizenship Initiative at Harvard Medical School through the efforts of Executive Director **Carmel Shachar**
- Book projects based on our conferences, with authors from a variety of institutions
- A variety of projects with the Berkman-Klein Center for Internet and Society at Harvard University, including the continuation of our Digital Health @ Harvard series, the ongoing development of a proposal seeking funding for a joint project on legal and ethics issues around digital health, and new collaborative work with the Global Access in Action project
- A series of events co-organized with the Center for Health Law and Policy Innovation, as well as early discussions on the development of a funding proposal to support a joint project on the medicalization of the social determinants of health



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- A conference – our second in as many years – coorganized with the Edmond J. Safra Center for Ethics at Harvard University, with whom we are in discussions about further collaborative efforts in the future
- Collaboration with the Harvard Medical School’s Center for Bioethics on events, conferences, and their Master’s program in bioethics

We collaborated with the following groups to pursue programming or other joint effort in areas of mutual interest:

- The Berkman-Klein Center for Internet & Society at Harvard University
- The Broad Institute at MIT and Harvard
- The Center for Advanced Studies in Biomedical Innovation Law at the University of Copenhagen
- The Center for Law, Brain and Behavior at Massachusetts General Hospital
- Countway Library of Medicine
- The Coalition to Transform Advanced Care (C-TAC)
- Edmond J. Safra Center for Ethics at Harvard University
- Global Access in Action, a project of the Berkman-Klein Center
- Harvard Catalyst
- Harvard Health Publications at Harvard Medical School
- Harvard Law School Project on Disability
- The Hastings Center
- Health Affairs
- The Health Ethics and Policy Lab, University of Zurich
- HLS | 200
- HLS American Constitution Society
- HLS Animal Law and Policy Program
- HLS Center for Health Law and Policy Innovation
- HLS Food Law Lab
- HLS Harvard Health Law Society
- HLS Human Rights Program
- HLS Lambda
- HLS Library
- HMS Center for Bioethics
- The Institute for Laboratory Animal Research at the National Academies of Science, Engineering, and Medicine
- The Massachusetts Bar Association
- Northeastern University School of Law Center for Health Policy and Law
- The Program On Regulation, Therapeutics, And Law (PORTAL) at the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women’s Hospital
- Public Responsibility in Medicine & Research (PRIM&R)
- Ropes & Gray LLP



2018–19 Plans for Activities

(Fiscal Year 2019: July 2018–June 2019)

During the coming year, the Petrie-Flom Center will have three areas of focus: developing new projects and collaborations, strengthening ties to the health law practitioner community, and refreshing our digital presence. Additionally, we plan to continue our ongoing sponsored research projects and other collaborations, host a compelling slate of public events and conferences, offer a range of opportunities for students and visitors, and contribute to the HLS teaching program.

Research, Scholarship, and Project Activities

Sponsored Research

As described above, our sponsored research projects will be changing during FY19, with some kicking into high gear while others will sunset:

The Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL)

Our new Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL) with the University of Copenhagen's Research Program in Biomedical Innovation Law (CeBIL) will enter a new phase when our Research Fellow for Precision Medicine, **Sara Gerke**, officially joins the Center in August 2018. We anticipate an uptick in scholarship and events around precision medicine and artificial intelligence during this new phase of PMAIL.

A major focus of PMAIL is to generate a comparative analysis of intellectual property issues related to black-box personalized medicine, explaining the shortcomings of the current innovation policy landscape in Europe and the US, and provide a comprehensive examination of various policy options to better align incentives. Although the Center published some articles that relate to the work of PMAIL during FY18, we anticipate that the arrival of **Sara Gerke** will increase the productivity of the project. Already Center staff are scheduled to attend and present at an international symposium in September 2018 at Cambridge University on artificial intelligence. We are also exploring opportunities for collaboration and cross-pollination with a relevant team from Google, and are in discussions with members of the Berkman-Klein Center for Internet and Society and the Harvard Global Health Institute who work on artificial intelligence issues in health.



Harvard Catalyst

Our collaboration with Harvard Catalyst's Regulatory Foundations, Ethics, and Law Program continued until the end of the original Catalyst grant from NIH in April 2018. Because the priorities of Catalyst are changing with the start of their next grant, we are currently in discussions with Catalyst leadership as to the future of our collaboration with them.

Patient-Centered Outcomes Research Oversight Study (PCOROS)

Our work on the Patient-Centered Outcomes Research Oversight Study (PCOROS) will conclude at the end of August 2018. The last full year of the Project focused on conducting a Delphi process to generate recommendations for Institutional Review Board oversight of Patient-Centered research, completing a whitepaper and guidance document, and engaging with key stakeholders for adoption and implementation, culminating in a large public conference at Harvard Law School held in June 2018. The work in FY19 will consist of sunsetting the project, and will largely focus on completing and publishing any remaining articles relating to our work. For example, the results of the Delphi process we conducted will be published in the *Annals of Internal Medicine* during FY19.

Project Activities

Journal of Law and the Biosciences

In January 2018, the Petrie-Flom Center took over the managing editorship of the journal. For the next two years, Visiting Researcher **Jean-Christophe Bélisle Pilon** will assume the role of Managing Editor. J-C is co-founder of the Canadian Journal of Bioethics (previously known as *BioéthiqueOnline*). Over the next two years, we will focus on publishing issues of the journal dedicated to specific themes in law and biosciences in order to deeply explore topics that are particularly timely or important. We are anticipating receiving an impact factor score in FY19 for the journal, which will help us quantify its reach. We are also working to develop a closer relationship between the journal and our blog, Bill of Health, to help promote the articles published in the journal.

The Project on Law and Applied Neuroscience

Our collaboration with Massachusetts General Hospital's Center for Law, Brain and Behavior will continue for the sixth year of the Project on Law and Applied Neuroscience. Program activities will again include expert symposia and public events, as well as a Law and Neuroscience seminar taught by the **Hon. Nancy Gertner**.



2018–2019 Area of Inquiry: Dementia and the Law

Building on the successful conference “Our Aging Brains: Decision-Making, Fraud, and Undue Influence” in April 2018, in FY19 the Project on Law and Applied Neuroscience will continue to explore the intersection of dementia and law. Medical advances and demographic trends in the United States are producing previously unseen numbers of elderly citizens. Understanding the neurobiology of dementia has become increasingly relevant to policy, as this aging generation faces a variety of legal challenges. For instance, anticipating over 70 million Baby Boomers retiring, elder financial exploitation has been labeled the “Crime of the 21st Century.”

At present, the legal system relies upon an array of concepts – such as competency, testamentary capacity, and undue influence – that are difficult to define and understand. Applying these legal definitions (which often date back to the nineteenth century) is fraught with difficulty in large part because the descriptive standards are not well aligned with the behavioral and neurological measures that have been developed over the past decade. Interdisciplinary dialogue between law, neuroscience, psychology, psychiatry, neurology, neuropsychology, and related disciplines is needed to assess how these legal frameworks can be better informed by medical and neuroscience frameworks.

The Project will continue to assess the utility of law’s traditional approaches to capacity, competency, and undue influence in light of emerging science on the neurobiology of dementia; consider the future legal utility and ethics of new biomarkers for dementia; and develop new theoretical and practical frameworks for more fairly and effectively adjudicating cases in which dementia plays a role. **Francis Shen**, who will remain affiliated with CLBB as well as with the Petrie-Flom Center as a Visiting Scholar in FY19, and **Carmel Shachar**, will work to identify grant and funding opportunities for work on this topic. This work will include multiple CLBB faculty, including **Judge Nancy Gertner**, **Judith Edersheim** (both affiliated faculty of the Petrie-Flom Center), and **Bruce Price**.

One of our FY19 Student Fellows, James Toomey (HLS ‘19) will focus his research on the attitudes that senior citizens have in regard to the legal treatment of dementia and decision-making capacity. He will conduct interviews with Boston-area seniors on their perspectives around decision-making competency. This work will complement the work being done at CLBB and the Center.



The Project on Advanced Care and Health Policy

Mark Sterling, MPP, JD will continue as the Senior Fellow on this Project.

People with advanced illness often face fragmented care, treatments they do not want or need, and an overly burdensome and costly health care experience. The Center for Medicare & Medicaid Innovation (CMMI) and others have tested several successful new models of advanced illness management and care. Recently, HHS Secretary Alex Azar released a letter acknowledging the need for a payment demonstration for the serious illness population. The Secretary was responding to recent recommendations from the Physician-focused Payment Technical Advisory Committee (PTAC) regarding several payment model proposals submitted by stakeholder groups, including C-TAC, our collaboration partner on the Project on Advanced Care and Health Policy. Senior Fellow **Mark Sterling** served as a member of the planning committee for C-TAC's proposal. Secretary Azar indicated that C-TAC's model, along with a proposal by the American Academy of Hospice and Palliative Medicine's proposal, are of particular interest to him. On the PTAC process, Secretary Azar said "HHS is clearly benefitting from PTAC's comments and recommendations as we explore designing a future payment model for seriously ill beneficiaries." Following review of their proposals by PTAC, C-TAC and AAHPM are actively working together with the Centers for Medicare & Medicaid Services (CMS) to address HHS' comments on the proposals and develop one demonstration.

Preparing for the new serious illness payment environment, including related state and federal policy issues, is a likely area of focus for the Project during the coming year. The Project aims to produce materials helpful to key stakeholders looking to improve the regulatory landscape around care for serious and advanced illness. HLS students will likely be engaged to assist with background legal research and preliminary drafting. In addition, the Project is contemplating events on other topics related to advanced care. As before, these events are expected to lead to whitepapers and reports with recommendations for policymakers and other stakeholders. The Project is also exploring potential funding opportunities for an Advanced Care Policy Fellowship, to bring young thought leaders in this field to Harvard University during the academic year and C-TAC during the summers to further their development.

The Innovative Funding Models in Translational Research Project

The Center will host a one-day working group and conference exploring the challenges in pursuing for-profit private funding for early stage translational research, to be held on the Harvard Law School campus in October 2018. The purpose of this event is to bring together the leaders in the field to investigate the inherent challenges and safeguards necessary to accelerate the development and application of new health care technologies through intelligent and thoughtful private for-profit investment and support. The working group will consist of 25–30 individuals representing a variety of



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stakeholders, including leading research centers, hospitals, principal investigators, pharmaceutical companies, and other entities.

Translational research is vital, as targeted translational science can ensure that new treatments and research knowledge actually reach the patients or populations waiting for these breakthroughs. Nevertheless, in the age of frequent governmental budget crises and government spending cutbacks, relying on a government agency to promote such important developments may be problematic. An obvious solution to the funding gap that exists in current health care and biomedical research is the close investment and involvement of private, for-profit entities. The increased involvement of for-profit funding in early stage research is relatively new and therefore raises questions about the best practices for supporting research through these funding models. This event aims to explore the current funding landscape for translational research and develop a sense of whether best practices exist to address challenges or if additional research and work must be done to support innovative funding models for translational research.

The Project, led by Senior Fellow **Douglas Eby** and Executive Director **Carmel Shachar**, will produce a report evaluating the extent to which utilizing non-governmental sources of funding for translational research, especially in the early stages, raises legal and ethical questions distinct from government-funded clinical and translational research. This report is intended to be a road map for ethicists and other scholars working in this area.

Scholarship

Academic Fellows

For a variety of reasons, we have not accepted a new Academic Fellow to join the Center this year. Going forward, and discussed below, we are reconsidering our plans for the Academic Fellowship program and considering possible alternatives, including development of a policy or senior fellowship. Our goal is to reconfigure the Academic Fellowship program to broadly seed the fields of health law policy and bioethics, including placing future fellows at key non-profits and other thought leading institutions. We hope to relaunch the program when additional funding is secured in the near future.



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Faculty

In the summer of 2018, the Center will once again provide research support to **Prof. Cohen** and **Elhauge**.

I. Glenn Cohen will begin work on a new volume based on the Center's 2018 annual conference, "Beyond Disability: Disability, Law, and Bioethics." He will continue working on the new online course "OL: Introduction to American Law" that is set to launch August 1.

Professor Cohen will be working on a number of other projects, including:

- A book chapter on reproductive technology and the law for the OXFORD HANDBOOK OF U.S. HEALTH CARE LAW
- Publications and other grant related activities pertaining to the Patient-Centered Outcomes Research Oversight Study (PCOROS) project, which concludes at the end of August 2018
- Publications and other grant-related activities pertaining to the Petrie-Flom Center's new project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL)
- Work on a new casebook on COMPARATIVE HEALTH LAW AND BIOETHICS
- Completion of the Center's new edited volume on TRANSPARENCY IN HEALTH AND HEALTH CARE IN THE UNITED STATES (forthcoming 2019)

Einer Elhauge's summer funding is supporting the completion of the book project A LITTLE LOWER THAN GOD: REDESIGNING HUMANS – WHAT LIMITS?

Visitors

The Center continues to receive a number of high-quality applications from potential Visiting Scholars, both international and domestic. The following have been accepted as Visiting Scholars in the 2018–2019 academic year. While additional Visitors may be added throughout the year, the following are confirmed:

John Tingle

John Tingle will join the Center as a Visiting Scholar in November 2018. John is Associate Professor at the Nottingham Trent University Law School (UK), and a frequent contributor at the Petrie-Flom Center's blog, Bill of Health. The main focus of his current research is the exploration of the legal aspects of the British government's health quality policy initiatives, such as clinical risk management and clinical governance. He explores the consistency of policy development in these areas in comparison with similar policies in the United States.



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During his visit, John will present his work in progress at a session of Petrie-Flom Faculty Director **I. Glenn Cohen**'s Health Law, Policy, Bioethics, and Biotechnology Workshop.

Alessandra Colaianni

Alessandra Colaianni, a current resident at Mass Eye and Ear Infirmary, will join the Petrie-Flom Center as a Visiting Researcher in Spring 2019. Alessa is a graduate of Duke University, where she received degrees in biology and philosophy. She attended medical school at Johns Hopkins School of Medicine and concurrently completed an MPhil in History and Philosophy of Science at the University of Cambridge as a Gates Cambridge Scholar, where her work focused on historical and sociological factors contributing to the culture surrounding end-of-life care in the United States and the United Kingdom.

She has published several articles examining the influence of institutional culture on Do-Not-Resuscitate decision-making as well as moral distress regarding futile treatments at the end of life amongst medical trainees. Her research interests include medical/surgical ethics, the history and philosophy of science, and the concept of narrative medicine and how medical storytelling can be used to benefit physicians and patients.

Jennifer D. Oliva

Jennifer Oliva will join the Petrie-Flom Center as a Visiting Scholar in Spring 2019. Jennifer is an Associate Professor at West Virginia University in the College of Law and School of Public Health, where she teaches evidence and public health law courses and directs the WVU Veterans Advocacy Clinic, which represents West Virginia veterans in litigation before administrative agencies and courts, on benefits, discharge upgrades, employment claims and other civil and criminal matters. An honors graduate of Georgetown University Law Center, Jennifer was a Public Interest Law Scholar and served as Executive Notes & Comments Editor of The Georgetown Law Journal. Prior to attending Georgetown University Law Center, she earned a Master's in Business Administration at Balliol College, Oxford University. She was elected as a Rhodes and Truman Scholar while a cadet at the United States Military Academy at West Point.

Jennifer is a United States Army veteran and admitted to the bar in Delaware, California, the District of Columbia, and West Virginia. She also is admitted to numerous United States district and appellate courts, including the United States Court of Appeals for Veterans Claims and the United States Supreme Court. Her professional memberships include the American Bar Association (ABA), American Health Lawyers Association (AHLA), American Society of Law, Medicine & Ethics (ASLME), National Organization of Veterans Advocates (NOVA), and



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National Law School Veterans Clinic Consortium (NLSVCC). Her work has been published by or is forthcoming in the *Northwestern Law Review*, the *North Carolina Law Review*, the *George Mason Law Review*, the *West Virginia Law Review*, *The Conversation*, and the *Oxford Human Rights Hub*.

Jennifer will use her time at the Center to advance her health care law and policy research focusing on disability law and policy, access to treatment and services for individuals with substance abuse, behavioral, and mental health-related disorders, the intersection of public health policy and policing, and the costs, benefits, and trade-offs of federal and state health care-related legislation and regulation.

Jennifer S. Bard

Jennifer Bard likely will join the Petrie-Flom Center as a Visiting Scholar in Spring 2019. Jennifer is currently Professor of Law in the College of Law and Professor in the Department of Internal Medicine at the University of Cincinnati.

During her time at the Center, Jennifer plans to work with faculty affiliate Mark Barnes (Ropes & Gray LLP) to complete the first ever Nutshell in Human Subject Research, with a particular focus on issues involving vulnerable populations such as prisoners, asylum seekers, and those detained for violation of immigration laws. Jennifer's work will address the fact that the current review of the Common Rule for the protection of human subjects does not address the Appendixes to 45 CFR 46, which have been largely untouched since the 1990s and therefore do not reflect what we know today about issues such as genetic privacy, vulnerability, stigma, and intersectionality.

Book Projects

We continue to pursue edited volumes out of a variety of Petrie-Flom Center events and collaborations:

- We have submitted the manuscript **TRANSPARENCY IN HEALTH AND HEALTH CARE** (co-edited by I. Glenn Cohen, Holly Fernandez Lynch, Barbara J. Evans, and Carmel Shachar), which stems from our 2017 annual conference. The book will be published by Cambridge University Press in 2019.
- We are currently developing a proposal for an edited volume based on our 2018 annual conference, "Beyond Disadvantage: Disability, Law, and Bioethics," to be co-edited by conference organizers I. Glenn Cohen, Michael Stein, Anita Silvers, and Carmel Shachar.



Events Programming and Conferences

Over the 2018–2019 academic year the Center will continue to host and co-sponsor a variety of exciting public events dealing with issues at the intersection of health law policy, biotechnology, and bioethics. We have a significant number of additional events currently under development, particularly under the banners of the Project on Law and Applied Neuroscience and the Project on Advanced Care and Health Policy, and potentially in collaboration with a leading health care law firm. The following events are confirmed to date:

Major Events/Conferences

HGHI Global Outbreak Week

September 24–28, 2018

Sponsored by the Harvard Global Health Institute, with additional cosponsors to be confirmed.

The following events will take place at Harvard Law School:

Symposium: Media in the Age of Contagions

September 26, 2018

Symposium: Vaccines for Outbreaks in the Modern World

September 27, 2018

Full-day conference: Preventing Epidemics in a Connected World

September 28, 2018

Keynote Speaker: Anthony S. Fauci, Director, National Institute of Allergy and Infectious Diseases

Conference: Innovative Funding Models for Translational Research Roundtable October 1, 2018

Keynote Speaker: Robert Urban, Global Head, Johnson & Johnson Innovation

Conference: From Development to Delivery: Drug Pricing Policies in the United States and Globally

October 24, 2018

Cosponsored by Global Access in Action (GAIA), a project of the Berkman-Klein Center for Internet & Society at Harvard University

Seventh Annual Health Law Year in P/Review

December 7, 2018

HMS Center for Bioethics Annual Conference

April 2018



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2019 Petrie-Flom Center Annual Conference
May 17, 2018 (tentative)

Lectures, Panels, and Other Events

2018 Petrie-Flom Center Open House
September 12, 2018

Book Launch: Big Data, Health Law, and Bioethics
September 12, 2018

Sponsored by the Harvard Law School Library, the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, and the Berkman-Klein Center for Internet & Society at Harvard University.

Special Evening with John Carreyrou, Author of *Bad Blood: Secrets and Lies in a Silicon Valley Startup*
October 2, 2018

Digital Health @ Harvard Series: Medicaid Work Requirements: Limitations in Digitally Identifying Individuals for Exemption Due to Disability
A talk by **Rachel Gershon (HLS/HSPH '10), Commonwealth Medicine**
October 16, 2018

Sponsored by the Berkman-Klein Center for Internet and Society at Harvard University and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

Digital Health @ Harvard Series: Simulation and Deliberation to Prepare for Clinical Trials in Infectious Disease Emergencies
A talk by **Marc Lipsitch, Harvard School of Public Health**
October 24, 2018

Sponsored by the Berkman-Klein Center for Internet and Society at Harvard University and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

Health Policy and Bioethics Consortia
Monthly, September 2017–April 2018

Organized by the Program On Regulation, Therapeutics, And Law (PORTAL) in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital and hosted by the Center for Bioethics at Harvard Medical School, in collaboration with the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and the Harvard Program in Therapeutic Science.



Contributions to HLS Teaching Program

Petrie-Flom affiliates will continue to make substantial contributions to the HLS health law curriculum this year, through workshops and seminars, as well as **I. Glenn Cohen's** award-nominated Massive Open Online Course (MOOC), first launched in fall 2016, available to the public via HarvardX. They will also lecture on an ad hoc basis around the university, for example as part of Harvard Catalyst. **I. Glenn Cohen** also delivers an annual lecture for the Health Policy PhD program in FAS.

Health Law, Policy, Bioethics, and Biotechnology Workshop

I. Glenn Cohen

Fall 2018

This seminar will feature the presentation and discussion of cutting edge scholarship on health law, health policy, biotechnology, and bioethics. Because the papers are different every term, students can take the class as many times as they wish. Presenters will come from a wide range of disciplines and departments, and papers may feature doctrinal, economics, philosophical, political science, or other methods, but students need not have prior training in these disciplines.

The 2018–2019 workshop will host the following scholars:

- **Zack Buck**, Assistant Professor of Law and Wilkinson Junior Research Professor, University of Tennessee at Knoxville College of Law
- **Timothy Caulfield**, Canada Research Chair in Health Law and Policy, Professor in the Faculty of Law and the School of Public Health, and Research Director of the Health Law Institute, University of Alberta (Canada)
- **Christina S. Ho**, Professor of Law, Rutgers Law School
- **James Hodge**, Professor of Law, Sandra Day O'Connor College of Law, Arizona State University
- **Craig Konnoth**, Associate Professor of Law, Colorado Law
- **Matthew J. B. Lawrence**, Assistant Professor of Law, Penn State Dickinson Law
- **S. Matthew Liao**, Director of Center for Bioethics and Arthur Zitrin Professor of Bioethics, NYU College of Global Public Health
- **Anya Prince**, Associate Professor of Law at the University of Iowa College of Law and Member of the University of Iowa Genetics Cluster
- **Natalie Ram**, Assistant Professor of Law at the University of Baltimore School of Law and Associate Director of the University of Baltimore's Center for Medicine and Law



- **Ameet Sarpatwari**, Instructor in Medicine, Harvard Medical School; Associate Epidemiologist, Brigham and Women's Hospital; and Assistant Director, Program On Regulation, Therapeutics, And Law (PORTAL), Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital
- **John Tingle**, Associate Professor, Nottingham Law School, Nottingham Trent University (UK)
- **Kristen Underhill**, Associate Professor of Law, Columbia Law School

Health Care Rights in the 21st Century
Carmel Shachar (co-taught with Kevin Costello)
Fall 2018

Health care has become a dominant political issue in contemporary America – to the point of swaying national elections and consuming congressional calendars. Underlying this political debate is the fundamental question whether Americans enjoy a basic entitlement to health care. This course will briefly trace the history of the American conception of health care rights through the last half-century of administrative and political cycles. We will contrast a diverse array of ideological perspectives over this progression to understand the context of the current climate.

Building on this background, we will consider a broad range of rights-affording sources across the landscape of the modern American health care system: Federal civil rights statutes; the laws and agreements that govern public and private health insurance arrangements; data privacy and ownership rights; and other state and federal statutes that govern health care consumers, insurers, institutions and spending. We will also consider negative rights in the context of the now defunct individual mandate of the Affordable Care Act and relevant Religious Freedom Restoration Act developments. We will place congressional and common law health care rights provisions in the broader context of civil rights jurisprudence, including anti-discrimination regimes. Applying a lens of civil rights and enforcement to these sources of law, we will consider differing avenues available to achieve enforcement of health care rights, including through administrative and policy-based advocacy, as well as more formalized litigation.

The seminar is designed to be limited lecture, incorporating debates, role-plays, and other interactive sessions. Class participation is expected. The seminar will culminate in a student project arising from the course materials. Students will have the option of further honing their health care rights skills by participating in the Health Law and Policy Clinic in conjunction with this seminar.

The seminar will appeal to law students interested in working across the spectrum of the health care field generally, to those interested in the intersection between law and health care, and to those who aspire to be civil rights lawyers.



Law and Neuroscience

Nancy Gertner

Spring 2019

This seminar examines cutting edge and even controversial linkages between law and neuroscience. We seek to highlight neuroscientific basis for behavior patterns with legal implication including how neuroscience intersects with criminal law, its normative assumptions and criminal punishment, evidentiary rules, memory bias and enhancement, lie and deception detection, adolescent brains and juvenile law. We will look critically at efforts to use neuroimaging in court in connection with in the prediction of criminality and predispositions towards mental illness and addiction, as well as efforts to identify neurobiological influences on the brain. Is there such a thing as a criminally violent brain? Does it make sense to speak of the neurobiology of violence or the psychopathology of crime, and how are (or should) such concepts translated into criminal law. The seminar will necessarily lead us to consider the relationship between law and science, more generally, and neuroscience in particular. Speakers will provide insights into their work and research.

Bioethics: The Law, Medicine, and Ethics of Reproductive Technologies and Genetics

I. Glenn Cohen (HarvardX)

Most recent session launched on June 1, 2018. Slated to relaunch a new session in late fall (exact date TBD).

Bioethics provides an overview of the legal, medical, and ethical questions around reproduction and human genetics and how to apply legal reasoning to these questions. This course includes interviews with individuals who have used surrogacy and sperm donation, with medical professionals who are experts in current reproductive technologies like In Vitro Fertilization and Preimplantation Genetic Diagnosis, and bioethicists and journalists who study the ownership and use of genetic information within human tissue. Additional Harvard colleagues will also share their thoughts on topics such as disability law as it relates to reproductive technology.

While the law and ethics surrounding these technologies are a central component to this course, it will also provide examples of the deeply personal and human side of these issues. Throughout the course, students will discuss leading legal cases in this field, which will illuminate the types of questions the law has struggled with – stretching and evolving over time. From the famous Baby M surrogacy case, to cases on the paternity of sperm donors, to a case related to the ownership of human tissue turned into a commercial product, and others. The course will explore the ethical, legal, and rhetorical underpinnings that have served as the basis for various court decisions over the past 20-30 years. It will also explore potential future technologies and their implications for society: genetic enhancements to increase our intelligence, let us live



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a hundred years longer, or make us immune to diseases – and the possibility of creating animal-human hybrids, for example a mouse with a humanized brain.

The content within this course is intended to be instructive, and show how legal reasoning has been applied, or could be applied, to questions related to parenthood, reproduction, and other issues surrounding human genetic material. The material organized within this course should be considered an authoritative overview, but is not intended to serve as medical or legal advice.

This course is designed for a diverse audience including, but not limited to, law students, prospective law students, medical professionals, as well as members of the general public interested in questions and topics related to surrogacy, parenthood, genetic and reproductive technology, ownership of genetic material, and more.

Bioethics and Health Law: Selected Topics

I. Glenn Cohen

Winter 2019

This class covers selected topics in health care law, public health law, and (especially) bioethics. Among the topics that may be covered are: informed consent, medical confidentiality (including issues pertaining to medical big data), the duty to treat, conscientious objection in health care, ownership and patenting of human tissue, organ donation and allocation, abortion, reproductive technologies, end of life decision-making, the definition of death, and mandatory testing for diseases.



Participation of HLS Students in Program Activities

We will continue to engage students in a variety of ways, through our event programming, courses, and other mechanisms. We will also continue to offer opportunities for selected students to work directly with the Petrie-Flom Center as Student Fellows, research assistants, and bloggers.

Student Fellowship Program

As we do each Fall, we will welcome a new crop of Harvard graduate Student Fellows this year who will pursue independent research under the supervision of Center faculty and fellows, regularly contribute to our blog, and enroll in the Health Law Policy, Bioethics, and Biotechnology Workshop. For the upcoming year we allowed Harvard Law School students to apply before other Harvard graduate students. As a result, we already have three Harvard Law Students selected as Fellows for FY19, with several more interested in applying during the general round of applications. The remaining Student Fellows will be selected in mid-August.

Every year we require our Student Fellows to contribute to our blog, Bill of Health, but in the coming year we will significantly strengthen our digital media training for the Student Fellows. Communications Manager Alex Pearlman will support the Center's Student Fellows with more digital training, drawing upon her background and expertise. This additional training is in response to interest from previous Student Fellows as well as an acknowledgement that social media and non-traditional internet media outlets are becoming increasingly important in building a thought leader's reputation.

Research Assistants

We will continue to work with graduate student research assistants on our sponsored research projects, book projects, and other initiatives as needed.

Student Bloggers

Bill of Health is home to a number of graduate student bloggers. In addition to our Student Fellows, who each year are required to blog regularly throughout their fellowship, we have invited graduate students at HLS and around Harvard to apply to be Student Contributors on the blog.

Since Alex Pearlman's appointment as Editor in chief of Bill of Health, student bloggers have already benefited from her expertise through mentorship and editing help. Alex also hosted a digital media training seminar organized to teach students and interns about



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improving their digital voices and teaching them how to disseminate their work online. The training was open for students and interns from the wider HLS student community, including at CHLPI and the Berkman Klein Center.

Student Interns

We plan to continue to work with a small number of paid interns, including Harvard students and high school students in the Cambridge Housing Authority's WorkForce program, who will contribute to a variety of Center projects (see Student Interns section above for details).



New Initiatives and Collaborations

The Petrie-Flom Center anticipates that Fiscal Year 2019, along with the next several years, will be an exciting time in our history. With one of our sponsored projects ending at the start of FY19, we are excited to seek out new areas of focus. We will continue to think creatively about our project portfolio, our role within the Harvard community, collaborations with within and outside of Harvard, our institutional structure, and our outward facing communications and media. We look forward to fully diving into our work on artificial intelligence in the context of health care, an important topic that has already garnered significant attention, with our recently launched Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL). Our hope is to also pursue research in new areas of work, such as value-based care, the ethics of sexual consent capacity for individuals with intellectual disabilities, and the intersection of substance use and immigration. In addition to our research projects, we are focused on building the Center's connections and reputations among health law practitioners and health care entities. To help us do so, we will continue to seek out events that are targeted to lawyers in this field and to launch our Health care General Counsels Roundtable. Another major focus of FY19 will be to strengthen our online presence through the relaunch and refresh of our blog, *Bill of Health*. Of course, these plans are contingent upon finding appropriate sources of funding.

Expanding our Signature Projects

The Petrie-Flom Center recognizes that American health law policy is in a period of tremendous flux. Additionally, the pace of scientific development, especially in the field of genetics and data science, continues at a breakneck pace, leaving significant ethical and regulatory questions in its wake. As such, our goal is for the Center to establish several new projects that will be funded, staffed, organized, and interacting substantively with policymakers at all levels, providing independent expert analysis, policy recommendations, empirical research, and practical solutions to pressing issues. If funded, these projects would pair an expert staff with faculty, students, and other collaborators at Harvard and beyond to generate policy briefs, white papers, model legislation, public commentary, and real-time responses to emerging issues and opportunities. In so doing, we will continue our central commitment to unbiased, non-partisan, expert analysis.

The Center is in the very preliminary stages of exploring several potential projects. All of these projects are contingent upon securing appropriate funding. These possible projects include:

Digital Health Project

This Project, a collaboration with the Berkman-Klein Center for Internet and Society, will seek to better understand the use of big data in health care as well as articulate legal and regulatory responses to the challenges these new technologies pose. The Project will focus on four core areas of interest to better understand the interaction



between big data and the health care system, as well as generate best practices and recommendations for laws and regulations that will promote innovative use of health care big data while preserving the rights of patients. These four core areas will be:

1. analytics in medical decision making;
2. the internet of things and medical decision making;
3. pandemics and big data; and
4. technology to combat counterfeit drugs.

The Berkman-Klein Center is currently working to identify potential funders for this Project.

Opioid Epidemic

We are exploring ways in which the Center might examine the impact of the opioid epidemic on American health care. One potential initiative, in collaboration with Center for Bioethics at Harvard Medical School Fellow Stephen Wood, would examine access to care for undocumented patients living with substance use disorder. If funded, the project will seek to understand the challenges that medical providers face connecting these patients to care. Informed by this work, the project will articulate best practices for getting these patients into care and identify opportunities for improving the delivery of care and connections between medical, legal, and social services providers.

Value-based Health Care

Building on our successful conference on this subject in Spring 2018, we are exploring a collaboration with the Institute for Strategy & Competitiveness at Harvard Business School to explore the regulation of value-based health care. Value-based payment structures are widely touted as critical to controlling runaway health care costs, but are often difficult for health care entities to incorporate into their existing infrastructures, especially due to strict fraud and abuse regulations. Because value-based health care initiatives have bipartisan support, it is likely that these programs will continue to play a major role in both the public and private health insurance systems. As such, there is a pressing need to evaluate the implementation of these initiatives thus far and to discuss the direction that American health care financing will take in the coming years.

These projects are in the exploratory phase and we are actively seeking funding to expand our capacity to undertake these projects and other, similar ones in the health law policy and bioethics space.



Expanding Our Structure

As the Petrie-Flom Center enters its newest chapter, we are also considering how to modify our structures to maximize the reach and impact of the Center. In order to better support the Center, we are launching a Health Care General Counsel Roundtable, evaluating the potential of an Advisory Board to help shepherd the Center, and modifying the Academic Fellowship to have a broader focus to expand the reach of the Center.

Health Care General Counsel Roundtable

In FY19 we plan to launch our Health Care General Counsel Roundtable. The purpose of the Health Care General Counsel Roundtable is to gather lawyers who represent leading health care entities in a small peer group to facilitate discussions around the challenges facing health care in-house counsels today. The Roundtable will explore the unique position of in-house counsel in guiding health care entities in today's regulatory environment. It will leverage the convening power of the Petrie-Flom Center and Harvard Law School to create a forum for informed, thoughtful, and useful discussions among a select group of general counsels, as supported by expert presentations. The Roundtable will consist of ten to fifteen general counsels of companies from across the spectrum of health care entities. Members of the Roundtable will represent providers, pharmaceutical companies, device manufacturers, insurers, and digital health companies. The Roundtable will be carefully constructed to maximize diversity of perspectives and health care stakeholder representation. We already have interest from the General Counsels of Memorial Sloan Kettering Cancer Center, the Mayo Clinic, and Children's Hospital Philadelphia, among others. Our hope is to use the Roundtable to strengthen the Center's connections to leaders in the health law field. This will allow us to improve our programming, get a sense of what issues are important for health law practitioners, facilitate access to key leaders for students, and improve the Center's reputation outside of academia.

Advisory Board

We are continuing to explore whether to expand the Petrie-Flom Center's structure to include a formal Advisory Board. The purpose of this Board would be to secure the financial future of the Center and involve a wider range of stakeholders in the workings of the Center, including industry leaders from the health care and life sciences fields, community advocates, and experts in health law policy and bioethics within and outside Harvard University. Our goal for the Advisory Board would be to create a group that will provide input to the Center's leadership as we decide our next steps and to increase the financial and intellectual resources and network of the Center. We are in discussion with peer centers and programs that have advisory boards in order to better understand the implications of adopting this structure.



Academic Fellowship

We are also interested in reinvigorating the Academic Fellowship program to include fellows who are interested in a career trajectory outside of academia. As discussed above, the Academic Fellowship is currently on hiatus for a variety of reasons. Increasingly, non-profit advocacy organizations are providing thought leadership on health law policy issues, including health care reform. Our goal for the remodeled fellowship would be provide career development for individuals early to mid-career in health law policy, including people with a background in government and advocacy work. The Academic and Policy Fellowship would allow these individuals to leverage the incredible health law policy resources of Harvard to contribute and advance key health policy debates while providing the Center with additional capacity to take on health law policy projects. This fellowship program would also build the relationship of the Center with health law and policy organizations outside of academia. Revitalization of this program is dependent on securing additional funding, however.

Expanding Communications and Digital Offerings

The Center will also focus on refreshing and expanding its communication efforts and digital offerings during FY19. Spearheading this initiative will be our Communications Manager and Research Associate, Alex Pearlman, who joined the Center in May 2018. In her new role at the Petrie-Flom Center, Alex will use her dual communications and bioethics expertise to support the Center's mission to promote interdisciplinary scholarship and to grow the reach of the Center's work through strategic digital growth and public outreach. Our hope is to further raise the Center's profile and reach a broader audience through this work.

As a digital product leader, Alex has previously held management roles at The Boston Globe and the GroundTruth Project, a non-profit operating in partnership with WGBH. She has also had a successful freelance career covering human rights and social justice, with a specific focus on ethical issues in emerging science and technology. Most recently Alex has devoted her reporting to the rise of biohacking and DIY science.

Our blog, Bill of Health, was launched in 2012 and has proven to be a successful venue for hosting news, commentary, and scholarship in the fields of health law policy, biotechnology, and bioethics. Since its launch, 90 contributors from 49 different institutions across the globe have contributed to build this platform. Over 970,000 unique users have visited the blog, which generates over 17,000 pageviews per month. During FY19 we will build upon the initial success of Bill of Health to further expand the Center's digital presence. In September 2018 we will launch a refresh of the blog, with a new layout and re-engaged authorship. This update will bring the blog in line with current industry standards by providing social media share tools, featured images, and suggested content features. Alex will be responsible for seeking out content for Bill of Health from thought leaders and scholars around the globe.



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We will also focus on further placing our scholarship and projects in digital media properties to improve our outreach to non-academic venues. Alex has already begun work on this initiative. Specifically, Alex has worked with the Center's leadership to amplify the reach of **I. Glenn Cohen**'s scholarship and some of the Center's major initiatives through press releases and public relations work, getting our large reports into the hands of reporters. In addition, she has placed writing by Executive Director **Carmel Shachar** at Cognoscenti, a popular op-ed and commentary destination managed by WBUR. Alex has will continue to develop other publishing relationships, raising the profile of our work by curating research and analysis from our affiliate scholars and helping them craft their commentary into op-eds meant for a broad audience.