



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

*Annual Report, Fiscal Year 2017
July 2016–June 2017*

Executive Summary

Summer 2017 marked the start of an exciting new era at the Petrie-Flom Center, as we welcomed **Carmel Shachar** to our Leadership team. Carmel joined the Center in June as our new Executive Director, succeeding **Holly Fernandez Lynch**, who served in the role since 2012. Holly, a member of the Center’s inaugural cohort of Academic Fellows in 2006, will join the Department of Medical Ethics and Health Policy at the University of Pennsylvania’s Perelman School of Medicine as Assistant Professor in Fall 2017. Carmel earned both her J.D. and M.P.H. from Harvard, was a Petrie-Flom Center student fellow in 2008–2009, and joins us from the law school’s Center for Health Law Policy and Innovation. With expertise in health policy, and in particular the regulation of access to care for vulnerable individuals, health care anti-discrimination law and policy, and the use of all-payer claims databases in health care research, Carmel is well-poised to guide the Center through a new bout of national health reform. Carmel will join Faculty Director Professor **I. Glenn Cohen** to continue our many ongoing initiatives and launch new projects at the intersection of health law policy, biotechnology, and bioethics.

We are also thrilled to announce that we successfully wrapped our work on the **Law and Ethics Initiative** of the Football Players Health Study this academic year, publishing a 493-page comprehensive **analysis** of the legal and ethical responsibilities of various stakeholders capable of protecting and promoting player health and well-being. The report includes 76 recommendations for improvement and was accompanied by a conversation with relevant stakeholders in the **Hastings Center Report** regarding our primary recommendation to address the conflicts of interest inherent in the current structure of player medical care. In addition, we published a **comparative analysis** of the major professional sports leagues to assess what lessons



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could be imported to the NFL to improve player health, as well as an [article](#) in the University of Pennsylvania Law Review analyzing the potential for various health and performance-related tests of NFL players to violate the protections offered by disability law, privacy law, and law governing genetic testing. Additional publications from the project are forthcoming. The work has garnered national media attention from the Boston Globe, STAT News, the Washington Post, and other outlets. We are very proud of this unique project, and hope that our work will bring attention to the structural factors that influence player health.

Our other sponsored research projects also enjoyed a productive year. We continued to make progress on ways to improve recruitment to clinical trials, in collaboration with the [Regulatory Foundations, Ethics, and Law Program](#) of Harvard Catalyst, generating [guidance](#) and an academic [article](#) on the use of social media for recruitment, hosting a symposium on the ethics of payment to research participants, and evaluating ways to [prioritize trials](#) that might compete with one another for the same group of eligible patients. And our work on the [Patient-Centered Outcomes Research Oversight Study](#) completed its phase of qualitative interviews with thought leaders in the field, and launched its survey of Institutional Review Board chairs to better understand the key issues in the ethical review and oversight of research that engages patients in non-traditional roles.

Next year, pending final approval between the relevant entities, we are looking forward to launching a new collaborative project spearheaded by one of our former Visiting Scholars, [Timo Minssen](#) from the University of Copenhagen Faculty of Law. The project is called [CeBIL, the Collaborative Research Program in Biomedical Innovation Law](#), and it aims to contribute to the translation of groundbreaking biomedical research into safe, effective, affordable and accessible therapies by analyzing the most significant legal challenges to pharmaceutical innovation and public health from a holistic cross-disciplinary perspective. Funded by the Novo Nordisk Foundation, CeBIL will propose new frameworks for drug development incentives and regulations that take into account patient-needs, access aspects, market complexities, and economic sustainability. Petrie-Flom will serve as a key partner in the collaboration, leading 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. Former Petrie-Flom Center Academic Fellows [Jeffrey Skopek](#) and [Nicholson Price](#) will also collaborate on the project at their new respective home institutions, University of Cambridge (UK) and University of Michigan, as will Petrie-Flom Center faculty affiliate [Aaron Kesselheim](#) of Harvard Medical School.

Our [Project on Law and Applied Neuroscience](#) is going strong, wrapping up its third year with a workshop co-sponsored by the Federal Judicial Center on “Tailoring Justice: Science-Informed Decision Making,” designed to help federal criminal justice



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practitioners develop improved collaborative responses to individuals with mental health and substance use disorders. In Fall 2017, we look forward to welcoming our new Senior Fellow on the Project, Francis X. Shen who will visit us from the University of Minnesota Law School for the year.

The first year of our Project on Advanced Care and Health Policy has also helped facilitate the Center's relationship with health policymakers, health care providers, and legal practitioners through a host of public events and workshops focused on mechanisms to improve care for serious illness. Senior Fellow Mark Sterling will continue in his inaugural role for another year, as we work to develop publications and additional projects out of the collaboration.

As always, we have kept our community busy with a slate of fascinating public events this year, covering the ethical involvement of patients in FDA review of new drugs, concerns surrounding concurrent surgeries, juvenile sentencing and neuroscience, health policy and the presidential election, approaches to biosimilar regulation, opiate regulation, crowdfunding medical care, gun control and responses to community violence. We were lucky enough to host William B. Schultz, former general counsel of the U.S. Department of Health and Human Services (2011-2016), for a candid lecture, and we also hosted our first ever webinar, on President Trump's health policy agenda. We collaborated with the Harvard Medical School Center for Bioethics on a number of conferences and events, including the year-long health policy and bioethics consortium and a symposium on the ethics of early embryo research. We also collaborated with our friends at the Berkman-Klein Center to launch the Digital Health @Harvard brownbag lunch series, bringing together interested individuals from all pockets of the university doing related work in this space. We hosted our 5th Annual Health Law Year in P/Review, along with another successful online symposium at the Health Affairs blog, and this year's annual conference focused on transparency in health and health care.

We have, of course, been active in the scholarship department, publishing an array of articles in legal, medical, and bioethics journals, in addition to several edited volumes. This year, we released *Nudging Health: Health Law and Behavioral Economics* (Johns Hopkins University Press), and put the finishing touches on two volumes that will be released this year: *Law, Religion, and Health in the United States* (Cambridge University Press, July 2017), and *Specimen Science: Ethics and Policy Implications* (MIT Press, October 2017). We have also just submitted the final manuscript for *Big Data, Health Law and Bioethics*, stemming from our 2016 annual conference, which should be released in early 2018.

Our fabulous student fellows joined the Center from across campus and pursued projects related to organ donation policy, intellectual property, health solidarity, and the neuroscience of eye witness testimony, while our student contributions to the Journal of Law and Biosciences covered gender in professional sports, amnesia and



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criminal responsibility, drug prices, and lab-developed genetic tests. Our Bill of Health [blog](#) is now firmly established as a leading source of intellectual and policy insight in the realm of health care and bioethics, with 15,000 unique users each month. The blog even earned a “shout out” from Steve Usdin, Washington Editor of BioCentury, as “very influential.” Bill of Health continues to host insightful analysis from contributors at Harvard and beyond, as well as online symposia on a range of cutting edge topics, including emerging infectious disease, citizen science, and employment discrimination based on health status. And our online presence is broader than ever, with more people around the world engaging with us and our content through social media than ever before.

We are excited to embark on this next chapter in Petrie-Flom history. The Center is well positioned to emerge as a thought leader in health law policy during this new turbulent phase in American health care politics. In addition to maintaining its strengths in clinical research ethics and other longstanding areas of core competency, the Center will use its bioethical expertise in projects designed to further a better understanding of ethical health care access. We are also planning to thoughtfully expand the Center’s capacity through several new initiatives. One of these will be to begin creating an advisory board, to better expand the resources that the Center can bring to the projects it explores. Another of these new initiatives will be to consider relaunching the academic fellowship as an incubator program for the next generation of health care policy leaders. We are eager to see the Center continue to grow over the next few years as it rounds out its health law policy projects in addition to its bioethics portfolio and continues to thoughtfully add to its family through bold new initiatives.

With sincere thanks to everyone who supports our work,

I. Glenn Cohen

Handwritten signature of I. Glenn Cohen in black ink.

Faculty Director &
Professor of Law, HLS

Holly Fernandez Lynch

Handwritten signature of Holly Fernandez Lynch in black ink.

Outgoing Executive
Director, 2012–2017

Carmel Shachar

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Incoming Executive
Director, 2017–



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2016–17 Report of Activities

(Fiscal Year 2017: July 2016–June 2017)

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 events and conferences; extensive media commentary; our popular health policy and bioethics blog, Bill of Health, boasting nearly 12,000 unique monthly users; and our website filled with guides and other resources for the public.
- (2) ***Academic programs***, including programs for visitors and senior scholars; a range of curricular contributions and workshops; 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 human subjects research regulation and ethics, the health of professional football players, patient-centered outcomes research, and more, alongside additional collaborations covering law and neuroscience, food law policy, 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, 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 FY17, the Center was led by Faculty Director Professor **I. Glenn Cohen** and Executive Director **Holly Fernandez Lynch**, with **Carmel Shachar** joining as incoming Executive Director in June 2017. Holly will join the Department of Medical Ethics and Health Policy at the University of Pennsylvania's Perelman School of Medicine as Assistant Professor this fall.

Carmel joins Petrie-Flom from the Center for Health Law and Policy Innovation at Harvard Law School (CHLPI), where she was a Clinical Instructor on Law and helped lead CHLPI's access to care and Affordable Care Act implementation work. During her time at CHLPI, Carmel focused on analyzing and translating health policy issues and opportunities for a broad range of audiences, including many federal and state-level health policy coalitions. She also coordinated and led a major multi-state initiative to document discriminatory benefit designs on the health insurance Marketplaces. Carmel previously practiced health care law at Ropes & Gray, LLP in Boston, Massachusetts. She currently serves on the board of Fishing Partnership Support Services as well as on the Institutional Animal Care and Use Committee of Boston University.

Carmel's scholarship focuses on law and health policy, in particular the regulation of access to care for vulnerable individuals, health care anti-discrimination law and policy, and the use of all-payer claims databases in health care research. She is currently a Lecturer on Law at HLS, and co-teaches a course on "Health Care Rights in the Twenty-First Century." Carmel graduated *cum laude* from HLS, where she was a student fellow at the Petrie-Flom Center, and the Harvard T. H. Chan School of Public Health.



Research, Project Activities, and Scholarship

The Petrie-Flom Center has developed a strong reputation for the production of 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, completing the Law and Ethics Initiative of the Football Players Health Study, and also took steps in some new directions. These accomplishments are described in more detail below.

Sponsored Research

The Center was engaged in three sponsored research projects in FY17, one of which closed in May 2017 though we expect to continue working on related publications in the coming year. We also continued preparation of an edited volume based on the proceedings of a project funded in FY16. We also continue to seek additional funding opportunities, and submitted three new funding applications in FY17, one of which will be funded starting in FY18.

The Football Players Health Study at Harvard University Law and Ethics Initiative

Drawing on expertise from across Harvard University's schools and its affiliated academic healthcare centers, the goal of the Football Players Health Study (FPHS) at Harvard University is to understand the causes of the physical and mental health conditions afflicting former NFL players, with the goal of improving their health and wellbeing, while furthering our understanding of the benefits—and risks—of participating in football.

FPHS is funded through an award from the National Football League Players Association (NFLPA), and largely utilizes funds allocated for research by the Collective Bargaining Agreement between the NFLPA and the NFL. Importantly, FPHS is an independent research study. The research is not directed by the NFL, NFLPA, or any other external stakeholder, nor do any of these organizations exercise control over the research direction, findings, or recommendations.

FPHS is comprised of both clinical research studies and a Law and Ethics Initiative led by the Petrie-Flom Center. The Law and Ethics Initiative began in February 2014 and we completed our funded term in May 2017, although a few publications remain outstanding.



The Law and Ethics Initiative

Glenn Cohen and **Holly Fernandez Lynch** co-led the FPHS Law and Ethics Initiative, and advised on legal and ethical issues that arose in other components of the Football Players Health Study, such as participant confidentiality, results return, and the like. **Christopher Deubert** was the Senior Law and Ethics Associate on this project, which was supported by **Justin Leahey**, Project Coordinator. The work was also guided by the **FPHS Leadership Team** and an independent panel of experts who comprised the **Law and Ethics Advisory Panel (LEAP)**.

Key projects are described below. Our work received substantial media attention, including coverage by the Boston Globe, STAT News, the Washington Post, USA Today, ESPN, and a variety of other media outlets, podcasts, and blogs.

To learn more about the Law and Ethics Initiative, please visit the [website](#).

Completed Projects

**Protecting and Promoting the Health of NFL Players:
Legal and Ethical Analysis and Recommendations**

This initiative identified stakeholders in player health, analyzed their legal and ethical obligations, evaluated current successes, and identified gaps and opportunities for each stakeholder in protecting and promoting player health. Finally, it applied a series of legal and ethical principles to arrive at recommendations for positive change where needed. The stakeholders discussed are: NFL players; the NFL; NFL clubs and personnel; NFL coaches; NFL club medical staff; second opinion, neutral, and personal doctors; the NFLPA; contract advisors; financial advisors; equipment managers and manufacturers; players' family members; officials; the media; NFL business partners; and fans. Our [report](#) containing 76 recommendations aimed at improving player health was released in November 2016.

**The Hastings Center Special Report:
A Proposal to Address NFL Club Doctors' Conflicts of Interest and to Promote
Player Trust**

In this Special Report, we urged the NFL, NFLPA, and other stakeholders to adopt our proposed solution for resolving conflicts of interest inherent in the current structure of NFL player healthcare, in which club medical staff provide services to both the club and players. Read the lead article [here](#).



The Special Report also includes invited commentaries from a diverse and highly qualified group of experts, including lawyers, bioethicists, a former player, a former player who is now a doctor, a current player who is also a medical student, an NFLPA consultant, and the NFL Physicians Society, the organization that represents NFL club doctors. The commentaries, and our response, are available [here](#).

**Evaluating NFL Player Health and Performance:
Legal and Ethical Issues**

Conducted in collaboration with our colleague [Jessica L. Roberts](#) (University of Houston Law Center), expert in disability and health discrimination law, this article investigated the path of a hypothetical college football player with aspirations to play in the NFL, addressing from legal and ethical perspectives the types of health and performance evaluations he would likely be subjected to throughout his career. Some of these evaluations are commonplace and familiar, while others are more futuristic – and potentially of unproven value. How much information about themselves should aspiring and current professional players be expected to provide in the context of employment? What are the current legal standards for employers as they collect, and act on, an individual’s health-related information? Drawing on disability law, privacy law, and the laws regarding genetic testing, this article analyzes these questions, and provides recommendations to better protect the health and privacy of professional football players. The [article](#) was published in the *University of Pennsylvania Law Review* in January 2017.

Comparing Health-Related Policies and Practices: The NFL and Other Professional Sports Leagues

This project examined the policies and practices of the NFL that concern player health, comparing them to those of other major professional sports leagues and organizations: Major League Baseball, the National Basketball Association, the National Hockey League, the Canadian Football League, and Major League Soccer. After analyzing the leagues, the report compares each one to the NFL on the following health-related issues: (1) Club Medical Personnel (including discussion of conflicts of interest); (2) Injury Rates and Policies (including detailed comparisons of concussion rates); (3) Health-Related Benefits (including health insurance and retirement benefits for current and former players); (4) Drug and Performance-Enhancing Substance Policies; (5) Compensation (including guaranteed compensation); and (6) Eligibility Rules (including discussion of the “readiness” of athletes for professional play). Ultimately the [report](#) included [nine recommendations](#) for better protecting and promoting NFL player health, and was released in May 2017.



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Ongoing Projects

Although the Law and Ethics Initiative has officially come to a close, we are continuing work to finalize several additional projects undertaken during the course of the Initiative.

Qualitative Study/Listening Tour

In collaboration with our colleague Sarah McGraw (The Hastings Center), this study consisted of a series of one-on-one interviews that solicited direct feedback from approximately 25 NFL players and 25 family members of NFL players on issues related to player health and well-being. One article stemming from the interviews and focused on NFL player mental health is currently under peer review, with additional articles forthcoming on challenges related to transitioning out of the NFL, NFL player healthcare, and potential issues related to risk taking and understanding among NFL players.

Events

In the past year, we have participated in the following public events concerning our work as part of the Football Players Health Study:

The NFL as a Workplace: Uncertainties and Opportunities in Assessing and Managing the Health and Safety Risks of Playing Professional Football

December 12, 2016

Panel session at the Society for Risk Analysis Annual Meeting in San Diego, CA

Legal and Ethical Issues Affecting NFL Player Health

March 7, 2017

Panel session at CSEL Sports Symposium, Harvard Law School. Sponsored by the Committee on Sports and Entertainment Law

Legal and Ethical Issues Affecting NFL Player Health

March 30, 2017

Stonehill College, Easton, MA

Legal and Ethical Issues Affecting Player Health

May 19, 2017

Panel session at the Sports Lawyers Association Annual Conference in Denver, CO



**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 is slated to continue this work through at least April 2018. Our work will ideally continue thereafter, pending renewal of the CTSA for another 5-year term; the renewal application was submitted in May 2017.

The Center's work on this project has been co-led by **I. Glenn Cohen** and **Holly Fernandez Lynch**. **Luke Gelin** 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.

The Center's main focus for this collaboration is on developing 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. We have disseminated the guidance document at various venues, and this year published two related academic articles, *Using Social Media as a Research Recruitment Tool: Ethical Issues and Recommendations* and *Nonexceptionalism, Research Risks, and Social*



Media in the American Journal of Bioethics, alongside replies from scholars across the research community.

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 a comprehensive law review article on these topics, *Paying Research Participants: Regulatory Uncertainty, Conceptual Confusion, and a Path Forward*, in the Yale Journal of Health Policy, Law, and Ethics in early 2017, and a second article directed at helping IRBs and investigators promote “fair” payment, *The Outsized Influence of Undue Influence*, has been accepted for publication at IRB: Ethics & Human Research (forthcoming 2017). In December 2016, we hosted a public symposium bringing together thought leaders on this topic, and convened a subsequent expert working group to collaborate on practical guidance materials for investigators and IRBs. A guidance document offering definitions and an ethical framework for paying research participants was completed in Summer 2017, and a companion article is currently under peer review.

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. We published a feature article examining the ethical and practical grounds for prioritizing trials in the Journal of Medical Ethics, *When Clinical Trials Compete: Prioritising Study Recruitment*, as well as a response to expert commentaries, *Institutions as an Ethical Locus of Research Prioritisation*.



Motivations for Participating in Biobanking for Research

At present, a substantial portion of research with biospecimens – e.g., blood and tissue samples collected from patients and research participants – falls outside the scope of federal law and does not require informed consent from specimen sources. However, there are circumstances where prospective consent is needed or sought as a way of building trust with and empowering patient populations. In that context, it is essential to better understand why individuals agree or do not agree to have their biospecimens used for research purposes. This project undertakes an empirical research project, in collaboration with colleagues at other research institutions, aimed at answering this question. The data will be used to target educational efforts and refine biobank recruitment processes. To date, we have completed the survey instrument and are preparing a pilot study, in order to launch the survey in mid-to-late 2017.

Consent Initiatives

Despite significant attention to consent as a cornerstone of ethical research, there remain significant challenges to modernizing and optimizing consent processes. There is, for example, growing interest in the research community in documenting informed consent for research using digital platforms and electronic means, but there remains uncertainty about how to implement e-consent in ways that comply with state laws and minimize ethical concerns. In addition, there is a widely recognized need to simplify consent forms in the service of enhancing participant understanding and to develop standardized consent form language and templates. This project, launched in 2017 and operationalized in part through the Consent Committee of the Regulatory Foundations, Ethics, and Law Program, will advance these goals.

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.



Events

We have participated in a number of events related to our Harvard Catalyst work in FY17, with several additional events planned:

Social Media as a Recruitment Tool

September 9, 2016

Presentation at conference hosted by Johns Hopkins Institute for Clinical Translational Research, Research Participant and Community Partnership Core, "Research Participant Recruitment and Retention: What Is Working Across the Nation?"

Prioritizing Study Recruitment

October 6, 2016

Presentation at the American Society for Bioethics and Humanities Annual Conference

Using Social Media as a Research Recruitment Tool: Ethical Issues and Recommendations

October 9, 2016

Presentation at the American Society for Bioethics and Humanities Annual Conference

Paying Research Participants: Ethical and Regulatory Parameters

December 9, 2016

Public symposium (and launch of expert working group), hosted by the Petrie-Flom Center, Harvard Catalyst, and the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

Social Media as a Research Recruitment Tool: Ethical Considerations and Guidelines for IRBs

February 2017

National PRIM&R Webinar

Evaluating Payment to Participate in Research: Ethical and Regulatory Issues

April 2017

Schulman IRB Webinar

Practical Guidance on the Use of Social Media for Recruitment

May 15, 2017

Technology and Rare Neurological Diseases Symposium, University of Rochester



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 co-led by **I. Glenn Cohen** and **Holly Fernandez Lynch**. In March 2017, **Luke Gelin** joined the project as Research Associate, splitting his time between PCOROS and work for Harvard Catalyst.

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?

To date, we have completed 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 has been accepted for publication in *IRB: Ethics & Human Research*, forthcoming 2017. We are also in the midst of data collection on a national survey of IRB members on PCOR and human subjects protection and oversight. Beginning in Fall 2017, we will launch a Delphi process to develop and hone key recommendations for oversight of PCOR, which will culminate in a whitepaper comprised of guidance for IRBs, investigators and other stakeholders, and a public event in Spring 2018. We anticipate focusing on several areas of interest, including the participation of patients in non-traditional roles (beyond research subject) in PCOR, utilization of mHealth technologies, and overarching logistical issues.

Specimen Science: Ethics and Policy Implications **Book Project**

In November 2015, the Center hosted a conference called Specimen Science: Ethics and Policy Implications on research involving biospecimens and their associated data, including important questions about consent, ownership, data-sharing, privacy considerations, group harms, and standards for responsible specimen stewardship. The conference was supported in part by a grant from the National Human Genome Research Institute of the National Institutes of Health (Award Number R01HG005691, PI Suzanne M. Rivera) called “Advancing Collaborative Genetic Research: Ethical and Policy Challenges.”



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Conference presenters, and additional invitees, contributed chapters for an edited volume, and work on the manuscript was completed this year. The volume, also called *Specimen Science* and co-edited **Holly Fernandez Lynch**, **Barbara E. Bierer**, **I. Glenn Cohen**, and **Suzanne M. Rivera**, is forthcoming from MIT Press in October 2017. The book is particularly timely given recent regulatory revisions regarding research with biospecimens and data.

Additional Efforts

In FY17, we submitted three applications for sponsored research projects, one of which was successful. This reflects a fairly typical return on competitive research funding applications.

Research Program in Biomedical Innovation Law (CeBIL)

Award period: January 1, 2018–December 31, 2022

Funded amount: \$449,497

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 for an international and interdisciplinary research program centered around various aspects of biomedical innovation law. We were notified in June that the project has been approved and the final contract is currently being negotiated between the funder and the prime sponsor, with the contracts expected to be finalized shortly after the submission of this report and the work expected to begin in FY18. Further detail is provided our discussion of 2017–18 Plans for Activities below.

Greenwall Foundation Making a Difference in Real-World Bioethics Dilemmas Grants Program Nudging Toward Research: Ethical and Regulatory Issues

This grant submission proposed to address public under-involvement in medical research, a perennially challenging problem that impedes the development of disease treatments and cures. We proposed a two-year project to explore one potential mechanism for improving participation rates, which would be to leverage insights from behavioral economics to structure choice situations in ways that nudge individuals to enroll and/or remain in various types of research. **Glenn Cohen**, **Holly Fernandez Lynch**, and **Luke Gelin** would have analyzed foundational ethical and regulatory issues involved with nudging toward research with the goal of providing a framework for assessing



the different values at stake and offering concrete guidance on a number of issues in this domain. 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.

National Institutes of Health Funding Opportunity Announcement Controlled Drugs for Pain: Bioethical, Legal, and Societal Barriers to Research

The Petrie-Flom Center submitted a proposal to work via subcontract, under PIs Rosamond Rhodes and Henry Sacks at the Mt. Sinai School of Medicine, on a five-year project conducting a legal survey of applicable federal and state laws, regulations, guidance documents, and other policies governing controlled substances, such as cannabis, gabapentin, and heroin, including their use, possession, sale, manufacture, and inclusion in research protocols. Given the vast regulatory structure around illicit drugs, we planned to focus specifically on the legal parameters surrounding medical and research uses. **Glenn Cohen** and **Holly Fernandez Lynch** would have overseen a review of any available case law specific to the medical and research use of controlled substances, including, as appropriate, an international comparative analysis to identify successful regulatory mechanisms governing controlled substances for medical and research use in other countries. In addition, they would have conducted legal research into any concerns or misconceptions that might have arisen during the course of Focus Group Discussions (FGDs) conducted by the prime institution. Finally, the Center proposed to host a national conference on legal reform issues related to research involving controlled substances at the end of the grant period. This was the fourth submission of this proposal, which at various points had received encouraging feedback from reviewers, but ultimately went unfunded.



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). JLB is now in its fourth 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. Graduate students at each of the participating institutions write “**Notes and Developments**” for each issue, comprised of brief summaries of and commentary on recent legislation, regulation, and case law relevant to the biosciences; **Holly Fernandez Lynch** oversaw the involvement of Harvard contributors to this section of the journal. This year’s student contributions from Harvard are listed in the section of this report dedicated to Participation of HLS Students in Program Activities. Notably, student contributions are among the most downloaded pieces in each issue of JLB.

The journal continues to experience extraordinary growth, with roughly 89,000 downloads in 2016—up from 15,000 in its first year and 39,000 in 2015.

All of the partners have been thrilled with the journal’s performance to date, and in December 2016 we signed a new agreement that extends the journal until 2019. As part of the agreement, the Petrie-Flom Center will take over the managing editorship of the journal in 2018 and 2019.

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 includes a Senior Fellow in



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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 2015, **Robert Kinscherff, PhD, JD**, became the second Senior Fellow in Law and Neuroscience. His term was extended and he remained in residence through the end of AY16–17. Dr. Kinscherff is currently a senior administrator and doctoral clinical psychology faculty member at William James College; faculty at the Center for Law, Brain and Behavior at Massachusetts General Hospital; and Senior Associate at the National Center for Mental Health and Juvenile Justice. During his fellowship, he has pursued original research, mentoring, and public engagement related to issues of neurodevelopment and juvenile justice, which has included expert symposia and public events to promote focused discussion on questions at the intersection of adolescent neurodevelopment, juvenile justice, and the law. This year, Robert mentored Petrie-Flom Student Fellow Shailin Thomas in support of his paper entitled, “Eyewitness Malpractice: A Tort Solution for Faulty Eyewitness Testimony Procedures.”

Events

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

Battling Blood in the Streets: How Can Neuroscience Promote Public Health and Support Public Policy to Prevent Violence?

September 7, 2016

Federal Judicial Center-Harvard Law School Conference on Pre-Trial Justice: What Works and Why?

September 26–28, 2016

Cosponsored by the Federal Judicial Center, with support from the Criminal Justice Policy Program at Harvard Law School.

Half a Life: Legal and Policy Implications of Releasing Youth Incarcerated for Murder

November 15, 2016

Opiate Regulation Policies: Balancing Pain and Addiction

April 3, 2017

Healing in the Wake of Community Violence: Lessons from Newtown and Beyond

April 18, 2017

Cosponsored by William James College and the Science, Religion, and Culture Program at Harvard Divinity School.



Federal Judicial Center-Harvard Law School Conference: Tailoring Justice

June 26–28, 2017

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, 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



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Hospice Care of the District of Columbia, and as a Board member of Comprehensive Care Management Corporation (now CenterLight Health 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 November, 2016, we hosted a panel discussion, "The 21st-Century Advanced Illness Care Team: How Team-based Care is Moving Medicine Beyond the Clinic into the Home and Community." Panelists included the CEO of the American Academy of Nursing, a nationally recognized palliative care physician engaged in delivery system redesign, a resident physician who has published extensively early in his medical career, and a senior clinical research scientist who has published on new teams for late life care. Senior Fellow Mark Sterling served as moderator for the panel. A report on the 21st Century Advanced Illness Care Team, stemming from the panel discussion, is in development and will be published in the coming months.

In March and June 2017, we hosted two related meetings on "Critical Pathways to Improved Care for Serious Illness" as part of a project, 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 panel discussions 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. A report with the guiding framework will be issued shortly.

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 engage in policy and research projects that will 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 at the state and federal level. 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 58 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.

Digital Health @ Harvard

This year marked the second year of Digital Health @ Harvard, our informal collaboration with the Berkman Klein Center for Internet and Society that brings together an interdisciplinary community of scholars, researchers, practitioners, and others at Harvard with an interest and expertise in digital health issues, broadly conceived. Through a monthly brown-bag lunch series in the Spring, the program facilitated discussion of ongoing research in this area, sharing of new developments, identification of opportunities for collaboration, and exploration of the digital health ecosystem more generally. We plan to restart the series in the Fall to run throughout the academic year.

Events

Free, Independent Health Records

Adrian Gropper, MD

January 26, 2017

Public Health Echo Chambers in a Time of Mistrust and Misinformation

Natalie Gyenes and Brittany Seymour

February 23, 2017

Using Mobile Phone Data to Map Migration and Disease: Politics, Privacy, and Public Health

Caroline Buckee

March 30, 2017



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Holding Hospitals Hostage: From HIPAA to Ransomware

Josephine Wolff

April 27, 2017



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 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/international influence that we receive a number of requests to visit with us each year. When a potential visitor has demonstrated academic success in our areas of interest, has a current project that would benefit from collaboration with our affiliates, and has a perspective that may be of value to our students, fellows, and faculty, we have welcomed visitors to our Center through a variety of flexible arrangements.

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 blog about their work at Bill of Health.

We hosted several outstanding visitors whose terms extended into FY17:

Peng Zhao, August 2015–August 2016

Peng Zhao is Associate Professor at the China University of Political Science & Law and, after his return to China in 2016, he was appointed deputy dean of the Institute of Law-based Government at CUPL. He is an expert on Chinese food and drug law, administrative law, and risk regulation. Professor Zhao visited the Center with support from the China Scholarship Council, and focused primarily on studying U.S. food and drug law, health law, and bioethics. Based on his research on U.S. regulatory models, he worked on several papers and newspaper commentaries discussing how to improve China's food and drug regulation.



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Due to his participation in the Center's workshop, lectures, and conferences, Professor Zhao developed a new academic interest in human subjects research regulation. He initiated a new project on China's oversight of life sciences research, which received funding from China's National Social Science Foundation.

Kuei-Jung Ni, June–August 2016

Kuei-Jung Ni was a return visitor at the Center, having been a Visiting Scholar previously from August 2013–July 2014. He rejoined us in June 2016 for the summer.

Professor Ni holds an LLM from the University of California, Berkeley, School of Law, and a PhD in Law from the University of Edinburgh School of Law. During this visit, he was on leave from his role as Professor and Director at the Institute for Technology Law, National Chiao Tung University, Taiwan. In addition to continuing his research on the systems of governmental food safety regulation in the United States and Europe, he worked on completing a book project about risk analysis in food safety regime.

We also hosted two visitors for short terms falling fully in FY17:

Rosanna Hertz, September–November 2016

Rosanna Hertz is the Classes of 1919–1950 Reunion Professor of Sociology and Women's and Gender Studies at Wellesley College, where she has taught since 1983. She is currently chair of the Women's and Gender Studies Department. Professor Hertz teaches courses on changing families and social policy; the social construction of gender; and women, work, and the global economy; as well as a first-year seminar on "The Body." Her research focuses on families in a changing economy and how social inequality at home and in the workplace shape the experiences of women and men. She also researches the complexity of "modern families" created through the use of donor gametes and embryos and how the Internet is both revolutionizing the choices for people seeking to enter into third-party reproduction arrangements and creating new possibilities for connection.

Frances Kamm, Senior Fellow, October–November 2016

Frances Kamm has twice been a Senior Fellow at the Petrie-Flom Center. Professor Kamm is the Littauer Professor of Philosophy and Public Policy at Harvard's Kennedy School of Government, and also holds an



appointment at the Harvard Faculty of Arts and Sciences as a member of the Department of Philosophy. During her time at Petrie-Flom in Fall 2016, she advanced her current research on bioethics and death, including topics of relevance to the Project on Advanced Care and Health Policy.

Faculty Summer Research Support

The Center contributes summer support for HLS faculty research projects related to our areas of interest. In Summer 2016, we supported the following:

I. Glenn Cohen worked on a number of Petrie-Flom Center projects, including two edited volumes and several papers and reports related to the Football Players Health Study. He also worked on papers on reproductive technologies and a number of other projects.

Einer Elhauge, Petrie-Flom'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.

2016–2017 Affiliate Scholarship

Petrie-Flom'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, behavioral economics, religion and health, reproductive technologies, juvenile neuroscience, 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.

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

CHRISTOPHER R. DEUBERT, I. GLENN COHEN, & HOLLY FERNANDEZ LYNCH, **PROTECTING AND PROMOTING THE HEALTH OF NFL PLAYERS: LEGAL AND ETHICAL ANALYSIS AND RECOMMENDATIONS** (2016); also published at 7 HARV. J. SPORTS & ENT. L. 1 (2017).

➤ Awarded the Weiler Writing Prize, Harvard Law School, 2017



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I. Glenn Cohen, Holly Fernandez Lynch, and Christopher R. Deubert, ***NFL Player Healthcare: Proposed Solutions to Club Doctors' Conflicts of Interest*** (target article and response to commentaries), HASTINGS CTR. REP. – SPEC. RPT. (Nov./Dec. 2016).

Jessica L. Roberts, I. Glenn Cohen, Christopher R. Deubert, & Holly Fernandez Lynch, ***Evaluating NFL Player Health and Performance: Legal and Ethical Issues***, 165 UNIV. PENN. L. REV. 227 (Jan. 2017).

Jessica L. Roberts, I. Glenn Cohen, Christopher R. Deubert, & Holly Fernandez Lynch, ***Open Peer Commentary: The Legality of Biometric Screening of Professional Athletes***, 17 AM. J. BIOETHICS 65 (2017).

CHRISTOPHER R. DEUBERT, I. GLENN COHEN, & HOLLY FERNANDEZ LYNCH, ***COMPARING HEALTH-RELATED POLICIES AND PRACTICES IN SPORTS: THE NFL AND OTHER PROFESSIONAL LEAGUES***, May 2017; also published in a special issue of HARV. J. SPORTS & ENT. L. (May 2017).

I. Glenn Cohen, Holly Fernandez Lynch, & Christopher R. Deubert, ***When NFL Calls the Doctor***, BOS. GLOBE, Nov. 17, 2016.

Harvard Catalyst

Luke Gelinas, Robin Pierce, Sabune Winkler, I. Glenn Cohen, Holly Fernandez Lynch, & Barbara Bierer, ***Using Social Media as a Research Recruitment Tool: Ethical Issues and Recommendations***, 17 AM. J. BIOETHICS 3 (Feb. 16, 2017).

Luke Gelinas, Robin Pierce, Sabune Winkler, I. Glenn Cohen, Holly Fernandez Lynch, & Barbara Bierer, ***Nonexceptionalism, Research Risks, and Social Media: Response to Open Peer Commentaries***, 17 AM. J. BIOETHICS 5, W1–W3 (Apr. 21, 2017).

Luke Gelinas, Holly Fernandez Lynch, Barbara E. Bierer, & I. Glenn Cohen, ***When Clinical Trials Compete: Prioritising Study Recruitment***, ___ J. MED. ETHICS (Jan. 20, 2017).

Luke Gelinas, Holly Fernandez Lynch, Barbara Bierer, & I. Glenn Cohen. ***Institutions as an Ethical Locus of Research Prioritisation*** ___ J. MED. ETHICS (Apr. 6, 2017).



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Holly Fernandez Lynch, I. Glenn Cohen, & Barbara E. Bierer, **Public Engagement, Notice-and-Comment Rulemaking, and the Common Rule**, 39 IRB: ETHICS & HUMAN RES. 1 (Jan./Feb. 2017).

Holly Fernandez Lynch, I. Glenn Cohen, & Barbara Bierer, **Common Rule Revisions: Impact of Public Comment, and What's Next?** HASTINGS CTR. BLOG (Feb. 8, 2017).

Emily A. Largent & Holly Fernandez Lynch, **Paying Research Participants: Regulatory Uncertainty, Conceptual Confusion, and a Path Forward**, 17 YALE J. HEALTH POL'Y, L., & ETHICS 61 (Winter 2017).

Emily A. Largent & Holly Fernandez Lynch, **Paying Research Participants: The Outsized Influence of Undue Influence**, 39 IRB: ETHICS & HUMAN RES. 4 (2017).

PCOROS

Emily A. Largent, I. Glenn Cohen, Holly Fernandez Lynch, Melissa Abraham, Ronen Rozenblum, Avni Gupta, & Joel S. Weissman, *Stakeholder Perspectives and Ethical and Regulatory Oversight Issues in Patient-Centered Outcomes Research*, IRB: ETHICS & HUMAN RES. (forthcoming 2017).

Center-Edited Volumes

I. GLENN COHEN, HOLLY FERNANDEZ LYNCH, & CHRISTOPHER T. ROBERTSON, EDs., **NUDGING HEALTH: HEALTH LAW AND BEHAVIORAL ECONOMICS** (2016).

HOLLY FERNANDEZ LYNCH, I. GLENN COHEN, & ELIZABETH SEPPER, **LAW, RELIGION, AND HEALTH IN THE UNITED STATES** (forthcoming Aug. 2017).

HOLLY FERNANDEZ LYNCH, BARBARA E. BIERER, I. GLENN COHEN, & SUZANNE M. RIVERA, EDs., **SPECIMEN SCIENCE: ETHICS AND POLICY IMPLICATIONS** (forthcoming Oct. 2017).

I. GLENN COHEN, HOLLY FERNANDEZ LYNCH, EFFY VAYENA, & URS GASSER, **BIG DATA, HEALTH LAW, AND BIOETHICS** (forthcoming 2018).

HOLLY FERNANDEZ LYNCH, I. GLENN COHEN, BARBARA J. EVANS, & CARMEL SHACHAR, **TRANSPARENCY IN HEALTH AND HEALTH CARE** (under review).



Affiliate Scholarship¹

I. Glenn Cohen

Embryo Disposition Disputes: Controversies and Case Law, 46 HASTINGS
CTR. REP. 5 (July/Aug. 2016) (co-authored with Eli Y. Adashi).

***Medical Assistance in Dying and 'Suicide Tourism' to Canada: Bill C-14
from a Comparative Perspective***, J. ETHICS MENTAL HEALTH (July 31, 2016)
(co-authored with Konstanin Tretyakov).

The FDA is prohibited from going germline, 353 SCI. 6299 (Aug. 5, 2016)
(co-authored with Eli Y. Adashi).

Mitochondrial Replacement Therapy: Unmade in the USA, JAMA FORUM
(Dec. 21, 2016), (co-authored with Eli Y. Adashi).

Traveling for Assisted Suicide, in EUTHANASIA AND ASSISTED SUICIDE: GLOBAL
VIEWS ON CHOOSING TO END LIFE, MICHAEL J. CHOLBI, ED. (Jan. 2017).

Disruptive reproductive technologies, 9 SCI. TRANSLATIONAL MED. 372 (Jan.
11, 2017) (co-authored with George Q. Daley and Eli Y. Adashi).

***Medical Tourism, Medical Migration, and Global Justice: Implications
for Biosecurity in a Globalized World***, 25 MED. L. REV. 3 (Apr. 11, 2017).

Religion and Reproductive Technology, in LAW, RELIGION, AND HEALTH IN
THE UNITED STATES, HOLLY FERNANDEZ LYNCH, I. GLENN COHEN, & ELIZABETH
SEPPER, EDS. (forthcoming July 2017).

Holly Fernandez Lynch

***Ethical Considerations for Zika Virus Human Challenge Trials: Report and
Recommendations***, in REPORT TO NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS
DISEASES AND WALTER REED ARMY INSTITUTE OF RESEARCH (Feb. 2017) (with Seema
K. Shah, Jonathan Kimmelman, Anne Drapkin Lyerly, Francine McCutchan,
Franklin G. Miller, Ricardo Palacios, Carlos Pardo-Villamizar, & Carmen
Zorrilla).

***Bosses in the Bedroom: Religious Employers and the Future of Employer-
Sponsored Health Care***, in LAW, RELIGION, AND HEALTH IN THE UNITED STATES,

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



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HOLLY FERNANDEZ LYNCH, I. GLENN COHEN, AND ELIZABETH SEPPER, EDs.,
(forthcoming 2017) (with Gregory Curfman).

Regulating Research with Biospecimens Under the Revised Common Rule,
47 HASTINGS CTR. REP. 3 (2017) (with Michelle N. Meyer).

Revised 'Common Rule' Shapes Protections for Research Participants, 36
HEALTH AFFAIRS 5 (2017)(with Barbara E. Bierer & Mark Barnes).

Robert Kinscherff

Level-Headed Responses to Students Who Make Threats, in LESSONS FROM SCHOOL
PSYCHOLOGY: PRACTICAL STRATEGIES AND EVIDENCE BASED PRACTICE FOR PROFESSIONAL AND
PARENTS, GAYLE L. MACKLEM & ARLENE SILVA, EDs., 2017.

***Solitary Confinement of Juveniles in Adult and Juvenile Correctional
Settings***, SPEC. ED.: CHILDREN IN CONFINEMENT, J. INT. NETWORK PREVENTION CHILD
MALTREATMENT (forthcoming 2017) (co-authored with Frank DiCataldo & S.
Domas).

The Recidivism of Juveniles Convicted of Homicide and Released as Adults,
SPEC. ED.: CHILDREN IN CONFINEMENT, J. INT. NETWORK PREVENTION CHILD
MALTREATMENT (forthcoming 2017) (co-authored with Frank DiCataldo et al.).

Luke Gelinas

Rights, Nudging, and the Good of Others, 16 AM. J. BIOETHICS 11 (Oct. 17,
2016).

Pediatric Social Media Recruitment, in ETHICS AND RESEARCH WITH CHILDREN: A
CASE-BASED APPROACH, ERIC KODISH, ED. (2nd ed. forthcoming 2017) (with
Jennifer C. Kesselheim)

Peng Zhao

***How E-Commerce Platforms Have Assumed Administrative Sanction for its
User's Conduct: Analysis Focused on Food and Drug Law and Advertising
Law***, in THE 2016 ANNUAL FORUM OF CHINA ADMINISTRATIVE LAW SOCIETY (2017).

***Beyond Platform Liability: Reflection on Regulations on Online Food
Business***, 1 J. E. CHINA U. POL. SCI. & L. (2017).



2016–2017 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 Petrie-Flom’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, ESPN, NPR, NBC, PBS, the Boston Globe, Business Insider, the Christian Science Monitor, Forbes, Health Affairs, the New York Times, Politico, Reuters, Sports Illustrated, STAT, the Times of Israel, US News & World Report, the Wall Street Journal, the Washington Post, Vox, and more. Selected highlights in which Center affiliates authored commentary or were extensively interviewed are featured below:

I. Glenn Cohen & Holly Fernandez Lynch

Behavioral science suggests that Obamacare may not change as much as Republicans claim, STAT NEWS: FIRST OPINION (Jan 3, 2017)(co-authored with Christopher Robertson).

I. Glenn Cohen

Interview: ***Organ Transplant Troubles***, WGBH, (August 18, 2016).

Interview: ***Radio Sputnik Interview: Medical Tourism***, Radio Sputnik, (August 19, 2016).

How Is It Even Possible For Sofia Vergara’s Embryos To Sue Her? A Harvard Law Prof Weighs In, REFINERY29 (Dec 8, 2016).

Prohibiting sperm donor anonymity in the US and possible effects on recruitment and compensation, BIONEWS (April 3, 2017)(co-authored with Andrew Hellman).

Holly Fernandez Lynch

Science Needs Your Cells, THE NEW YORK TIMES (April 21, 2017) (co-authored with Steven Joffe).



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Understanding the Final Revisions to the Federal Policy for the Protection of Human Subjects, AMERICAN HEALTH LAWYERS ASSOCIATION PRACTICE GROUP ALERT (February 16, 2017).

A New Day for Oversight of Human Subjects Research, HEALTH AFFAIRS BLOG (February 6, 2017).

Interview: ***Does Human Specimen Research Always Need Consent?***, SCIENCE FRIDAY WITH HOST IRA FLATOW (PRI) (July 8, 2016).

Robert Kinscherff

Interview and Consultant: ***Second Chance Kids***, PBS FRONTLINE (May 2, 2017).

Christopher Robertson

Interview: Lisa Ward, ***The Case for Giving Health Care Consumers a 'Nudge'***, WALL STREET JOURNAL (June 25, 2017)(Discussing *Nudging Health: Health Law and Behavioral Economics*, co-edited with I. Glenn Cohen and Holly Fernandez Lynch).



Public Events Programming and Conferences

In addition to a variety of invited presentations given by Center affiliates around the world each year, the Petrie-Flom Center hosted a number of fantastic events again this year, from major conferences to smaller panel discussions, many independently and some in collaboration with our colleagues from Harvard and elsewhere. In developing our substantive event agenda, we strive to plan events that are timely, interdisciplinary, and offer exposure to a variety of leading experts, from academics to policymakers to practitioners.

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' 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

What Works and Why?: Federal Judicial Center Workshop on Pretrial Diversions

September 26–28, 2016

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

The Ethics of Early Embryo Research & the Future of the 14-Day Rule

November 7–8, 2016

Sponsored by the Harvard University Office of the Vice Provost for Research, the Edmond J. Safra Center for Ethics at Harvard University, and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, with support from the International Society for Stem Cell Research, the Center for Bioethics at Harvard Medical School, and the Harvard Department of Stem Cell and Regenerative Biology.

The Animal Welfare Act at 50

December 2–3, 2016

Sponsored by the Animal Law & Policy Program at Harvard Law School, cosponsored by 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.



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Paying Research Participants: Ethical and Regulatory Parameters

December 9, 2016

Part of the collaboration between the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and the Regulatory Foundations, Ethics, and Law Program of Harvard Catalyst | The Harvard Clinical and Translational Science Center at Harvard Medical School. Cosponsored by the MRCT Center of Brigham and Women's Hospital and Harvard.

Fifth Annual Health Law Year in P/Review

January 23, 2017

Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, Harvard Health Publications at Harvard Medical School, Health Affairs, the Hastings Center, the Program On Regulation, Therapeutics, And Law (PORTAL) in the Division of Pharmacoeconomics 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.

Critical Pathways to Improved Care for Serious Illness, Part I

March 10, 2017

Part of the Project on Advanced Care and Health Policy, a collaboration between the Coalition to Transform Advanced Care (C-TAC) and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

Center for Bioethics Annual Conference: The Ethics of Making Babies

April 6-7, 2017

Sponsored by 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.

2017 Petrie-Flom Annual Conference: Transparency in Health and Health Care: Legal and Ethical Possibilities and Limits

April 28, 2017

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

Critical Pathways to Improved Care for Serious Illness, Part II

June 23, 2017

Part of the Project on Advanced Care and Health Policy, a collaboration between the Coalition to Transform Advanced Care (C-TAC) and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

Tailoring Justice: Science-Informed Decision Making

June 26-28, 2017

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.



Lectures, Panels, and Other Events

Battling Blood in the Streets: How Can Neuroscience Promote Public Health and Support Public Policy to Prevent Violence?

September 7, 2016

Part of the Project on Law and Applied Neuroscience.

2016 Petrie-Flom Center Annual Open House

September 7, 2016

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

Health Care after the Election

October 24, 2016

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

Concurrent Surgeries: Medical, Legal, and Ethical Issues

October 27, 2016

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

The 21st-Century Advanced Illness Care Team: How Team-based Care is Moving Medicine Beyond the Clinic into the Home and Community

November 2, 2016

Part of the Project on Advanced Care and Health Policy, a collaboration between the Coalition to Transform Advanced Care (C-TAC) and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

Half a Life: Legal and Policy Implications of Releasing Youth Incarcerated for Murder

November 15, 2016

Part of the Project on Law and Applied Neuroscience.

Book Launch: Nudging Health: Health Law and Behavioral Economics

November 16, 2016

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

President-Elect Trump's Health Policy Agenda: Priorities, Strategies, and Predictions

December 19, 2016



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Free, Independent Health Records: Adrian Gropper, MD

January 26, 2017

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.

Looking Forward: The Next Generation of Biosimilars

February 7, 2017

Sponsored by the [Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics](#) at Harvard Law School and [Eagle Biologics](#).

**Public Health Echo Chambers in a Time of Mistrust and Misinformation:
Natalie Gyenes and Brittany Seymour**

February 23, 2017

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.

**The Affordable Care Act: Past, Present, and Future: A lecture by William B.
Schultz, General Counsel of HHS, 2011–2016**

March 23, 2017

**Using Mobile Phone Data to Map Migration and Disease: Politics, Privacy,
and Public Health: Caroline Buckee**

March 30, 2017

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.

Opiate Regulation Policies: Balancing Pain and Addiction

April 3, 2017

Part of the [Project on Law and Applied Neuroscience](#).

Crowdfunding Medical Care: Identifying Ethical Implications

April 5, 2017

Sponsored by the [Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics](#) at Harvard Law School and the [Center for Bioethics](#) at Harvard Medical School, with support from the Oswald DeN. Cammann Fund.

**Healing in the Wake of Community Violence: Lessons from Newtown and
Beyond: Panel discussion and screening of the documentary Newtown**

April 18, 2017

Part of the [Project on Law and Applied Neuroscience](#).

Holding Hospitals Hostage: From HIPAA to Ransomware: Josephine Wolff

April 27, 2017

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

The Health Policy and Bioethics Consortia were 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*, with support from the Oswald DeN. Cammann Fund at Harvard University. This monthly series convened two international experts from different fields or vantage points at each session to discuss how biomedical innovation and health care delivery are affected by various ethical norms, laws, and regulations. While most of the sessions were hosted on the Harvard Medical School campus, on February 10, 2017, the Petrie-Flom Center hosted a session at Harvard Medical School on "**Returning Results to Research Participants.**"

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 took the lead in organizing and hosting, we also collaborated on several other events organized by our Harvard colleagues:

The Domain of Torts: A Lecture by Alexander Stein October 18, 2016

Hosted by the [Project on the Foundations of Private Law](#) at HLS

Yuval Noah Harari in conversation with Michael Sandel: A discussion of Harari's new book *Homo Deus: A Brief History of Tomorrow* February 22, 2017

Sponsored by the [Harvard Book Store](#), with cosponsorship from the [Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics](#) at Harvard Law School.

2017 Just Food? Conference: Forum on Labor across the Food System April 1, 2017

*A collaboration of the [Harvard Food Literacy Project](#) and [Harvard Law School Food Law Society](#).
Co-sponsored by the [Food Law and Policy Clinic](#) at Harvard Law School.*

Annual Health Law Conference: Between Complacency & Panic: Legal, Ethical, and Policy Responses to Emerging Infectious Diseases April 14, 2017

This conference was co-sponsored by the [Northeastern University School of Law](#) and its [Center for Health Policy and Law](#), and the [American Society of Law, Medicine & Ethics](#), with support from the [Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics](#) at Harvard Law School, [Trident Legal](#), and The John and Sonia Lingos Family Foundation.



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Editorial Aspirations: Human Integrity at the Frontiers of Biology

April 26–28, 2017

This workshop sponsored by the Program on Science, Technology, and Society at the Harvard Kennedy School of Government, and was co-sponsored by the Center for Biology and Society, Arizona State University with support from Templeton Religion Trust; the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and the Center for Bioethics at Harvard Medical School, with support from the Oswald DeN. Cammann Fund; the Institute for Global Law and Policy at Harvard Law School; the Weatherhead Center for International Affairs; and The Future Society.



Contributions to the HLS Teaching Program

Petrie-Flom affiliates make substantial contributions to the university's health law curriculum through various courses and frequent guest lectures, for example as part of Harvard Catalyst and the Football Players Health Study. Of particular note this year, FPHS Senior Law and Ethics Associate **Christopher Deubert** delivered a series of lectures in Professor Peter Carfagna's Sports Law courses, and **Holly Fernandez Lynch** and **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, **Glenn Cohen** launched a new HarvardX course in fall 2016, "Bioethics: The Law, Medicine, and Ethics of Reproductive Technologies and Genetics." During its initial run, more than 10,600 learners enrolled in the original course, with 225 paying associated fees to receive a certificate of completion. The class was reopened as a self-paced course in April 2016, and since then more than 6,000 learners have registered with 144 paying associated fees toward a verified certificate of completion (learners have until October 16, 2017, to complete this self-paced version of the course).

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

Health Law, Policy, Bioethics, and Biotechnology Workshop

I. Glenn Cohen

Fall 2016–Spring 2017

The Health Law Policy and Bioethics 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 2016–2017 workshop welcomed the following scholars:

- **Leo Beletsky**, Associate Professor of Law and Health Sciences with a joint appointment with the School of Law and Bouvé College of Health Sciences, Northeastern University
America's Favorite Antidote: Murder-By-Overdose in the Age of the Opioid Epidemic
- **Khiara Bridges**, Professor of Law, Boston University School of Law and Professor of Anthropology, Boston University
Untitled book proposal: "an ethnography of the fraught reproduction of middle and upper middle-class black and Latina women in the United States"
- **Judith Daar**, Interim Dean and Professor of Law, Whittier Law School; joint appointment at the UCI School of Medicine
A Clash at the Petri Dish: Transferring Embryos with Known Genetic Anomalies
- **Frances Kamm**, Littauer Professor of Philosophy and Public Policy, Harvard Kennedy School of Government; Professor of Philosophy, Harvard University; Visiting Scholar, Petrie-Flom Center, Fall 2016
Advanced and End of Life Care: Cautionary Suggestions
- **Elizabeth Weeks Leonard**, J. Alton Hosch Professor of Law, University of Georgia School of Law
Book proposal: Healthism: Health Status Discrimination and the Law
- **Trudo Lemmens**, Professor and Scholl Chair in Health Law and Policy, University of Toronto Faculty of Law
While Canada Ventures into Legalized Medical Assistance in Dying, What Can It Learn from the Belgian Euthanasia Experience?
- **Brendan S. Maher**, Professor of Law and the Director of the independently endowed Insurance Law Center at UConn School of Law
Unlocking Exchanges
- **W. Nicholson Price II**, Assistant Professor, University of Michigan School of Law
Regulating Black-Box Medicine
- **Amy Sepinwall**, Assistant Professor of Legal Studies and Business Ethics and James G. Campbell, Jr. Memorial Term Assistant Professor of Legal Studies and Business Ethics, the Wharton School, University of Pennsylvania
The Challenges of Conscience in a World of Compromise
- **Lindsay Wiley**, Associate Professor of Law, Washington College of Law at American University
Social Norms, Legal Foundations, and Noncommunicable Disease Prevention
- **Kathryn Zeiler**, Professor of Law and Nancy Barton Scholar, Boston University School of Law
Communication-And-Resolution Programs: The Numbers Don't Add Up
- **Patricia J. Zettler**, Associate Professor of Law, Georgia State University College of Law
Pharmaceutical Federalism



Law and Neuroscience

Nancy Gertner

Spring 2017

With guest lectures and contributions to classroom discussion from Senior Fellow **Robert Kinscherff**, 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 Law, Policy, and Bioethics

Holly Fernandez Lynch and **Aaron Kesselheim**

Spring 2017

Note: This seminar was offered as part of the Masters Program in Bioethics at Harvard Medical School. However, it was open to HLS students for cross-registration and was heavily promoted to HLS students through all Petrie-Flom outlets.

This seminar offers an introduction to legal topics in health policy and bioethics, including legal aspects of the doctor-patient relationship, medical malpractice, privacy issues, health care finance, end-of-life issues, organ donation, mental health, public health, medical product regulation, and intellectual property. Students learn to engage in policy discussion through several Op-Ed writing assignments and in-class debates.



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 policy, 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 upon successful completion of their written work or writing credit, 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.

Since 2013, one of our students each year with a focus on food and drug law has been named the Peter Barton Hutt Student Fellow, in honor of our friend and colleague Peter Barton Hutt.

The Center's 2016–2017 student fellows and projects were as follows:

Seán Finan

Harvard Law School, LLM '17

Paper: "Changing Morality: Reframing the Article 53(a) 'Morality Test' of the European Patent Convention"



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Wendy Salkin

Harvard University, PhD '18, Philosophy

Paper: "The Ties that Bind: The Anatomy of Health Solidarity"

J. Bradley Segal

Harvard Medical School, MBioethics '17, MD '18

Paper: "Organ Donation: First, Do No (Wrongful) Harm"

Shailin Thomas

Harvard Law School, JD '18

Paper: "Eyewitness Malpractice: A Tort Solution for Faulty Eyewitness Testimony Procedures"

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:

Football Players Health Study

- Nimat Lawal, HLS '18
- Scott Sherman, HLS '17

Harvard Catalyst

- Juliana Carreiro Avila, HLS '17

PCOROS

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

Specimen Science

- Jose Lamarque, HLS '17
- Ethan Stevenson, HLS '17
- Shailin Thomas, HLS '18



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Big Data, Health Law, and Bioethics:

- Wilfred Beaye, HLS '17
- Colin Herd, HLS '18
- Ethan Stevenson, HLS '17
- Brian Yost, HLS '19

Transparency in Health and Health Law

- Grace Wallack, HLS '19

Other Petrie-Flom Projects

- Katherine Kwong, HLS '17
- Mark Satta, HLS '19

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. This year we invited applications for student summer bloggers, and as a result the following students actively contributed to Bill of Health in summer 2016:

- Kelly Amal Dhru, HLS LLM '17
- Shailin Thomas, HLS '18

Journal of Law and the Biosciences Student Contributors

As described above, the Petrie-Flom Center collaborates on publication of the *Journal of Law and the Biosciences*. The journal includes a “Notes and Developments” section, comprised of brief summaries and commentary on recent legislation, regulation, and case law written by graduate students at the collaborating schools. Petrie-Flom is responsible for providing the “Notes and Developments” for one issue per volume. This year’s student contributors, published in [April 2017](#), were:

Gawon Go, Harvard Law School, ***Amnesia and criminal responsibility***

Nisarg A. Patel, Harvard School of Dental Medicine, ***Fee-for-value in the pharmaceutical industry: a policy framework applying data science to negotiate drug prices***



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Maayan Sudai, Harvard Law School, ***The testosterone rule—constructing fairness in professional sport***

Quinn Walker, Harvard Medical School, ***Designing a standard of proof: the case for professional standards in next-generation sequencing laboratory-developed tests***

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 Health Law News, Affiliate News, Affiliate Scholarship, and Opportunities sections of the website 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 2016–2017 interns were:

- Emily Jung, Harvard FAS '18
- Megha Majumder, UC Berkeley '18
- D. J. Dumeran, Cambridge Rindge and Latin, '17
- Soliana Yebio, Cambridge Rindge and Latin, '18



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 **J. Glenn Cohen** and Founding Director **Einer Elhauge**, **Nancy Gertner**, Lecturer on Law, has continued to support our collaborative Program on Law and Applied Neuroscience; **Urs Gasser** was a key collaborator for our 2016 annual conference on big data, health, and bioethics and worked with us in FY17 to edit the related conference volume; and **Kristin Stilt** worked with us to develop programming bringing Petrie-Flom together with the **Animal Law and Policy Program** at HLS. We also continue to collaborate with **Robert Greenwald** and **Emily Broad Leib** of the **Center for Health Law Policy and Innovation**, and **Michael Stein** of the **Harvard Law School Program on Disability**. Finally, this year we worked with **Vivek Krishnamurthy** of the Cyberlaw Clinic to develop suitable student projects.

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

- **John Aach**, HMS
- **Danielle Allen**, FAS and Edmond J. Safra Center for Ethics
- **Jerry Avorn**, HMS
- **Peter Barton Hutt**, HLS
- **Barbara E. Bierer**, HMS
- **David Borsook**, HMS
- **Eric Campbell**, HMS
- **Amitabh Chandra**, HKS
- **George Church**, HMS
- **Gregory Curfman**, HMS
- **Jonathan Darrow**, HMS
- **Judith G. Edersheim**, HMS
- **Michelle Bosquet Enlow**, HMS
- **Nir Eyal**, HMS
- **Sheila Jasanoff**, HKS
- **Frances Kamm**, HKS
- **Aaron S. Kesselheim**, HMS
- **Louise P. King**, HMS
- **John McDonough**, HSPH
- **William Meehan III**, HMS
- **Christine Mitchell**, HMS
- **Lee Nadler**, HMS
- **Alvaro Pascual-Leone**, HMS
- **Ahmed Ragab**, HDS
- **Michael Sandel**, FAS



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- [Ameet Sarpatwari](#), HMS
- [Vincent Schiraldi](#), HKS
- [Carmel Shachar](#), HLS
- [Cass Sunstein](#), HLS
- [Robert D. Truog](#), HMS
- [Joel Weissman](#), HMS
- [Ross Zafonte](#), HMS

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

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

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

Finally, the Center has a substantial cohort of formally affiliated faculty members, primarily from Harvard, but also open to [alumni](#) of our Academic Fellowship program. Our faculty affiliates blog with us, help organize and publicize events, participate in internal workshops, and mentor interested students and fellows. A complete list of affiliated faculty is available [here](#). The following individuals were added over the 2016–2017 academic year:

- [Jonathan Darrow](#), HMS
- [Robert Kinscherff](#), William James College
- [Holly Fernandez Lynch](#), Perelman School of Medicine, University of Pennsylvania (Fall 2017)

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** serves as a member of the Standing Committee on Ethics of CIHR (Canadian Institute for Health Research; the Canadian equivalent to NIH). In September 2016, he was invited to serve on the new National Academy of Sciences committee on Issues in Organ Donor Intervention Research. He has also recently been elected to join the Ethics Committee for the American Congress of Obstetricians and Gynecologists (ACOG).

Holly Fernandez Lynch

Executive Director **Holly Fernandez Lynch** has served as a member of the Secretary's Advisory Committee on Human Research Protections (SACHRP), U.S. Department of Health and Human Services, since 2014, and was appointed a member of its Subcommittee on Harmonization in Fall 2015. In January 2017, the Department of Health and Human Services (along with several other federal agencies) released long awaited revisions to the regulations governing research with human subjects. Holly provided substantial public analysis and explanation of the new regulations, including to members of the Congressional Research Service and the health law bar.

In November 2016, Holly was invited to join an expert consultation to the National Institute of Allergy and Infectious Diseases and the Walter Reed Army Institute of Research addressing the ethics of conducting human challenge studies (intentional infection) to develop a vaccine for Zika virus. The consultation report was released in February 2017, Ethical Considerations for Zika Virus Human Challenge Trials: Report and Recommendations, setting forth the ethical



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parameters for whether Zika virus challenge studies can appropriately proceed at this time.

This year, Holly has also been engaged in the Bioethics Collaborative of the Multi-Regional Clinical Trials Center of Harvard and Brigham and Women's Hospital. The Bioethics Collaborative is a neutral forum to encourage the discussion of bioethical issues among stakeholders in global clinical trials for drug and device development, including individuals from academia, industry, patient groups, and government. Key topics addressed to date include expanded access to investigational products and diversity in clinical research.

Finally, in addition to various academic presentations and lectures, Holly has been engaged in community events hosted by the NY Academy of Sciences and Partnering for Cures.

Luke Gelinas

Senior Researcher Luke Gelinas serves 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.

Robert Kinscherff

Senior Fellow in Law and Applied Neuroscience Robert Kinscherff engaged in the following policy and training events:

- **Strengthening Collaboration Between the Behavioral Health and Juvenile Justice Systems to Improve Reentry Outcomes.** Webinar for Justice Center, National Council of State Governments, July 29, 2016.
- **Advances in Addressing Violence: Assessment, Attachment, Treatment.** With Dr. Lisa Firestone. 124th Annual Convention of the American Psychological Association, August 4, 2016.
- **Mental Health and Substance Use Conditions Among Juvenile Justice Involved Youth.** Webinar for National Center for Mental Health and Juvenile Justice, October 11, 2016.
- **What is the Relationship Between Violence and Mental Illness in Youth People?** Grand Rounds, Cambridge Hospital, October 16, 2016.



- **Working with Persons Who Have Been Violent: Attachment, Transference and Countertransference.** William James College, December 3, 2016.
- **The Neuropsychological Underpinnings of Implicit Bias.** MA Association of Family and Conciliation Courts, January 25, 2017.
- **A Primer on Adolescent Neurodevelopment.** Boston Inns of Court, February 28, 2017.
- **Threat Assessments in Schools.** Grand Rounds, New Hampshire Hospital, March 3, 2017.
- **Adolescent Neurodevelopment: Implications for Law and Policy.** Program in Neuroscience and Public Policy, Joint Program of the School of Medicine and Public Health and the Law School, University of Wisconsin, March 9, 2017.
- **What Is the Current Science on the Adolescent Brain: Culpability, Capacity for Rehabilitation and Competency?** Forum on Adolescent Murder, Flaschner Judicial and Social Law Library, June 9, 2017.
- **Adolescent Neurodevelopment: Implications for Judicial Practice from Arraignment Through Disposition.** New Hampshire Circuit Court Judicial Training, June 16, 2017.

Robert also presented at additional trainings for clinical, legal, and social services professionals on the neuroscience of adolescent development, mental health, and addiction, with a focus upon legal and policy implications for clinical intervention, law enforcement practice, and juvenile justice and criminal justice policy. He continued to consult to defense attorneys and prosecutors in a number of states on post-*Miller* juvenile homicide resentencing and parole cases, served as an expert evaluator for juvenile homicide parole cases in Massachusetts, and was a consultant and/or a co-signatory on amicus briefs related to juvenile justice and correctional appellate issues (proportional sentencing, and felony murder/joint venture doctrines as applied to juvenile felony defendants).

In February 2017, Robert participated for the National Center on Mental Health and Juvenile Justice and the National Council of Juvenile and Family Court Justice in providing on-site technical assistance to an innovative Juvenile Drug Treatment Court in Lancaster, OH, a community beleaguered by an opiate and methamphetamine epidemic.



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. During the past year, Mark also helped C-TAC launch a new non-profit affiliate, C-TAC Innovations, and acquire Respecting Choices, which operates an internationally-recognized evidence-based model for advanced care planning and shared decision-making among patients and clinicians. The Respecting Choices model was developed by the Gundersen Lutheran Medical Foundation and its program now has a network of over 10,000 trained facilitators.

Sponsored and Other Research

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

- Our work on the Football Players Health Study endeavored to develop a variety of practical recommendations that could be implemented to improve the health of NFL players.
- 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 project with 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, will help pave the way forward for medical advancement via biospecimen research, as the federal government 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 explore 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.
- 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.



Website and Social Media

The Petrie-Flom Center’s website is a critical component of our public engagement strategy, 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. We are constantly revising and expanding the website to provide up-to-date resources. The overarching goal is to make the Petrie-Flom Center’s website a central resource for anyone looking to learn more about our fields of interest—from academics to students to journalists to interested members of the community.

Our ongoing efforts to enhance our social media presence, primarily on Facebook and Twitter, have continued to increase awareness of the Center and also to drive traffic to the website, blog, and event videos. The results have been impressive: overall engagement (comments, likes, shares, etc.) increased across all platforms, and most importantly, we have seen a steady increase in requests to be included in our resources (e.g., opportunities on the website) and in attendance at our events.

Our website continues to draw almost 5,000 unique users per month, with visitors from over 120 countries. Our video-hosting site, Vimeo, saw about 3,500 views in AY2016–2017, and our slide-sharing site receives over 1,000 views per month. Our social media feeds continue to grow, helping us reach audiences beyond Harvard to share Center events and scholarship as well as health law news, opportunities, and other resources. Our Facebook following increased 40% this year, and our Twitter feed, in particular, continues to grow, with our community now numbering almost 2,200 followers. Based on a recent internal review, the Petrie-Flom Center has one of the most robust followings among health law centers and related organizations on Twitter!

We continue to circulate an electronic newsletter every other week with information about upcoming events, recent blog posts, affiliate news and commentary, opportunities at Petrie-Flom and elsewhere, and other information relevant to our community. This year our subscription list increased to over 5,000 members.

These numbers demonstrate that we are successfully utilizing a variety of web-based media to extend our community well beyond the confines of the Boston area and the academy. In the coming year as Project Coordinator **Justin Leahey** transitions into a full-time role with the Center, he will be taking a more active role in communications strategy and development. We are looking forward to the results of Justin’s work in improving our existing communications and expanding to new outlets.



Bill of Health

Bill of Health, our collaborative blog on health law policy, biotechnology, and bioethics co-edited by **I. Glenn Cohen** and **Holly Fernandez Lynch**, continues to be a resounding success. We have bloggers from all over Harvard, as well as the leading health law scholars at universities around the country and internationally. The site remains active, with new bloggers joining us regularly and an average of 1–2 new posts per day. We routinely hear that our colleagues in the field stay up to date through our blog, and the caliber of contributors and contributions is stellar. Media outlets are also paying attention, as posts regularly result in follow-up interviews and quotes.

We continue to actively develop new bloggers, including Harvard students involved with the *Journal of Law and the Biosciences* and the Harvard Health Law Society, and have begun hosting series based on selected Petrie-Flom events that are cross-posted by other prominent blogs including the *Health Affairs* blog and the Hastings Center's *Bioethics Forum*. In addition, this year, we hosted several blog “symposia” with selected contributions around a specified topic, including the following:

- *Between Complacency and Panic – Legal, Ethical and Policy Responses to Emerging Infectious Diseases*, with the Center for Health Policy and Law at the Northeastern University School of Law
- *Critical Studies of Citizen Science in Biomedical Research*, with colleagues at King’s College London
- *How Patients Are Creating the Future of Medicine*, with the University of Minnesota’s Consortium on Law and Values in Health, Environment & the Life Sciences
- *Healing in the Wake of Community Violence: Lessons from Newtown and Beyond*, part of the Project on Law and Applied Neuroscience
- *Applying the Americans with Disabilities Act and Genetic Information Nondiscrimination Act to the NFL Workplace*, part of the Football Players Health Study

Bill of Health currently sees roughly 15,000 unique monthly users, and over 22,000 pageviews per month.



Events with Industry Participation

As noted above, Petrie-Flom hosted several events this academic year with participants from the health care and pharmaceutical industries. These are critically important to expose students to real-world issues and maintain connections with practical challenges arising in our fields of inquiry:

What Works and Why?: Federal Judicial Center Workshop on Pretrial Diversions

September 26–28, 2016

This workshop for federal judges and law enforcement officials addressed issues relating to pretrial diversionary courts, with a focus on our increasing understanding of the neuroscience behind trauma, mental health, and addiction, as well as evidence-based models of care for people in the criminal justice system who qualify for pretrial diversion.

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

Industry participants:

- **Judge Ann Aiken**, U.S. District Judge, District of Oregon
- **Judge Mary Gordon Baker**, District of South Carolina
- **Daniel Josev Brewer**, Assistant U.S. Attorney, District of South Carolina
- **Allyson Lorimer Crews**, Deputy Chief U.S. Probation Officer, The RISE Program, District of Massachusetts
- **Maria D’Addieco**, U.S. Probation Officer, The RISE Program, District of Massachusetts
- **J. Robert Haley**, Assistant Federal Public Defender, District of South Carolina
- **Judge Page Kelley**, District of Massachusetts
- **Judge Leslie Kobayashi**, District of Hawaii
- **Chris Maloney**, District of Massachusetts, Chief U.S. Probation Officer
- **Shannon McAuliffe**, Director, Roca Boston
- **Brian McDonald**, Assistant Deputy Chief U.S. Probation Officer, District of Massachusetts
- **Susanna Merchant**, Federal Judicial Center
- **Carol Miyashiro**, Chief U.S. Pretrial Services Officer, District of Hawaii
- **Florence Nakakuni**, U.S. Attorney, District of Hawaii
- **Shanlyn Park**, Assistant Federal Public Defender, District of Hawaii
- **Mark Parrent**, Assistant U.S. Attorney, Western District of Washington
- **Jennifer Pucci**, Assistant Federal Public Defender, District of Massachusetts



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- **Katrina Robinson-Curtis**, U.S. Probation Officer, District of South Carolina
- **Mark Sherman**, Federal Judicial Center
- **Connie Smith**, Chief United States Probation and Pretrial Services Officer, Western District of Washington
- **Cassandra Snyder**, Federal Judicial Center
- **Judge Leo Sorokin**, District of Massachusetts
- **Tremaine Sumter**, U.S. Probation Officer, District of South Carolina
- **Alison Thom**, Senior U.S. Pretrial Services Officer, District of Hawaii
- **Jennifer Van Flandern**, Drug and Alcohol Treatment Specialist, Senior United States Probation Officer, Western District of Washington

Health Care after the Election

October 24, 2016

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

Speakers:

- Opening Remarks: **Gregory Curfman**, Editor in Chief, Harvard Health Publications, Harvard Medical School
- **Joseph R. Antos**, PhD, Wilson H. Taylor Scholar in Health Care and Retirement Policy, American Enterprise Institute
- **Chris Jennings**, Founder and President, Jennings Policy Strategies, Inc.
- Moderator: **I. Glenn Cohen**, Professor of Law, Harvard Law School and Faculty Director, Petrie-Flom Center

The 21st-Century Advanced Illness Care Team: How Team-based Care is Moving Medicine Beyond the Clinic into the Home and Community

November 2, 2016

Part of the Project on Advanced Care and Health Policy, a collaboration between the Coalition to Transform Advanced Care (C-TAC) and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

Speakers:

- **Cheryl Sullivan**, Chief Executive Officer, American Academy of Nursing
- **Sandra Schellinger**, Senior Scientist, Late Life Supportive Care Research, Allina Health System
- **Brad Stuart**, Chief Medical Officer, Coalition to Transform Advanced Care
- **Ravi Parikh**, Clinical Fellow, Harvard Medical School, Resident in Internal Medicine, Brigham and Women's Hospital
- **Mark Sterling**, Senior Fellow, Project on Advanced Care and Health Policy at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School



President-Elect Trump's Health Policy Agenda: Priorities, Strategies, and Predictions

December 19, 2016

Expert panelists addressed what health care reform might look like under President-elect Trump's administration, including the future of the Affordable Care Act under a "repeal and replace" strategy, alternative approaches to insurance coverage and access to care, the problem of high drug prices, innovation policy, support for scientific research, and other topics.

Speakers:

- **Joseph R. Antos**, Wilson H. Taylor Scholar in Health Care and Retirement Policy, American Enterprise Institute
- **Lanhee J. Chen**, David and Diane Steffy Research Fellow, Hoover Institution; Director of Domestic Policy Studies and Lecturer, Public Policy Program; affiliate, Freeman Spogli Institute for International Studies, Stanford University
- **Douglas Holtz-Eakin**, President, American Action Forum
- Moderator: **Gregory Curfman**, Editor-in-Chief, Harvard Health Publications

Fifth Annual Health Law Year in P/Review

January 23, 2017

The Fifth Annual Health Law Year in P/Review symposium featured leading experts discussing major developments during 2016 and what to watch out for in 2017. The discussion at this day-long event covered hot topics in such areas as health policy under the new administration, regulatory issues in clinical research, law at the end-of-life, patient rights and advocacy, pharmaceutical policy, reproductive health, and public health law.

Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, Harvard Health Publications at Harvard Medical School, Health Affairs, the Hastings Center, the Program On Regulation, Therapeutics, And Law (PORTAL) in the Division of Pharmacoeconomics 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.

Industry participants:

- **Joseph R. Antos**, Wilson H. Taylor Scholar in Health Care and Retirement Policy, American Enterprise Institute
- **Claire Laporte**, Partner, Foley Hoag, LLP



Looking Forward: The Next Generation of Biosimilars

February 7, 2017

This panel of experts discussed the current state of biosimilars in the healthcare ecosystem and what comes next from a technical and legal perspective. Topics included how the next generation of biosimilars could improve patient access to standard-of-care therapies, the concept of “biobetters,” economic and intellectual property considerations, and policy approaches to support existing and future biosimilars.

Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and Eagle Biologics.

Speakers:

- **Jennifer DiGiacinto**, RRD International
- **Robert S. Langer**, MIT; Consultant, Eagle Biologics
- **Benjamin Roin**, MIT Sloan School of Management
- Moderator: **Aaron S. Kesselheim**, Brigham and Women's Hospital / Harvard Medical School

The Affordable Care Act: Past, Present, and Future: A lecture by William B. Schultz, General Counsel of HHS, 2011–2016

March 23, 2017

This lecture discussed the complicated politics surrounding the Affordable Care Act and the policy options for the future.

Speakers:

- **William B. Schultz**, Partner, Zuckerman Spader LLP
- Moderator: **Einer Elhauge**, Petrie Professor of Law at Harvard Law School and Founding Director of the Petrie-Flom Center

Critical Pathways to Improved Care for Serious Illness, Part I

March 10, 2017

Part II

June 23, 2017

Leading health care executives, experts, policymakers, and other thought leaders came together on a project to develop a guiding framework for providing improved care for people with serious illness. At these sessions, distinguished panelists discussed innovations in program design and pathways for delivering high quality care to an aging population with chronic illnesses, especially those with declining function and complex care needs.

Part of the Project on Advanced Care and Health Policy, a collaboration between the Coalition to Transform Advanced Care (C-TAC) and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.



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Speakers:

- **Namita Ahuja, MD**, Senior Medical Director, Medicare, UPMC Health Plan; Clinical Assistant Professor of Medicine, University of Pittsburgh
- **Gary Bacher, JD, MPA**, Founding Member, Healthsperien; Director, Institute for Health System Solutions, AHIP
- **John Eldridge Barkley, MD, FCCP, CM PACS**, Carolinas Healthcare System
- **Janice Bell, PhD, MPH, MN**, Associate Professor at the Betty Irene School of Nursing, University of California, Davis
- **Jon Broyles, MSc**, Executive Director, C-TAC
- **K. Eric De Jonge, MD**, Director of Geriatrics at MedStar Washington Hospital Center; Associate Professor of Medicine, Georgetown University School of Medicine
- **Timothy Ferris, MD, MPH**, Senior Vice President of Population Health Management, Partners HealthCare; Medical Director, Mass General Physicians Organization
- **Torrie Fields, MPH**, Senior Program Manager, Palliative Care, Healthcare Quality & Affordability, Blue Shield of California
- **Diana M. Franchitto, MBA**, President & CEO, HopeHealth
- **Muriel Gillick, MD**, Director, Program in Aging, Harvard Pilgrim Health Care Institute; Professor of Population Medicine, Harvard Medical School
- **Anna Gosline, SM**, Senior Director of Health Policy and Strategic Initiatives, Blue Cross Blue Shield of Massachusetts
- **Lauran Hardin, MSN**, Senior Director, Cross Continuum Transformation, Camden Coalition and the National Center for Complex Health and Social Needs
- **Emma Hoo**, Director, Pacific Business Group on Health
- **Kathleen Kerr**, Healthcare Consultant, Kerr Healthcare Analytics
- **Tom Koutsoumpas**, Co-Founder and Co-Chair, Coalition to Transform Advanced Care (C-TAC)
- **Khue Nguyen, PharmD**, Chief Operating Officer, C-TAC Innovations
- **David Longnecker, MD**, Chief Clinical Innovations Officer, C-TAC
- **Sally Okun, RN, MMHS**, Vice President, Advocacy, Policy, and Patient Safety, PatientsLikeMe
- **Russell Portenoy, MD**, Executive Director, MJHS Institute for Innovation in Palliative Care; Chief Medical Officer, MJHS Hospice and Palliative Care
- **David Posch, MS**, Executive Vice President, Population Health, Vanderbilt University Medical Center
- **Jay Rajda, MD, MBA, FACP**, Chief Clinical Transformation Officer, Aetna
- **Monique Reese, DSN**, Chief Clinical Officer Sutter Care at Home



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- **Theresa Schmidt, MA, PMP, CSPO**, Vice President of Strategy, Healthspieren; Director, Data and Quality, National Partnership of Hospice Innovation
- **Allison Silvers, MBA**, Vice President, Payment and Policy, Center to Advance Palliative Care
- **Robert Sowislo**, Government Affairs Officer, U.S. Medical Management
- **Mark Sterling, JD, MPP**, Senior Fellow, Project on Advanced Care and Health Policy, Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Harvard Law School; Chief Strategy Officer, C-TAC
- **Brad Stuart, MD**, Chief Medical Officer, C-TAC
- **Gwynn B. Sullivan, MSN**, Project Director, National Consensus Project, National Coalition for Hospice and Palliative Care
- **Jennifer Valenzuela, MSW, MPH**, Principal of Program Department, HealthLeads
- **Victoria Walker, MD, CMD**, Chief Medical & Quality Officer, The Evangelical Lutheran Good Samaritan Society
- **Robin Whitney, PhD**, Assistant Professor at University of California San Francisco School of Medicine

**Tailoring Justice: Science-Informed Decision Making
June 26–28, 2016**

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. *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.*

Industry participants:

- **Christine Dozier**, Chief Pretrial Services Officer, District of New Jersey
- **Martha Kane, PhD**, Clinical Director, West End Clinic Addiction Services, Massachusetts General Hospital
- **Mark Sherman**, Federal Judicial Center
- **Connie Smith**, Chief United States Probation and Pretrial Services Officer, Western District of Washington
- **Cassandra Snyder**, Federal Judicial Center



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 co-sponsor 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](#)
- Sponsored research projects primarily based at Harvard Medical School: the [Football Players Health Study at Harvard University](#) (with collaborators at [The Hastings Center](#) and a variety of other institutions) and [Harvard Catalyst](#) (with collaborators at various Harvard-affiliated medical centers and colleagues at Emory University)
- The [Patient Centered Outcomes Research Oversight Study](#), based out of Brigham and Women's Hospital
- Work with Case Western Reserve University (PI: Suzanne Rivera) on the [Specimen Science book project](#)
- Our [Project on Law and Applied Neuroscience](#) with the Center for Law, Brain, and Behavior at Massachusetts General Hospital
- Two major conferences, 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
- [Book projects](#) based on our conferences, with authors from a variety of institutions
- Collaboration with the Harvard Medical School's [Center for Bioethics](#) on events, conferences, and their Master's program in bioethics

We also 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
- Case Western Reserve University: [The Center for Child Health and Policy](#) and [University Hospitals Rainbow Babies & Children's Hospital](#)
- The [Center for Law, Brain and Behavior](#) at Massachusetts General Hospital
- The [Coalition to Transform Advanced Care \(C-TAC\)](#)
- [Edmond J. Safra Center for Ethics](#) at Harvard University
- [Harvard Catalyst](#)



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- [Harvard Department of Stem Cell and Regenerative Biology](#)
- [Harvard Health Publications at Harvard Medical School](#)
- [Harvard Law School Project on Disability](#)
- [Harvard Office of the Vice Provost for Research](#)
- [The Hastings Center](#)
- [Health Affairs](#)
- The [Health Ethics and Policy Lab](#), University of Zurich
- [HLS Animal Law and Policy Program](#)
- [HLS Center for Health Law Policy and Innovation](#)
- [HLS Criminal Justice Policy Program](#)
- [HLS Dean's Office](#)
- [HLS Human Rights Program](#)
- [HLS Library](#)
- [HLS Project on the Foundations of Private Law](#)
- [HMS Center for Bioethics](#)
- The [International Neuroethics Society](#)
- The [International Society for Stem Cell Research](#)
- [Multi-Regional Clinical Trials Center](#) at Harvard and Brigham and Women's Hospital
- The [New England Journal of Medicine](#)
- The [New York State Bar Association](#)
- 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 \(PRIM&R\)](#)



2017–18 Plans for Activities

(Fiscal Year 2018: July 2017–June 2018)

During the coming year, the Petrie-Flom Center will see the role of Executive Director transition from **Holly Fernandez Lynch** to **Carmel Shachar**. This transition provides an opportunity for the Center to re-evaluate its project portfolio as well as consider novel initiatives. 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.

Leadership Transition

The start of Fiscal Year 2018 will coincide with the transition of Center leadership from **Holly Fernandez Lynch** to **Carmel Shachar**. Holly finished her tenure as Executive Director of the Petrie-Flom Center on August 4, 2017. She will begin her new role at the Department of Medical Ethics and Health Policy at the University of Pennsylvania's Perelman School of Medicine as Assistant Professor and Assistant Faculty Director of Online Education in Fall 2017. Holly will continue to be involved in some key Petrie-Flom projects through Fiscal Year 2018. For example, she will be co-editor of the Center's volume on *Transparency in Health and Health Care*, along with Carmel Shachar, Professor of Law Barbara Evans (University of Houston), and Faculty Director Glenn Cohen. She will also continue on as a team member in the Patient Centered Outcomes Research Oversight Study (PCOROS).

Carmel, who joined the Center late in Fiscal Year 2017, will take over the Executive Director role as Holly departs. She will be responsible for the oversight of the Center's sponsored portfolio, event programming, fellowships, student engagement, development, and other duties of the Executive Director. Carmel will replace Holly on several key projects, such as providing leadership on the Center's collaboration with Harvard Catalyst's Regulatory Foundations, Ethics, and Law Program. The overlap between Holly and Carmel during the end of Fiscal Year 2017 and the start of Fiscal Year 2018 is intended to produce as smooth a transition in leadership as possible.

Carmel brings an expertise in health law policy to the Petrie-Flom Center. Her scholarship has recently focused on the impact that potential health care reform efforts by Congress and choices made by federal administrative agencies, such as the Department of Health and Human Services, will have on access to care for individuals living with chronic illnesses and disabilities. Carmel also has expertise in federal anti-discrimination laws, such as Section 1557 of the Affordable Care Act, as applied to health care access. She has extensive organizational and coalition leadership expertise, including leading key coalitions of disability focused organizations as they respond to federal health law and policy developments. Carmel's areas of expertise



will allow the Petrie-Flom Center to develop exciting new health law policy projects, including ones focused at the intersection of policy and bioethics.

Research, Scholarship, and Project Activities

Sponsored Research

As described above, we have three sponsored research projects that we will be working on during the next academic year:

- Our collaboration on **Harvard Catalyst's Regulatory Foundations, Ethics, and Law Program** will continue until the end of the current Catalyst grant from NIH in April 2018, during which time we will pursue various projects focused on improving recruitment and retention to clinical trials.

Our major project in FY18 will focus on the issue of “gatekeeping” recruitment. There exists a wide spectrum of practices across institutions concerning how patients and potential participants are approached for recruitment into clinical trials. Some institutions require patients to be approached by a clinician before researchers may have direct contact with them; others permit researchers to approach patients directly; still others give patients the opportunity to choose whether they would like clinicians to mediate or researchers to approach them directly. This project examines the ethical and practical issues involved with different approaches to gatekeeping clinical trials, and has an empirical and normative component. The empirical component involves reviewing institutional policies and practices and seeking feedback from key stakeholders, including IRB members and institutional officials, to better understand the current range of practices on this issue. The normative component enquires into the ethical assumptions made by different approaches to gatekeeping concerning patient autonomy, the physician-patient relationship, the appropriate roles and duties of researchers in clinical environments, and so on, mapping these considerations on to foundational ethical principles and seeking clarity on the optimal balance between competing considerations. Finally, this work explores in detail ethical issues implicated in emerging paradigms that seek to strike a balance between competing views about gatekeeping, for example, opt-in versus opt-out approaches to enrolling patients into research registries that give researchers the ability to contact them directly. This work will yield practical guidance outlining points to consider or best practices for institutions in this space.

As **Holly Fernandez Lynch** transitions out of her role, incoming Executive Director **Carmel Shachar** will take on a leadership role in this project alongside Faculty Director **Glenn Cohen**.



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Our work will ideally continue after April 2018, pending renewal of the CTSA for another 5-year term; the renewal application was submitted in May 2017.

- Our work on the **Patient Centered Outcomes Research Oversight Study (PCOROS)** will complete its second year in August 2017, with one remaining year of collaboration anticipated through August 2018. Work in year 3 will focus 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 HLS.
- Starting in January 2018, we will begin a new five-year project with the University of Copenhagen’s **Research Program in Biomedical Innovation Law (CeBIL)**. The Petrie-Flom Center, acting as a partner in a larger study funded by the Novo Nordisk Foundation, will provide 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. The Center’s work will include a detailed discussion of regulatory exclusivities and prize systems within the context of the ongoing development towards a more open, transparent, and collaborative innovation paradigm. Where possible, it will also consider ethical questions raised by innovation policy in this sphere including data ownership, transparency of algorithms, governance roles for patients, and equity in distribution of benefits. Among the key questions this study will address are:
 - What exactly are—or will be—the distinguishing features and added benefits of “black box” personalized medicine in comparison to traditional personalized medicine, and how relevant are these features to legal and ethical analysis?
 - What are the concrete scientific and legal hurdles to further development of “black box” personalized medicine, and how do these hurdles relate to failures of the current intellectual property regime and new case-law developments?
 - What alternative or complementary incentives can be considered, how do these interrelate and what are their advantages and drawbacks in different settings?
 - How much control should patients have over how their data is used to produce “black box” personalized medicine models and on the deployment of these models in their health care? What role should patient consent, patient governance, and transparency play in these contexts?



Glenn Cohen is committed to 5% effort over the five-year term of this project. He will participate in regular leadership meetings with other project leaders at the University of Copenhagen, and will both conduct research and supervise the work of a postdoctoral fellow to be hired for a three-year term. We anticipate beginning the search for the fellow in the fall 2017 semester and hiring the postdoctoral fellow to begin work at the start of calendar year 2018.

Project Activities

Journal of Law and the Biosciences

Our collaboration on JLB will continue for the journal's fifth volume, with the Petrie-Flom Center taking on the Managing Editorship of the journal in January 2018, when Project Coordinator **Justin Leahy** will add this role to his current slate of responsibilities. We will also oversee a new slate of Harvard contributors to the "Notes and Developments" section. Proposed contributions will be selected in early Fall 2018, and published in December 2018.

The Project on Law and Applied Neuroscience

Our collaboration with Massachusetts General Hospital's Center for Law, Brain and Behavior will continue for the fifth 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**.

2017–2018 Senior Fellow

Francis X. Shen, PhD, JD is the third Senior Fellow in Law and Neuroscience. Shen is currently an Associate Professor of Law and McKnight Presidential Fellow at the University of Minnesota; affiliated 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. In Spring 2015, he was a Visiting Scholar at the Petrie-Flom Center. He will pursue original research, mentoring, and public engagement on legal issues related to the aging brain, dementia, traumatic brain injury, and the law, as well as organizing a series of related events.

2017–2018 Area of Inquiry: Dementia and the 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.

Shen’s goal during his fellowship year will be to foster this interdisciplinary dialogue on dementia and the law. The Project on Law and Applied Neuroscience will 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 begin developing new theoretical and practical frameworks for more fairly and effectively adjudicating cases in which dementia plays a role.

Shen will be joined in this work by eminent CLBB faculty, including **Judge Nancy Gertner**, **Judith Edersheim** (both affiliated faculty of the Petrie-Flom Center), Lisa Feldman Barrett, , and Bruce Price.

Planned Events

Activities will include expert symposia and public events to promote focused discussion on how the law can more effectively respond to aging brain issues including dementia and traumatic brain injury. Some events that are currently in the early planning stages include:

- September 13, 2017: “The Neurolaw Revolution,” lecture by Senior Fellow **Francis Shen**
- November 3, 2017: Conference, co-sponsored by the ABA Journal, featuring Shen alongside Project Co-Lead **Judith Edersheim** and HLS Lecturer **Judge Nancy Gertner**, both of whom are Petrie-Flom affiliated faculty
- November 15, 2017: Panel discussion of dementia in judges and elected officials



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- February 14, 2018: Panel discussion on neuroscience and crimes of passion
- April 11, 2018: Panel discussion on youth sports concussions and the law
- April 26–27, 2018: Conference on dementia and the law, pending the procurement of additional funding

The Project on Advanced Care and Health Policy

Mark Sterling, 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. Yet these models face significant regulatory and policy barriers at the state level that inhibit their spread and thus limit access by patients and families. For instance, the current licensing structure in most states is institutional in nature, based on the practitioner furnishing care and the type of organization with whom the practitioner works, rather than on the nature of the services being provided.

These state-level policy barriers are 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 advanced care. These materials will include in-depth analyses of key states' legislation and regulation around this topic, factsheets on the key issues, and model legislation. 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, such as advanced care planning and shared decision-making. These events will be generative in the sense of developing recommendations, whitepapers, and reports.

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



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institutions. We hope to relaunch the program when additional funding is secured in the near future.

Faculty

In the summer of 2017, the Center will once again provide research support to **Profs. Cohen** and **Elhauge**.

I. Glenn Cohen will be finishing the Center's forthcoming edited volume, **BIG DATA, HEALTH LAW, AND BIOETHICS** (Cambridge University Press, 2018), and beginning work on a new volume based on the Center's 2017 annual conference, "Transparency in Health and Health Care" (under review). He will also work on new papers on artificial wombs, mitochondrial replacement therapy, ransomware, and other topics.

Einer Elhauge's summer funding is supporting preparation for his course "Redesigning Humans: What Limits" and 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 2017–2018 academic year; additional visitors may be added throughout the year:

Jean-Christophe Belisle Pipon, September 2017–October 2020

Jean-Christophe Belisle Pipon will complete his PhD in Bioethics at the University of Montreal in Fall 2017. He joins the Petrie-Flom Center as a Visiting Researcher 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 collaborate with Faculty Director 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.



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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 globalisation, and global public health. During her visit with Petrie-Flom, she will pursue research on the legal and ethical challenges associated with regulation of new technologies. She is also currently engaged in the application for Fulbright funding that would support her in a return visit in 2018 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 Petrie-Flom he will be pursuing research on assisted reproductive technologies in halakhic law, as well as a project entitled "Family Dichotomies and Their Moderation: Comparative Religious Perspectives."

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



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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 visit she will work 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, she is particularly interested in the work of the Project on Law and Applied Neuroscience and collaboration with the 2017–2018 Senior Fellow, Francis Shen.

Sara Gerke, April–July 2018

Sara Gerke will join 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 is 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 will pursue research on reproductive and regenerative medicine, from a comparative legal perspective (i.e., US, EU, German and UK law).



Book Projects

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

- We have completed all work on **LAW, RELIGION, AND HEALTH IN THE UNITED STATES** (co-edited by Holly Fernandez Lynch, I. Glenn Cohen, and Elizabeth Sepper), which will be released by Cambridge University Press in late summer 2017. This book stems from the Center's 2015 annual conference. The HLS Library will host a book launch in September 2017.
- **SPECIMEN SCIENCE: ETHICS AND POLICY IMPLICATIONS** (co-edited by Holly Fernandez Lynch, Barbara E. Bierer, I. Glenn Cohen, and Suzanne M. Rivera), stemming from our Fall 2015 conference on regulatory and ethical issues in biospecimen research, will be published by MIT Press in October 2017. The HLS and HMS libraries are jointly hosting a book launch in November 2017.
- We have recently submitted the full manuscript for the book **BIG DATA, HEALTH LAW, AND BIOETHICS** (co-edited by I. Glenn Cohen, Holly Fernandez Lynch, Effy Vayena, and Urs Gasser), stemming from the Center's 2016 annual conference. The manuscript is slated for publication by Cambridge University Press in early 2018.
- Finally, we have submitted a book proposal (co-edited by I. Glenn Cohen, Holly Fernandez Lynch, Barbara J. Evans, and Carmel Shachar) stemming from our 2017 annual conference, **TRANSPARENCY IN HEALTH AND HEALTH CARE**, which is currently under review by Cambridge University Press. We hope to have a contract finalized shortly, and have already begun working on the manuscript in hopes of publishing the book as soon as possible.



Events Programming and Conferences

Over the 2017–2018 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. The following are confirmed to date, with 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:

Major Events/Conferences

Conference on Neuroscience and the Law November 3, 2017

Sponsored by the ABA Journal. Part of the Project on Law and Applied Neuroscience.

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

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

Sixth Annual Health Law Year in P/Review December 12, 2017

Conference on animal research law January 2018

Cosponsored by the Animal Law and Policy Program at Harvard Law School and the Institute for Laboratory Animal Research.

Conference on value-based purchasing in health care March 2, 2018

Cosponsored by Ropes & Gray LLP, and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

Development and Certification of Decision Aids for Shared Decision Making April 2018

Part of the Project on Advanced Care and Health Policy.

HMS Center for Bioethics Annual Conference April 2018

Conference: Dementia and the Law April 26–27, 2018

Part of the Project on Law and Applied Neuroscience.



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Conference on evidence-based pre-trial diversions for mental illness and addiction (invitation only)

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. Part of the Project on Law and Applied Neuroscience.

Ordeals in Healthcare: Ethics and Efficient Delivery

May 10–11, 2018

Sponsored by the Edmond J. Safra Center for Ethics at Harvard University, the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, and the Mossavar-Rahmani Center for Business and Government at the Harvard Kennedy School of Government.

2018 Petrie-Flom Center Annual Conference on disability and health law

June 1, 2018

Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and the Harvard Law School Project on Disability.

Conference to conclude PCOROS research project

June 2018

Lectures, Panels, and Other Events

2017 Petrie-Flom Center Open House

September 13, 2017

The Neurolaw Revolution: A Lecture by Francis Shen

September 13, 2017

Part of the Project on Law and Applied Neuroscience.

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

September 27, 2017

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

Panel discussion on health care reform

October 3, 2017

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

Panel discussion pharmaceutical pricing and development

October 4, 2017



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**HLS in the World: New Technologies, New Dilemmas: Part of the HLS|200
Bicentennial Celebration**

October 27, 2017

This event is sponsored by Harvard Law School as part of the HLS|200 bicentennial celebrations.

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.

Panel discussion on dementia in judges and elected officials

November 15, 2017

Part of the Project on Law and Applied Neuroscience.

Panel discussion on neuroscience and crimes of passion

February 14, 2018

Part of the Project on Law and Applied Neuroscience.

Panel discussion on youth sports concussions and the law

April 11, 2017

Part of the Project on Law and Applied Neuroscience.

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.

Digital Health @ Harvard brown bag lunch series

Monthly, September 2017–April 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.



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 **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. **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 2017

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 2017–2018 workshop will host the following scholars:

- **Aziza Ahmed**, Northeastern University School of Law (Petrie-Flom Visiting Scholar, 2014)
- **Belinda Bennett**, Queensland University of Technology Law School (Petrie-Flom Visiting Scholar, Fall 2017)
- **Timothy Caulfield**, University of Alberta
- **Allison Hoffman**, University of Pennsylvania Law School (Petrie-Flom Academic Fellow, 2008–2010)
- **Renee Landers**, Suffolk University Law School
- **Jody Madeira**, IU Maurer School of Law
- **Thaddeus Pope**, Mitchell Hamline School of Law
- **Rachel E. Sachs**, Washington University School of Law (St. Louis) (Petrie-Flom Academic Fellow, 2014–2016)
- **William Sage**, Texas Law (UT Austin)
- **Francis Shen**, University of Minnesota Law School (Petrie-Flom Senior Fellow in Law and Applied Neuroscience, 2017–2018)
- **David Studdert**, Stanford Law School
- **Alicia Yamin**, Georgetown Law (Joseph H. Flom Global Health and Human Rights Initiative Fellow at Petrie-Flom, 2006–2007)



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

Fall 2017

Underlying the current health care debate engulfing Washington 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 Affordable Care Act's individual mandate and the relevant Religious Freedom Restoration Act developments. Building from this context, 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. It will culminate in a student-chosen project arising from the course materials—students will write a rights-enforcing instrument, which may include an administrative filing, a federal court complaint, or a regulatory comment. 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 2018

With guest lectures and contributions to classroom discussion from Senior Fellow **Francis X. Shen**, this course will again be offered as part of the Project on Law and Applied Neuroscience. 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.

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 will cover a range of literature on that topic.

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

I. Glenn Cohen (HarvardX)

Current session scheduled to end on October 16, 2017. HarvardX will launch 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



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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 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.



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 several 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. Student Fellows will be selected in mid-August.

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.

Journal of Law and the Biosciences Student Contributors

As noted above, the Petrie-Flom Center will be responsible for populating the “Notes and Developments” section for one issue of the annual JLB volume. Contributions will be written by Harvard graduate students and post-docs, who will be selected in spring 2018 for publication later in the year.



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 2018, along with the next several years, will be an exciting time in our history. We will focus on thinking creatively about our project portfolio as well as our internal structures and programs. We will focus on rounding out our project portfolio by adding projects focused on the intersection of health law policy and bioethics to complement our clinical research ethics expertise. We will also consider how best to grow the Center, including exploring the establishment of an advisory board and revamping our post-doctoral fellowship to have a broader focus. While we engage in this creative exploration, the Petrie-Flom Center will also remain focused on extending existing projects (such as our partnership with Harvard Catalyst) and nurturing our new collaboration with the University of Copenhagen that will launch in the coming year. 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. As such, our goal is for the Center to establish several new projects that will be funded, staffed, organized, and prepared to interact substantively with policymakers at all levels, providing independent expert analysis, policy recommendations, empirical research, and practical solutions to pressing health law policy 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 health law policy projects. All of these projects are contingent upon securing appropriate funding. These possible projects include:

- A collaboration with Northeastern University's Center for Health Policy and Law and Robert Greenwald's Center for Health Law and Policy Innovation, examining the ethical, policy, and public health impacts of including welfare services, such as nutrition and housing, within the medical system. Increasingly, medical providers and social services providers are collaborating on services to address the social determinants of health. The move to justify access to these services on the basis of health as opposed to on the basis that human beings have an *a priori* right to basic food and housing is an important shift in the ethical and policy framing of social services. This collaboration will seek to articulate what is gained and what is lost by explicitly connecting social services, such as housing, to medical need.



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- An initiative to articulate the importance of bioethical principles to health care reform and delivery, targeted to state level policymakers and regulators. We are entering a period in which state governments will have large latitude over consumer protections, the health of their health care markets and their Medicaid programs through federal 1332 and 1115 waivers. The initiative may be guided by a roundtable of health law policy and bioethics experts. This initiative will be designed to produce comprehensive and useful materials for state legislators, regulations, and other policymakers as they evaluate the choices available to them.
- A project to evaluate health care equity concerns in health insurance structures. As health care becomes increasingly expensive, stakeholders, such as insurers and providers, must develop creative allocation solutions. For example, in response to the skyrocketing cost of pharmaceuticals and new consumer protections, insurers are increasingly relying on novel benefit designs such as extremely high co-insurance for medications utilized by high cost enrollees. This project would seek to articulate when these benefit designs are a reasonable reflection of the high cost of health care and when they present equity concerns.

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 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 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.

We have begun contemplation of whether to expand the Petrie-Flom structure to include a formal Advisory Board. The purpose of this Board would be to 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 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.

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



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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.