



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

*Annual Report, Fiscal Year 2016
July 2015–June 2016*

Executive Summary

Every year, the Petrie-Flom Center seems to be more abuzz with activity – events, scholarship, sponsored research, and new collaborations – and this year was no exception. While we pride ourselves on constant forward motion, it is nice every now and then to reflect on where we have been and what we have accomplished so far. The process of writing each year’s annual report allows us to do just that, but this year, we also had the wonderful opportunity to celebrate the Center’s first decade with a banner event on the Future of Health Law and Policy, featuring commentary from prominent HLS alumni and our accomplished network of former Center fellows, who are now spread all over the country and beyond. This celebratory conference highlighted the impact the Center has had on health law, policy, and bioethics, and its extraordinary reputation as a leader in these fields (watch the short video [here](#)).

Never ones to stop moving, we also used the conference as an opportunity to unveil our plans for the Center’s second decade, during which we hope to expand our capacity to influence policymaking by establishing several new Topical Programs – Law and Bioethics; Health Care Delivery and Finance; and Medical Innovation and Law – that will provide independent expert analysis, policy recommendations, empirical research, and practical solutions to pressing issues, in the form of policy briefs, white papers, model legislation, public commentary, and real-time responses to emerging issues and opportunities. We are actively engaged in fundraising activities to help make this vision a reality.

The Center’s sponsored research portfolio made substantial progress this year. The Law and Ethics Initiative of the Football Players Health Study at Harvard is gearing



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up to launch a series of reports beginning in Fall 2016 through 2017 focused on structural mechanisms to improve the health of professional football players, including an extensive set of recommendations for various stakeholders to support this goal. Our work as part of Harvard Catalyst's Regulatory Foundations, Ethics, and Law Program has made strides toward improving recruitment to clinical research by generating guidance on how to ethically utilize social media tools for recruitment, evaluating the parameters for ethical payment of research participants, and considering the need to prioritize studies that compete for the same pool of potential participants, as well as launching new projects related to recruitment to biobanking studies, among others. We also launched a new sponsored research project focused on assessing ethical and regulatory oversight issues in patient-centered research, and developing recommendations for Institutional Review Boards as they are increasingly called on to review such studies. Each of these projects will continue through the next fiscal year.

Our collaboration with the Center for Law, Brain and Behavior at Massachusetts General Hospital, the Project on Law and Applied Neuroscience, continued for its second year with a focus on neuroscience and juvenile justice. We also launched a parallel program, the Project on Advanced Care and Health Policy, with collaborators at the Coalition to Transform Advanced Care; this new Project 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. In addition, our collaboration on the Journal of Law and the Biosciences continues, as the Journal has quickly become a leading source of cutting-edge, interdisciplinary scholarship in the field. Similarly, our collaborative, interdisciplinary blog, Bill of Health, remains a go-to source for real-time commentary and scholarly insights on range of health policy and bioethics issues, with increased attention from news media and others leading to press interviews and scholarly collaborations.

The Center's public events schedule was packed as always, with panel discussions, lectures, conferences, and workshops on a wide range of topics, including law and neuroscience, animal research, synthetic biology, bioenhancement, regulation of pharmaceutical products, fetal pain, research with biospecimens, advanced care policy, consumer models of health care, and non-invasive prenatal diagnosis, among others. We hosted national policymakers, including Margaret (Peggy) Hamburg, former FDA Commissioner, and Donald Berwick, former administrator of the Center for Medicare and Medicaid Services, as well as Andrew Dreyfus, President and CEO, Blue Cross Blue Shield of Massachusetts. This year's annual conference, Big Data, Health Law, and Bioethics, sparked collaboration with the Berkman Klein Center for Internet and Society at Harvard and the Health Ethics and Policy Lab at the University of Zurich.



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Many of our larger events result in publications, including edited volumes from academic presses. FDA in the 21st Century: The Challenges of Regulating Drugs and New Technologies, stemming from our 2013 annual conference, was released in Fall 2015, and Nudging Health: Health Law and Behavioral Economics, stemming from our 2014 annual conference, will be released this Fall. We are also in the midst of completing work on two additional volumes, Specimen Science: Ethics and Policy Implications and Law, Religion, and Health in the United States, for release in 2017.

Our affiliates continue to make important contributions to the teaching curriculum, with courses on health law policy and bioethics, medical innovation, and law and neuroscience. They are also prolific scholars, writing on such topics as religious freedom and health care, biospecimen research, reproductive technologies, health law policy, suicide risk, electronic health technologies, insurance, innovation law, neuroscience, research ethics, food and drug law, and more. Our departing Academic Fellow, Rachel E. Sachs, secured a phenomenal placement as a tenure-track professor at Washington University in St. Louis School of Law, and our Student Fellows developed scholarly contributions in the areas of food and drug law, genetic privacy, Medicaid policy, and intersex rights. A number of other students engaged substantively in Center projects as research assistants.

In the 2017 Fiscal Year, we look forward to continuing our core work related to sponsored research, scholarship, policy work, teaching and mentoring students, public engagement, and other collaborations, as well as making new strides toward our next phase of growth and development.

With sincere thanks to everyone who supports our work,

I. Glenn Cohen

A handwritten signature in black ink, appearing to read "I. Glenn Cohen".

Faculty Director and Professor of Law, HLS

Holly Fernandez Lynch

A handwritten signature in black ink, appearing to read "Holly Fernandez Lynch".

Executive Director



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2015–16 Report of Activities

(Fiscal Year 2016: July 2015–June 2016)

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 12,500 unique monthly users; and our website filled with guides and other resources for the public.
- (2) ***Academic programs***, including our post-doctoral fellowship, which has generated a cadre of leading health law professors; 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 end-of-life care.
- (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



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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. Our fellows bring their own areas of focus, ranging from medical innovation to health care finance to medical privacy, to name but a few.

Leadership

During FY16, the Center was led by Faculty Director Professor **I. Glenn Cohen** and Executive Director **Holly Fernandez Lynch**.



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, and also took steps in some new directions. These accomplishments are described in more detail below.

Sponsored Research

The Center is currently engaged in three sponsored research projects, and wrapped a fourth this year.

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 the risks – of participating in football.

FPHS began in 2014 in part through an award from the National Football League Players Association (NFLPA). The Study largely utilizes funds allocated for research by the Collective Bargaining Agreement between the NFLPA and the NFL. Many of the resources utilized by this initiative are shared across supporting Harvard institutions. 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 working on prevention, diagnostics, and treatment strategies for the most common and severe conditions affecting professional football players. We are focused on the integrated health of football players, not solely one concern or condition. In addition, the Study is working to understand the legal and ethical issues that may promote or impede player well-being, and developing responsive recommendations to resolve them. The Law and Ethics Initiative of the Football Players Health Study is led by the Petrie-Flom Center, and the Initiative's initial scope of work will be largely complete in May 2017.



The Law and Ethics Initiative

Glenn Cohen and **Holly Fernandez Lynch** co-lead the FPHS Law and Ethics Initiative. **Christopher Deubert** is the Senior Law and Ethics Associate on this project, which is supported by **Justin Leahey**, Project Coordinator. Our work is also guided by the **FPHS Leadership Team** and an independent panel of experts who comprise the **Law and Ethics Advisory Panel (LEAP)**.

Key Law and Ethics projects are described below. The Law and Ethics Initiative team also works to advise on legal and ethical issues that may arise in other components of the Football Players Health Study, for example participant confidentiality, results return, and the like.

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

Projects

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

Summary: This initiative identifies stakeholders in player health, analyzes their legal and ethical obligations, evaluates current successes, and identifies gaps and opportunities for each stakeholder in protecting and promoting player health. Finally, it applies 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 includes more than 70 recommendations aimed at improving player health, and will be released in Fall 2016.

**The Hastings Center Report – Special Report:
“NFL Player Healthcare: Proposed Solutions to Club Doctors’ Conflicts of Interest”**

Summary: This project urges the NFL, NFLPA, and other stakeholders to adopt the principal recommendation of our forthcoming Report, “Protecting and Promoting the Health of NFL Players: Legal and Ethical Analysis and Recommendations,” for resolving the 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. The publication includes commentaries from a diverse and highly-qualified group of experts, and will



be published as a Special Report of the leading bioethics journal, The Hastings Center Report, in November/December 2016.

Evaluating NFL Player Health and Performance: Legal and Ethical Issues

Summary: Conducted with our colleague, Jessica L. Roberts (University of Houston Law Center), this research investigates the path of a hypothetical college football player who has aspirations to play in the NFL, addressing from a legal and ethical perspective the types of health and performance evaluations he will 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 law regarding genetic testing, this article seeks to answer these questions, as well as provide recommendations to better protect the health and privacy of professional football players. It will be published in the University of Pennsylvania Law Review, January 2017.

Comparing the Health-Related Policies and Practices of the NFL to Other Professional Sports Leagues (“Comparative League Analysis”)

Summary: This initiative examines the policies and practices of the NFL that concern player health, comparing them to those of other major professional sports leagues and organizations, including Major League Baseball, the National Basketball Association, the National Hockey League, the Canadian Football League, and Major League Soccer. The goal of the Comparative League Analysis is to determine if there are ways the NFL can better support the safety, health, and welfare of its players, or ways in which the NFL’s policies are superior to those of the other leagues and organizations. The report includes approximately ten recommendations to improve player health, and will be released in early 2017.

Qualitative Study/Listening Tour

Summary: In collaboration with our colleague Sarah McGraw (The Hastings Center), this study consists of a series of one-on-one interviews that solicit direct feedback from approximately 40–60 players and their families. The goal is to better understand the perspectives of these key stakeholders on the following topics: overall NFL experience, improving player safety, health, family and social issues, support as a professional athlete, life after football,



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risk disclosure and risk taking, healthcare and club medical staff, medical screenings, and injury and pain management. Findings from this study will inform the NFL, NFLPA, and other stakeholders on how to better understand and prioritize action concerning player health matters.

Events

We are currently planning a public conference to introduce and discuss the various projects of the Law and Ethics Initiative in Spring 2017. We have also participated in the following events, and had a panel accepted for the December 2016 Society for Risk Analysis Annual Conference:

Is Professional Football Safe? Could We Make It Safer? Perspectives from Neuroscience, Law, and Ethics

October 15, 2015

Panel session at the 2015 Annual Meeting of the International Neuroethics Society in Chicago

The Football Players Health Study at Harvard University

June 3, 2016

Panel session at The American Society of Law, Medicine and Ethics Annual Health Law Professors Conference in Boston, MA

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

December 2016

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

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 through at least July 2017. The Center's work on this project is 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. In addition, HLS student **Emily Largent** (JD, PhD 2016) has served as a critical Research Associate, collaborating on various aspects of the project on payment to research participants, described below.

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

Summary: 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. The guidance document will be disseminated at various venues in the coming months, and a derivative academic article, *Using Social Media as a Research Recruitment Tool: Ethical Issues and Recommendations*, has been accepted for publication in the American Journal of Bioethics.

Evaluating Offers of Payment to Research Participants

Summary: 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. A law review article on these topics, *Paying Research Participants: Regulatory Uncertainty, Conceptual Confusion, and a Path Forward*, was accepted for publication by the Yale Journal of Health Policy, Law, and Ethics (forthcoming 2017), and a second article directed at helping IRBs and investigators promote "fair" payment will be completed shortly. These academic articles and an expert working group that will be launched in late 2016 will form the



basis for a set of practical guidance materials for investigators and IRBs, scheduled for completion in the spring of 2017.

When Clinical Trials Compete: Prioritizing Study Recruitment

Summary: 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. In FY16, this project completed a foundational article examining the ethical and practical grounds for prioritizing trials, which is forthcoming in the *Journal of Medical Ethics*. A second aspect of the project, currently underway, consists of an empirical study, interviewing individuals involved with prioritization procedures at their research institutions and convening focus groups to build consensus around best practices. This will result in a practical guidance document in early 2017.

Motivations for Participating in Biobanking for Research

Summary: 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, and this will become increasingly true if proposed revisions to the federal regulations are finalized. In that context, it is essential to better understand why individuals who are asked for permission to have their biospecimens used for research purposes say “yes” or “no.” This project undertakes an empirical research project, in collaboration with colleagues at Partners Healthcare, Emory University, and the Medical University of South Carolina (with others pending), administering surveys to individuals who are offered the opportunity to participate in biobanking protocols about why they agree or decline. This data will be used to target educational efforts and refine the biobank recruitment process, issuing in a practical guidance document to be completed for summer 2017.



e-Consent

Summary: There is growing interest in the research community in documenting informed consent for research using digital platforms and electronic means. While the federal government has issued guidance stating that e-consent is acceptable under certain circumstances, there remains uncertainty about how to implement e-consent in ways that comply with state laws and minimize ethical concerns. This project will provide recommendations to IRBs and investigators faced with navigating the legal and ethical challenges of using electronic means to document informed consent for research, in the form of a guidance document scheduled for completion in 2017.

Simplifying Consent

Summary: This project aims to create a simplified consent form separating the explanation of study-specific research information from common elements of consent (e.g., subject injury, HIPAA) that are held in common between institutional consent forms and therefore are capable of being templated. To accomplish this, language from different consent forms will be compared and harmonized and focus groups will be convened to reach consensus on what should be placed in a standardized section. The project aims to pilot its simplified consent forms in 2017.

Educational Initiatives

The Center's affiliates working on this project have also been involved in various educational initiatives, including lectures for Harvard Catalyst's Introduction to Translational Medicine (ITTM) course, the Catalyst Clinical Trial Design Course, and Catalyst's Program in Clinical and Translational Investigation (PCaTS).

Events

We have participated in a number of events related to our Harvard Catalyst work in FY16, with several additional events planned:

The Ethics of Paying Research Subjects: Perspectives from IRBs and Investigators

July 20, 2015

Presentation to the Staff of the Presidential Commission for the Study of Bioethical Issues

Evaluating Offers of Payment to Research Participants

June 15, 2016

Presentation at the Dana Farber Cancer Institute Ethics Grand Rounds



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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

The Patient-Centered Outcomes Research Oversight Study (PCOROS)

In September 2015, the Petrie-Flom Center joined a collaborative project called the "Patient-Centered Outcomes Research Oversight Study," or PCOROS, led by Principal Investigator Joel Weissman and informed by input from an advisory committee that includes ethics thought leaders, patient advisors, human subjects protection professionals, and investigators. The project is funded through a contract from the Patient-Centered Outcomes Research Institute (PCORI) to Brigham and Women's Hospital, with a subaward to the Petrie-Flom Center (to be renewed through August 2018). The Petrie-Flom Center's work on PCOROS is co-led by I. Glenn Cohen and Holly Fernandez Lynch. Emily Largent (HLS 2016) has been the Research Associate on this project, and will continue to serve in that role until August 31, 2016.

There is a substantial gap in evidence regarding the novel ethical and regulatory challenges, if any, that may be posed by patient-centered outcomes research (PCOR) as relevant to human subjects protection and oversight. The goal of this project 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?



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Key objectives include:

- A qualitative research study that will catalogue the practical and ethical challenges encountered by IRB members, patient research partners, and other stakeholders dealing with PCOR. This will be accomplished through focus groups, interviews with key thought leaders (largely conducted by **Emily Largent**), and in-depth case studies at research sites conducting PCOR.
- A national survey of IRB members on PCOR and human subjects protection and oversight.
- Development of an ethical framework and evidence-based policies (“whitepaper”) to guide investigators, sponsors, institutions, and IRBs in the conduct and oversight of PCOR.
- Public conferences, events, and publications to facilitate discussion of ethical and regulatory issues related to PCOR and to solicit feedback from stakeholders on the proposed ethical framework and policy recommendations.

In addition to participating in the empirical research projects, the Petrie-Flom Center will lead the development of the ethical framework and recommendations, and will host a public conference in 2018.

Specimen Science: Ethics and Policy Implications, Conference and Book Project

In Spring 2015, the Petrie-Flom Center joined forces with Suzanne M. Rivera, Principal Investigator of a grant from the National Human Genome Research Institute of the National Institutes of Health (Award Number R01HG005691) called “Advancing Collaborative Genetic Research: Ethical and Policy Challenges.” The Center was awarded a subcontract (expiring in February 2016) to collaborate on a public conference and development of an edited volume focused on topics associated with 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. These topics are particularly timely as the federal government is currently considering dramatic revisions to the regulations currently governing secondary research with biospecimens.

The Center hosted a conference on these issues on November 16, 2015, called Specimen Science: Ethics and Policy Implications, with additional support from Harvard Catalyst. The conference was an overwhelming success, with over 150 people in the audience from government, industry, and hospitals and universities around Boston and across the United States. Conference presenters, and additional invitees, contributed chapters for an edited volume, the



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manuscript for which was submitted at the end of June 2016 and is under contract with MIT Press. The volume is co-edited **Holly Fernandez Lynch**, **Barbara E. Bierer**, **I. Glenn Cohen**, and **Suzanne M. Rivera**.

Additional Efforts

To further develop our sponsored research portfolio, the Center again collaborated with **Rosamond Rhodes**, Icahn School of Medicine at Mount Sinai, to resubmit in December 2015 a proposal to NIH for a project on “Barriers to Research on Controlled Drugs for HIV-Related Treatment.” Despite scoring extremely well for the fourth time, the application went unfunded. We note that this is a particularly contentious area of research, due to its focus on controlled substances and drugs of abuse, likely subject to substantial political pressures and concerns. We do not plan to resubmit this application, although we remain convinced that the research is important and compelling.



Project Activities

In addition to sponsored research, the Petrie-Flom Center is involved with 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, advanced care planning, and food law.

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 third 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** oversees 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 has seen extraordinary growth this year, with nearly 70,000 downloads since July 1, 2015 (up from 15,000 in its first year). Slightly more than half of JLB’s readership comes from North America, with 20% in Europe and more than 15% located in Asia and Oceania.

Project on Law and Applied Neuroscience

In Fall 2014, the Petrie-Flom Center began 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



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in residence at the Petrie-Flom Center, public symposia at Harvard Law School, and a Law and Neuroscience Seminar (taught by the Hon. Nancy Gertner).

In Fall 2015, **Robert Kinscherff**, PhD, JD, became the second Senior Fellow in Law and Neuroscience; his term has just been extended, and he will be 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.

Events

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

From Troubled Teens to Tsarnaev: Promises and Perils of Adolescent Neuroscience and Law

September 28, 2015

Should the Science of Adolescent Brain Development Inform Legal Policy?: A Lecture by Laurence Steinberg, PhD

November 13, 2015

Fetal Pain: An Update on the Science and Legal Implications

February 10, 2016

Boys to Men to Boys: What is the Role for Psychology and Neuroscience in Resentencing and Parole after *Miller and Montgomery*?

April 13, 2016

Project on Advanced Care and Health Policy

In March 2016, the Petrie-Flom Center launched a brand new 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.



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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 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 aims to host a variety of public events and workshops with business leaders, policymakers, and legal scholars. On June 21, 2016, we hosted the inaugural event of the collaboration, a conference entitled "[Aligning People and Policy: Why the Time Is Right to Transform Advanced Care](#)," featuring policymakers, thought leaders, family caregivers, clinicians, consumer advocates, and others working to identify timely, practical, and actionable opportunities to transform care for people with advanced illness nearing end-of-life. The event, which concluded with a networking lunch, brought together over 100 scholars and practitioners. A press release describing the event is available [here](#).



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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 ramps up, 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 **Mark Sterling**) become a member of the **Massachusetts Coalition on Serious Illness Care**. The Massachusetts 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.

We are also coordinating with the Center for Health Law and Policy Innovation at HLS on areas of overlapping interest.

Digital Health @ Harvard

This year, the Petrie-Flom Center launched an informal collaboration with the Berkman Klein Center for Internet and Society, called Digital Health @ Harvard, in order to bring 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, the goal of the program is to discuss ongoing research in this area, share new developments, identify opportunities for collaboration, and explore the digital health ecosystem more generally.

Faculty Director **I. Glenn Cohen** gave the first lecture in the series on February 17, 2016, discussing the use of big data to create predictive algorithms for clinical use in hospitals and other health care systems.



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. We promote this scholarship through programs for post-graduate fellows, visiting scholars, and other Petrie-Flom affiliates. Contributions to student scholarship are described separately.

Academic Fellows

Since 2006, the Center's Academic Fellowship has offered a two-year post-doctoral program designed to identify, cultivate, and promote promising scholars early in their careers. In addition to their own independent research and writing, Academic Fellows have advanced the Center's mission by mentoring students, teaching seminars, presenting their work at Harvard and beyond, and planning and participating in a range of public events and closed workshops. Prior fellows are now employed as tenured or tenure-track professors at institutions such as Harvard, UC Berkeley, Cambridge (UK), Boston University, UCLA, Cornell, the University of Texas at Austin, the University of Arizona, the University of Michigan, and Union Graduate College.

As we celebrated the Center's 10th Anniversary this year, we were thrilled to host a gathering of nearly all of our former Academic Fellows in March 2016. Many of our former Fellows contributed to a video on the occasion, in which they reflected on their time at the Petrie-Flom Center and, more broadly, the Center's impact on scholarship in the fields of health law, health policy, and bioethics.

Although the fellowship has been a cornerstone of the Center since its inception, we have decided to discontinue it temporarily at the end of this fiscal year as we pursue new funding opportunities and Topical Programs. We hope to reinstate the Academic Fellowship as soon as possible.

The work of our departing Academic Fellow, **Rachel E. Sachs**, over the second year of her fellowship is summarized below. Rachel has been appointed an Associate Professor at the Washington University in St. Louis School of Law, where she will continue to teach and research at the intersection of patent law and health law, with a particular focus on problems of innovation in and access to health care technologies.



Rachel E. Sachs, 2014–2016

During her second year at Petrie-Flom, Rachel finished and published two law review articles, *Innovation Law and Policy: Preserving the Future of Personalized Medicine*, now published in the University of California-Davis Law Review, and *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, forthcoming in the Harvard Journal of Law & Technology, as well as a co-authored book chapter on the principle of justice in biospecimen research (forthcoming in the Center's edited volume on the subject) and a short essay linking bioethics research with patent infringement law, forthcoming in *IP Theory*. Rachel had the opportunity to present these papers at a dozen conferences, colloquia, and talks at law schools around the country. *Prizing Insurance* in particular has received attention from other scholars, who have written favorable reviews of the piece on widely read law professor blogs, including Written Description and IOTWELL. In her research, teaching, and blogging, Rachel has continued to focus on questions of innovation policy at the intersection of patent law and health law.

Rachel has also continued her work focused more specifically on innovation policy and the microbiome, an area which enables her to foster collaborations with physicians and scientists. She presented an essay she co-authored and published last year, *Ensuring the Safe and Effective FDA Regulation of Fecal Microbiota Transplantation*, at an NIH Working Group on the subject in December 2015. She also presented on the links between patent law and microbiome-based technologies at an MIT Translational Microbiome Workshop held in November 2015.

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 also generally expect visitors to present on the topic of their research at a public lecture, and blog about their work at Bill of Health.



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We hosted several outstanding visitors this year:

Peng Zhao, August 2015–August 2016

Peng Zhao is Associate Professor at the China University of Political Science & Law. 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.

Due to his participation in the Center’s workshop, lectures, and conferences, Professor Zhao has developed a new academic interest in human subjects research regulation. He has begun a new project on China’s oversight of life sciences research, which has been approved for funding by China’s National Social Science Foundation.

Mary Anne Bobinski, August–September 2015

Mary Anne Bobinski has been at the Allard School of Law at the University of British Columbia since 2003, where she served as Dean from 2003 to 2015. She previously served as the John and Rebecca Moores Professor of Law and Director of the Health Law and Policy Institute at the University of Houston Law Center in the United States. Professor Bobinski’s research and teaching interests include torts, health law, health care finance and bioethics, legal aspects of HIV infection, and reproductive health law issues. She is a co-author of two leading law school casebooks in the United States, HEALTH CARE LAW & ETHICS and AIDS: CASES AND MATERIALS; the co-author/co-editor of a two volume set on medical ethics; and has authored a number of law review articles and book chapters on health law topics.

During her time at the Petrie-Flom Center, Professor Bobinski focused on U.S. health care law issues while also broadening her comparative base to countries beyond the U.S. and Canada. Specifically, she worked on updates to her health law casebook as well as immersing herself in research and debate about a range of key issues in U.S. health care law and policy, biotechnology and bioethics.

Professor Bobinski returned to the Center in March 2016 to deliver a lecture on her current research, “The Limits to Consumerism in Health Care.”



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Kuei-Jung Ni, June–August 2016

Kuei-Jung Ni is 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 LL.M. from the University of California, Berkeley, School of Law, and a Ph.D. in Law from the University of Edinburgh School of Law. During his 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.

Faculty Summer Research Support

The Center contributes summer support for HLS faculty research projects related to our areas of interest. In Summer 2015, we supported the following:

I. Glenn Cohen worked on a number of book projects, including:

THE OXFORD HANDBOOK OF U.S. HEALTH CARE LAW (Oxford University Press, 2015-2016) (co-editor with Bill Sage and Allison Hoffman).

NUDGING HEALTH: HEALTH LAW AND BEHAVIORAL ECONOMICS (John Hopkins University Press, 2016) (co-editor with Holly Fernandez Lynch and Christopher Robertson).

LAW, RELIGION, AND HEALTH IN THE UNITED STATES (Cambridge University Press, forthcoming 2017) (co-editor with Holly Fernandez Lynch and Elizabeth Sepper).

He also authored numerous medical and legal journal articles that he worked on during this period of summer funding. Finally, he used the support to do significant writing and filming for an online HarvardX course on reproductive technologies and genetics.



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Einer Elhauge, Petrie-Flom's founding faculty director, worked on several projects:

Horizontal Shareholding, 109 HARVARD LAW REVIEW 1269 (2016).

Contrived Threats v. Uncontrived Warnings: A General Solution to the Puzzles of Contractual Duress, Unconstitutional Conditions, and Blackmail, 83 U. CHICAGO L. REV. 503 (2016).

Rehabilitating Jefferson Parish: Why Ties Without a Substantial Foreclosure Share Should Not Be Per Se Legal, 80 ANTITRUST LAW JOURNAL 463 (2016).

He also drafted a book on **MODERN ANTITRUST LAW AND ECONOMICS** and completed research for a project entitled **A LITTLE LOWER THAN GOD: REDESIGNING HUMANS – WHAT LIMITS?**

2015–2016 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, medical tourism, organ and blood donation, reproductive freedom and technology, health care reform, conscientious objection, intellectual property and innovation policy, 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, and Holly Fernandez Lynch, **PROTECTING AND PROMOTING THE HEALTH OF NFL PLAYERS: LEGAL AND ETHICAL ANALYSIS AND RECOMMENDATIONS** (report forthcoming Fall 2016).

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), THE HASTINGS CENTER REPORT – SPECIAL REPORT (forthcoming November/December 2016).



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

Harvard Catalyst

Luke Gelinas, Robin Pierce, Sabune Winkler, I. Glenn Cohen, Holly Fernandez Lynch, and Barbara E. Bierer, ***Using Social Media as a Research Recruitment Tool: Ethical Issues and Recommendations***, __ AM. J. BIOETHICS __ (forthcoming 2016)(peer reviewed).

Luke Gelinas, Holly Fernandez Lynch, Barbara E. Bierer, and I. Glenn Cohen, ***When Clinical Trials Compete: Prioritizing Study Recruitment***, __ J. MED. ETHICS __ (forthcoming 2016)(peer reviewed).

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

Center-Edited Volumes

Holly Fernandez Lynch and I. Glenn Cohen, eds., **FDA IN THE TWENTY-FIRST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES** (Columbia University Press, 2015).

I. Glenn Cohen, Holly Fernandez Lynch, and Christopher T. Robertson, eds., **NUDGING HEALTH: HEALTH LAW AND BEHAVIORAL ECONOMICS** (Johns Hopkins University Press, forthcoming Fall 2016).

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

Holly Fernandez Lynch, I. Glenn Cohen, and Elizabeth Sepper, **LAW, RELIGION, AND HEALTH IN THE UNITED STATES** (Columbia University Press, forthcoming 2017).

I. Glenn Cohen, Holly Fernandez Lynch, Urs Gasser, and Effy Vayena, **BIG DATA, HEALTH LAW, AND BIOETHICS** (Cambridge University Press, forthcoming, 2017-2018).



Holly Fernandez Lynch & I. Glenn Cohen

Balancing Religious Freedom and Health Care Access, LAHEY HEALTH J. MED. ETHICS (Fall 2015).

Confronting Biospecimen Exceptionalism in Proposed Revisions to the Common Rule, 46 HASTINGS CTR. REP. 4 (2016) (co-authored with Barbara Bierer).

I. Glenn Cohen

Going Germline: Mitochondrial Replacement as a Guide to Genome Editing, 164 CELL 832 (2016).

Preventing Mitochondrial DNA Diseases: One Step Forward, Two Steps Back, 315 JAMA __ (2016, Published online June 9, 2016) (co-authored with Eli Y. Adashi) (peer-reviewed).

From Medical Experimentation to Non-Medical Experimentation: What Can and Cannot be Learned from Medicine as to the Ethics of Legal and Other Non-Medical Experiments?, in MEDICAL EXPERIMENTATION: PERSONAL INTEGRITY AND SOCIAL POLICY, NEW EDITION (Oxford University Press, 2016) (co-authored with James D. Greiner).

THE OXFORD HANDBOOK OF U.S. HEALTH CARE LAW (Oxford University Press, 2015 – 2016) (co-editor with Bill Sage and Allison Hoffman).

The Relationship Between Bioethics and U.S. Health Law, in THE OXFORD HANDBOOK OF U.S. HEALTH CARE LAW (I. Glenn Cohen et al., eds., 2015–2016).

Effect of Patient and Therapist Factors on Suicide Risk Assessment, 39 DEATH STUD. 433 (2015) (co-authored with NC Berman, A Stark, A Cooperman, and S Wilhelm).

Clinical Decision Making Regarding Suicide Risk: Effect of Patient and Clinician Age, 40 DEATH STUD. 269 (2016) (co-authored with NC Berman, ES Tung, N Matheny, and S Wilhelm).

Effect of a Legal Prime on Clinician's Assessment of Suicide Risk, 40 DEATH STUD. 61 (2016) (co-authored with NC Berman, A Sullivan, and S Wilhelm).



Consensus Statement on Electronic Health Predictive Analytics: A Guiding Framework, eGEMS Vol. 4, Issue 1 (2016) (co-authored with Ruben Amarasingham, Anne-Marie J. Audet, and others).

Holly Fernandez Lynch

Incorporating Ethical Principles into Clinical Research Protocols: A Tool for Protocol Writers and Ethics Committees, J. MED. ETHICS (2016) (jointly-authored by the Multi-Regional Clinical Trials Center Ethics Working Group).

Bosses in the Bedroom: Religious Employers and the Future of Employer-Sponsored Health Care, in LAW, RELIGION, AND HEALTH IN THE UNITED STATES (co-authored with Gregory Curfman).

Einer Elhauge

Contrived Threats v. Uncontrived Warnings: A General Solution to the Puzzles of Contractual Duress, Unconstitutional Conditions, and Blackmail, 83 U. CHICAGO L. REV. 503 (2016).

Resolving Reverse-Payment Settlements with the Smoking Gun of Stock Price Movements, 101 IOWA L. REV. 1581 (2016)(with Thomas G. McGuire, Keith Drake, Raymond S. Hartman, and Martha Starr).

Obamacare and the Theory of the Firm, in THE FUTURE OF HEALTH CARE REFORM (Malani and Schill, eds., University of Chicago Press, 2015).

Horizontal Shareholding, 109 HARV. L. REV. 1269 (2016).

Rehabilitating Jefferson Parish: Why Ties Without a Substantial Foreclosure Share Should Not Be Per Se Legal, 80 ANTITRUST LAW JOURNAL 463 (2016).

The Welfare Effects of Metering Ties (2016)(with Barry J. Nalebuff).

Robust Exclusion and Market Division Through Loyalty Discounts, 43 INTERNATIONAL JOURNAL OF INDUSTRIAL ORGANIZATION 111 (Nov. 2015)(with Abraham L. Wickelgren).

How Italian Colors Guts Private Antitrust Enforcement by Replacing It With Ineffective Forms Of Arbitration, 38 FORDHAM INT'L L. J. 771 (2015).



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Rachel E. Sachs

Prizing Insurance: Prescription Drug Insurance as Innovation Incentive, 30 HARV. J. L. & TECH. __ (forthcoming 2016).

Divided Infringement and the Doctor-Patient Relationship, __ IP THEORY __ (forthcoming 2016) (invited).

Innovation Law and Policy: Preserving the Future of Personalized Medicine, 49 U.C. DAVIS L. REV. 1881 (2016).

Robert Kinscherff

JUVENILES AND THE LAW, invited volume for Oxford University Press, manuscript accepted (with Matthew Lahaie and Ronald Schouten).

RECIDIVISM OF JUVENILES CONVICTED OF HOMICIDE AND RELEASED AS ADULTS, manuscript in final preparation for submission (with Frank DiCataldo, Corey Linder, Jaclyn Neddenriep).

Distinguishing and Assessing Amenability to Treatment and Rehabilitation with Juvenile Offenders. Kirk Heilbrun, Ed., **APA HANDBOOK OF PSYCHOLOGY AND JUVENILE JUSTICE** (American Psychological Association Press, 2015).

Luke Gelinas

When and Why Is Research Without Consent Permissible? 46 HASTINGS CTR. REP. 2, 35–43 (2016)(with Alan Wertheimer and Franklin G. Miller).

Skeptical Worries for ICU Rationing, 15 AMERICAN PHILOSOPHICAL ASSOCIATION NEWSLETTER ON PHILOSOPHY AND MEDICINE 2, 2–6 (2016).

Frames, Choice-Reversal, and Consent, 18 ETHICAL THEORY AND MORAL PRACTICE 5, 1049–57 (2015).

Balancing the Surgeon’s Responsibility to Individuals and Society, THE SAGES MANUAL, ETHICS OF SURGICAL INNOVATION. Eds. Steven C. Stain, Aurora D. Pryor, and Phillip P. Shadduck (with Bruce D. White, Springer Publishing, 2016).



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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. THE 2016 ANNUAL FORUM OF CHINA ADMINISTRATIVE LAW SOCIETY (forthcoming).

Food and Drug vs. Common Product: Different or Unified Supervision System. 3 ADMIN. L. REV. (2016).

Making Food and Drug Concerns Relate to "People's Standard of Living" and "Public Safety": The Implications, Motivations, and Challenges, 9 CHINA PUBLIC ADMINISTRATION (2015)(with Ma Huaide).

2015-16 Affiliate Commentary

Our affiliates are highly sought after for their expert opinions on a number of pressing news items, including the Affordable Care Act, contraceptives coverage, abortion, reproductive technologies, the ban on blood donation by gay men, pharmaceutical regulation and pricing, medical tourism, human subjects research, medical error, right-to-die laws, 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 CBS News, PBS, NPR, CNNHealth, The New York Times, The Christian Science Monitor, Forbes, US News & World Report, WIRED, STAT, Politico, Health Affairs, The Washington Times, Boston Magazine, and more. Selected highlights in which Center affiliates authored commentary or were extensively interviewed are featured below:

I. Glenn Cohen & Holly Fernandez Lynch

Podcast: ***NPRM on the Common Rule***, THE WEEK IN HEALTH LAW (Nov 7, 2015).

Podcast: ***Research, Regulation, and Ethics***, SCIENCE FOR THE PEOPLE (July 2015).



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I. Glenn Cohen

Radio broadcast: **FDA Regulations Limit Blood Donations From Gay Men**, CBS SAN FRANCISCO (June 14, 2016).

Interview: **After The Orlando Massacre, Many In The LGBTQ Community Are Turned Away From Giving Blood**, GREATER BOSTON (WGBH) (June 14, 2016).

I. Glenn Cohen, **Planned Parenthood And Fetal Tissue Sale: Manufactured Controversy And The Real Ethical Debate**, HEALTH AFFAIRS BLOG (March 9, 2016).

Interview: **Fertility Tourism: Options and Ethics**, CREATING A FAMILY RADIO (Feb. 24, 2016).

Interview: **FDA eases blood donation ban on gay men**, CBS NEWS (Dec. 21, 2015).

Interview: **California: Euthanasia**, AUSTRALIA BROADCASTING COMPANY (Oct 27, 2015).

Panel discussion: **Blood Illuminated: Panel Discussion of FDA Blood Ban From Gay and Bisexual Men**, American University, Oct. 6 2015.

The Non-Spaces of Medical Tourism, 40 HARVARD DESIGN MAGAZINE (2015).

Holly Fernandez Lynch

Four Key Issues in Health Law That Are As Relevant As Ever in 2016, Health Affairs Blog (Jan. 20, 2016).

A Tool to Help Address Key Ethical Issues in Research. JOURNAL OF MEDICAL ETHICS BLOG (Feb. 22, 2016)(with Rebecca Li).

Interview: **The Summer Olympics And the Zika Virus — Is It Safe to Hold the Games in Brazil?**, GREATER BOSTON (WGBH) (June 1, 2016).

Rachel E. Sachs

Pharmaceutical Transparency Bills: Targeting Disclosure Purposefully, THE HASTINGS CENTER BIOETHICS FORUM, April 15, 2016.



Medicaid Expansion Through Section 1115 Waivers: Evaluating the Tradeoffs, HEALTH AFFAIRS BLOG, March 15, 2016.

Peng Zhao

How to Define the Administrative Liability of Online Platforms, CAIJING (April 18, 2016).

The Food and Drug Regulation in Public Security Perspective (1), MEDICINE ECONOMIC NEWS (December 14, 2015).

The Food and Drug Regulation in Public Security Perspective (2), MEDICINE ECONOMIC NEWS (December 21, 2015).

The Food and Drug Regulation in Public Security Perspective (3), MEDICINE ECONOMIC NEWS (January 4, 2016).

At the Starting Point of Standardization of Regulation: Comment on CFDA's Implementation of Generic Drug Quality Consistency and Curative Effect Evaluation, MEDICINE ECONOMIC NEWS (November 23, 2015).



Public Events Programming and Conferences

The Petrie-Flom Center hosted a number of fantastic events this year, from major conferences to smaller panel discussions, some 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

Second Annual HLS-UCLA Food Law and Policy Conference: Drugs, Animals, and Food: Law & Policy of Antibiotics in the Food System

October 23, 2015

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

Reflections in Honor of the Life and Influence of Professor Alan Wertheimer

November 4, 2015

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.



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Specimen Science: Ethics and Policy Implications

November 16, 2015

A collaboration between The Center for Child Health and Policy at Case Western Reserve University and University Hospitals Rainbow Babies & Children's Hospital; the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, with support from the Oswald DeN. Cammann Fund; the Multi-Regional Clinical Trials Center of Harvard and BWH; and Harvard Catalyst | The Harvard Clinical and Translational Science Center. This conference was supported by funding from the National Human Genome Research Institute.

Fourth Annual Health Law Year in P/Review

January 29, 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 Petrie-Flom Center's 10th Anniversary Conference Celebration: The Future of Health Law and Policy

March 29, 2016

Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, with support from the Harvard Law School Dean's Office.

2016 Petrie-Flom Annual Conference: Big Data, Health Law, and Bioethics

May 6, 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. Organized in collaboration with the Berkman Center for Internet & Society at Harvard University and the Health Ethics and Policy Lab, University of Zurich.

Radical Redesign of Health Care and Its Implications for Policy: A Lecture by Don Berwick, Administrator of the Centers for Medicare and Medicaid Services (2010–2011)

Part of ASLME's 39th Annual Health Law Professors Conference

June 2, 2016

This event was hosted by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and cosponsored by the American Society of Law, Medicine & Ethics, the Boston University School of Law, and the Center for Bioethics at Harvard Medical School, with support from the Oswald DeN. Cammann Fund.

Aligning People and Policy: Why the Time Is Right to Transform Advanced Care

June 21, 2016

The inaugural event of the Project on Advanced Care and Health Policy.



Lectures, Panels, and Other Events

From Troubled Teens to Tsarnaev: Promises and Perils of Adolescent Neuroscience and Law

September 28, 2015

Part of the Project on Law and Applied Neuroscience.

2015 Petrie-Flom Center Annual Open House

September 28, 2015

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.

Non-Human Primates in Research: Legal and Ethical Considerations

September 30, 2015

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

Synthetic Biology: Science, Policy, and Ethics

October 8, 2015

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.

Is Professional Football Safe? Could We Make It Safer? Perspectives from Neuroscience, Law, and Ethics

October 15, 2015

Panel session held at the 2015 Annual Meeting of the International Neuroethics Society in Chicago.

Moral Bioprediction, Bioenhancement, and the Law: A Lecture by Julian Savulescu

October 20, 2015

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. Part of a series of events cosponsored by the Center for Bioethics at Harvard Medical School and the Safra Center for Ethics at Harvard University.

Harvard Reception at the ASBH 17th Annual Meeting

October 23, 2015

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.



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Book Launch: FDA in the 21st Century

October 28, 2015

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

Harvard Reception at the 2015 PRIM&R Annual Conference

November 13, 2015

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, Harvard Catalyst | The Harvard Clinical and Translational Science Center at Harvard Medical School, and the MRCT Center of Harvard and BWH, with support from the Oswald DeN. Cammann Fund.

**Should the Science of Adolescent Brain Development Inform Legal Policy?: A
lecture by Laurence Steinberg, PhD**

November 13, 2015

Part of the Project on Law and Applied Neuroscience.

**Euthanasia in Belgium: The most recent legal developments and policy
challenges**

November 10, 2015

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.

A Conversation with Margaret A. Hamburg, FDA Commissioner 2009–2015

January 20, 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.

Fetal Pain: An Update on the Science and Legal Implications

February 10, 2016

Part of the Project on Law and Applied Neuroscience.

Assessing the Viability of FDA's Biosimilars Pathway

February 18, 2016

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

**Canaries in the Coal Mine: People with Disabilities and Noninvasive
Prenatal Diagnosis**

February 22, 2016

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.



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The Limits to Consumerism in Healthcare: A lecture by Mary Anne Bobinski

March 2, 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.

Book Talk and Panel Discussion: FDA in the 21st Century: The Challenges of Regulating Drugs and New Technologies

March 25, 2016

Hosted by the 92nd Street Y, New York, NY.

The National Security Implications of the Genetics Revolution

April 5, 2016

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

Boys to Men to Boys: What is the Role for Psychology and Neuroscience in Resentencing and Parole after *Miller and Montgomery*?

April 13, 2016

Part of the Project on Law and Applied Neuroscience.

The Football Players Health Study at Harvard University

June 3, 2016

Panel session at the ASLME 39th Annual Health Law Professors Conference.

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:

Litigating the Right to Health in Kenya: A lecture by Allan Maleche

November 2, 2015

Hosted by the Human Rights Program at Harvard Law School

Ethical Challenges in Compassionate Access to Investigational Medicines: A lecture by Joanne Waldstreicher, CMO Johnson & Johnson

December 7, 2015

Hosted by the Center for Bioethics at Harvard Medical School

Global Tobacco Control as a Public Health and Human Rights Imperative

February 8, 2016

Hosted by the Human Rights Program at Harvard Law School



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Negotiating for Health: The Role of Negotiation and Dispute Resolution in Health Care

February 27, 2016

Hosted by the Harvard Negotiation Law Review

Harvard Medical School's 2016 Bioethics Conference: Social Justice and Ethics Committees in Health Care: Core to Our Mission or None of Our Business?

April 14, 2016

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

Neuroethics Seminar Series

Fall 2015 and Spring 2016

Hosted by the Center for Bioethics at Harvard Medical School



Contributions to the HLS Teaching Program

This year, Petrie-Flom affiliates offered the following courses, open to students at HLS and other Harvard graduate schools.

Health Law, Policy, Bioethics, and Biotechnology Workshop

I. Glenn Cohen

Fall 2015–Spring 2016

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.

The 2015–2016 workshop welcomed the following scholars:

- **Robert Cook-Deegan**, Research Professor, Sanford School of Public Policy, with secondary appointments in Internal Medicine at the School of Medicine and Biology in the Trinity College of Arts and Sciences, all at Duke University
- **Nathan Cortez**, Associate Dean for Research and Associate Professor in Dedman School of Law, Southern Methodist University
- **Michael Frakes**, Associate Professor of Law, Northwestern Law; Faculty Research Fellow, National Bureau of Economic Research; Faculty Fellow, Northwestern University Institute for Policy Research; starting Fall 2016, Professor of Law, Duke University
- **Jaime S. King**, Professor of Law, UC Hastings Law School; Associate Dean and Co-Director of the UCSF/UC Hastings Consortium on Science, Law and Health Policy; Executive Editor of *The Source on Healthcare Price and Competition*; Co-Director of the Concentration on Law and Health Sciences, and **Erin Fuse Brown**, Assistant Professor of Law, Georgia State University School of Law
- **Adam Kolber**, Professor of Law, Brooklyn Law School



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- **Amanda C. Pustilnik**, Associate Professor of Law, University of Maryland School of Law
- **Michelle M. Mello**, Professor of Law, Stanford Law School; Professor of Health Research and Policy, Stanford School of Medicine
- **Jessica L. Roberts**, Director of the Health Law and Policy Institute and Associate Professor of Law, University of Houston Law Center
- **Julian Savulescu**, Uehiro Chair in Practical Ethics; Director, Oxford Centre for Neuroethics; Director, Oxford Uehiro Centre for Practical Ethics; Director, Institute for Science and Ethics, The Oxford Martin School
- **Seema Shah**, faculty member, National Institutes of Health Clinical Center, Department of Bioethics; joint appointment, Division of AIDS
- **Tom Shakespeare**, Senior Lecturer, Norwich Medical School, the University of East Anglia
- **Nicolas P. Terry**, Hall Render Professor of Law and Executive Director of the Hall Center for Law and Health, Indiana University Robert H. McKinney School of Law

Innovation in Medical Technologies: Law and Policy

Rachel E. Sachs

Spring 2016

This seminar considered the ways in which different areas of law contribute to the broader innovation ecosystem in the context of healthcare technologies such as drugs and medical devices, examining the relationships between legal doctrines and innovation incentives. Beginning with a focus on intellectual property law, the classic locus of innovation incentives, the course then took a broader view that included lesser-known incentive levers including grants, prize systems, and insurance reimbursement. The course also engaged in an intersystemic analysis of these innovation policy levers, exploring their interactions and their relationship to the relevant institutional actors.

Law and Neuroscience

Nancy Gertner

Spring 2016

With frequent 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



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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 2016

This course was offered as part of the new Masters Program in Bioethics at Harvard Medical School, with cross-registration opportunities for HLS students and others across the University. It served as an introduction to legal topics in health policy and bioethics for the non-lawyer, beginning with a brief primer on American law and how it works. Covered topics included legal aspects of the doctor-patient relationship, medical malpractice, privacy issues, health care finance, end-of-life issues, organ donation, disability, mental health, public health, medical product regulation, food regulation, and intellectual property.

In addition, Petrie-Flom affiliates make substantial contributions to the HLS health law curriculum through regular 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.



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 a small stipend upon successful completion of their written work and 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 2015–2016 student fellows and projects were as follows:

Dalia Deak

Harvard T.H. Chan School of Public Health, MPH '16, Health Policy and Management; Harvard Law School, JD '19

Paper: "Repurposing Transformative Drugs: Public Health, Policy, and Legal Issues"



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Elizabeth Guo

Harvard Law School, JD '16; Harvard T. H. Chan School of Public Health, '16
Peter Barton Hutt Student Fellow

Paper: "Reputation and Judicial Deference: An Examination of FDA's Reputation and Judicial Deference to Agency Action"

Katherine Kwong

Harvard Law School, JD '17

Paper: "Genetic Information and Identifiability in the Context of Research"

Michael Anne Kyle

Harvard T.H. Chan School of Public Health, MPH '16; Harvard University, Health Policy and Management, PhD '20

Paper: "Structural and Regulatory Aspects of Medicaid Accountable Care Organizations"

Emma Sandoe

Harvard University, PhD '19, Health Policy and Management, Harvard University (former spokesperson for Medicaid and HealthCare.gov at the Centers for Medicare & Medicaid Services)

Paper: "Medicaid's Growth and Role in Modern Southern Politics"

Maayan Sudai

Harvard Law School, SJD '18

Paper: "From Advocacy to Policy - The Case of the Intersex Rights Movement"

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.



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

Football Players Health Study:

- Thomas Blackmon, HLS '16
- Laura Escalona, HLS '16
- Jose Lamarque, HLS '17
- Nimat Lawal, HLS '18
- Russell Spivak, HLS '17
- Scott Sherman, HLS '17

Harvard Catalyst

- Russell Spivak, HLS '17

PCOROS

- Katherine Kwong, HLS '17 (via the HLS Cyberlaw Clinic)
- Abbas Rattani, Meharry Medical College

Specimen Science:

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

Nudging Health:

- Noah Marks, HLS '16
- Evelyn Blacklock, HLS '16
- Thomas Blackmon, HLS '16
- Jeffrey Zink, HLS 20 '16

Law, Religion, and Health in the United States:

- Noah Heinz, HLS '18
- Jessica Goodman, HLS '17
- Ariel Teshuva, HLS '18
- Eleanor Davis, HLS '18



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Big Data, Health Law, and Bioethics:

- Melinda Johnson, HLS '18
- Tess Hellgren, HLS '18

HLS Program of Study Fellow

- Amanda Brown-Inz, HLS 2017

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 partnered for the first time with the Harvard Health Law Society (HHLS), a student organization, to actively solicit new Student Contributors to the blog. As a result, [two HHLS members](#) posted regularly during the 2015–2016 academic year:

- Matthew Ryan, HLS '17
- George Maliha, 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 [February 2016](#), were:

Emily A. Largent, Harvard Law School and Harvard University
Recently proposed changes to legal and ethical guidelines governing human subjects research

Ian Vincent McGonigle, Harvard University
Patenting nature or protecting culture? Ethnopharmacology and indigenous intellectual property rights

J. Bradley Segal, Harvard Medical School
Inherited proclivity: When should neurogenetics mitigate moral culpability for purposes of sentencing?

Naren P. Tallapragada, Harvard Medical School
Off-patent drugs at brand-name prices: a puzzle for policymakers



Student Interns

During FY16 we have shifted our internship program toward employing paid interns who assist with various Center projects while gaining experience with the work of the Center. Intern projects included:

- Advertising and preparing materials for Petrie-Flom events;
- 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;
- Collecting and formatting material for drafts of Center reports;
- Research projects as assigned.

In addition to hiring Harvard students this year, we added high school students hired through the Cambridge Housing Authority's WorkForce program. Our 2015–2016 interns were:

- Phebe Hong, FAS '16
- Emily Jung, FAS '18
- Jonathan Dauphine, Cambridge Rindge and Latin, '19
- Rafael Salas, Cambridge Rindge and Latin, '20



Faculty Participation

As noted throughout this report, HLS faculty participation in the Petrie-Flom Center is both strong and essential. In addition to the clear investment by Faculty Director **I. Glenn Cohen** and Founding Director **Einer Elhauge**, **Jacob Gersen** has pushed forward the work of his Food Law Lab under the Petrie-Flom Center's umbrella; **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 will co-edit the related conference volume; and **Kristin Stilt** worked with us to develop programming bringing Petrie-Flom together with the new **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**.

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

- **Arthur Applbaum**, HKS
- **Jerry Avorn**, HMS
- **Lindsey Baden**, HMS
- **Peter Barton Hutt**, HLS
- **Barbara E. Bierer**, HMS
- **Richard Born**, HMS
- **Eric Campbell**, HMS
- **Dan Carpenter**, HKS
- **Michael Chernew**, HMS
- **George Church**, HMS
- **Thomas Cochrane**, HMS
- **Gregory Curfman**, HMS
- **Judith G. Edersheim**, HMS
- **Nir Eyal**, HMS
- **Aaron S. Kesselheim**, HMS
- **Louise P. King**, HMS
- **Isaac Kohane**, HMS
- **William Meehan III**, HMS
- **Christine Mitchell**, HMS
- **Lee Nadler**, HMS
- **Alvaro Pascual-Leone**, HMS
- **Ameet Sarpatwari**, HMS
- **Vincent Schiraldi**, HKS
- **Carmel Shachar**, HLS
- **Leah Somerville**, FAS



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- [Robert D. Truog](#), HMS
- [Joel Weissman](#), HMS
- [David R. Williams](#), HSPH
- [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 Harvard faculty; we have also opened the affiliation 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 2015–2016 academic year:

- **[Rebecca Weintraub Brendel](#)**, MD, JD, Assistant Professor of Psychiatry and Director of the Master's Program, Center for Bioethics, HMS
- **[Louise P. King](#)**, MD, JD, Assistant Professor of Obstetrics, Gynecology, and Reproductive Biology
- **[Robert Kinscherff](#)**, PhD, JD, Faculty and Associate Vice President for Community Engagement, William James College; Faculty, Center for Law, Brain, and Behavior, MGH
- **[Ameet Sarpatwari](#)**, JD, PhD, Assistant Professor, HMS and Brigham and Women's Hospital

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** submitted an amicus brief to the Supreme Court in support of the petitioners in *Whole Women's Health v. Hellerstedt* (along with Professors Melissa Murray and B. Jessie Hill). He also serves as a member of the Standing Committee on Ethics of CIHR (Canadian Institute for Health Research; the Canadian equivalent to NIH).

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 the Subcommittee on Harmonization in Fall 2015. She also served as a legal consultant on a case regarding allegations of human subjects research misconduct in Summer 2015, and presented on proposed revisions to the federal regulations governing human subjects research at a Boston Bar Association continuing legal education event in March 2016.

Rachel Sachs

Academic Fellow **Rachel Sachs** has continued collaborating with non-profit industry groups and with scientists in her work on the microbiome, recently presenting a paper she co-authored on the FDA regulation of fecal transplantation with the Director of Global Partnerships at a non-profit stool bank to an NIH working group on the subject.



Christopher Deubert

Football Players Health Study Senior Law and Ethics Associate Christopher Deubert performs research on behalf of the Sports Lawyers Association.

He also delivered a number of invited lectures at law schools around the country:

- **Concussion Litigation in Sports.** St. John's University School of Law, September 14, 2015.
- **Commissioner Discipline in Professional Sports.** Sports and the Law: Examining the Legal History and Evolution of America's Three "Major League" Sports: MLB, NFL and NBA, Harvard Law School, September 17, 2015.
- **Non-Statutory Labor Exemption in Professional Sports.** Sports and the Law: Examining the Legal History and Evolution of America's Three "Major League" Sports: MLB, NFL and NBA, Harvard Law School, October 22, 2015.
- **Careers in Sports.** Sandra Day O'Connor College of Law at Arizona State University, November 12, 2015.
- **Panelist, Conference on Concussive Injury.** Sandra Day O'Connor College of Law at Arizona State University, November 13, 2015.
- **Representing Professional Athletes.** Sports and the Law: Representing Professional Athletes, Harvard Law School, January 13, 2016.
- **Legal Issues Concerning the Health of NFL Players.** Northeastern University School of Law, February 10, 2016.

Robert Kinscherff

Senior Fellow in Law and Applied Neuroscience **Robert Kinscherff** has served on a number of legislative commissions, including:

- 2015–2016 Commissioner, Legislative Commission on Sexual Offender Recidivism (subject matter expertise on juvenile sexual offenders)
- 2015–2016 Designee of Chief Justice of the Juvenile Court, Legislative Commission on Developmental Evaluations of Juveniles Convicted of First Degree Murder

He also participated in a White House symposium on ***Race, Trauma, and Disrupting the Cycle of Violence: A Movement-Building Meeting*** chaired by Roy Austin, Deputy Assistant to the President, Office of Urban Affairs, Justice and Opportunity in the White House Domestic Policy Council, on June 9, 2016. Robert plans to liaise participation in that meeting into policy and research projects within the Project on Law and Applied Neuroscience.



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In addition, Robert engaged in the following policy and training events:

- **Youth with Co-Occurring Mental Health and Substance Abuse Issues.** Judicial Education Center, Illinois Trial Court, February 1 and April 4, 2016
- **Adolescent Development: Implications for Neurons, Neighborhoods, Pipelines and Public Policy.** Massachusetts State Child-Serving Agency Leadership Series for senior state agency officials, February 2, 2016
- **Adolescent Brain Development: Implications for Law Enforcement Responding to Youth.** Boston Police Academy. February 17, 2016
- **The Supreme Court and Adolescent Development: Implications for Parole in the Post-Miller Era.** Connecticut Board of Pardons and Pardons, February 28, 2016
- **Should We Ever Sentence Juveniles as Adults? A Look at Juvenile Justice.** Charles Hamilton Houston Institute for Race and Justice, Harvard Law School. May 10, 2016
- **What Juvenile Courts Need to Know About Providing Effective Services for Youth with Co-Occurring Disorders.** National Association of Drug Court Professionals, Anaheim CA, June 3, 2016
- **Neurodevelopment in a Social World: Adolescent Crime, Punishment and Effective Policy and Practice.** Co-presenting with Vincent Schiraldi (Harvard Kennedy School), Prosecutors' Training, Office of the District Attorney of Suffolk County, June 15, 2016.

Robert also served as a presenter at a wide variety of trainings on the neuroscience of juvenile development, mental health, and addiction as they relate to juvenile justice for professionals in law enforcement and the criminal justice system. He was a consultant to defense attorneys and prosecutors in a number of states on post-*Miller* juvenile homicide resentencing and parole cases, an expert witness for juvenile homicide parole cases in Massachusetts, and an expert witness in a criminal case involving an adolescent charged with murder and rape. Additionally, he was a consultant and/or a co-signatory on amicus briefs related to juvenile justice and correctional appellate issues.



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.

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 endeavors to develop a variety of practical recommendations 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 work on Specimen Science is helping pave the way forward for medical advancement via biospecimen research, as the federal government is actively engaged in considering revisions to the relevant regulations.
- 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 new 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, including the addition this spring of seven new Key Topics lists that provide links to essential primary and secondary resources on subjects ranging from biobanking to GMO foods and vaccines. Most recently, we published a database in June, developed by a Student Fellowship alumnus, of legislative documents tracing the history of the Biologics Price Competition Act of 2009. The overarching



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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 is currently accessed by nearly 4,700 unique users per month, with visitors from over 120 countries. Our video-hosting site, Vimeo, saw about 3,500 views in April 2016, and our slide-sharing site receives more than 1,000 views per month. With regard to social media, we have nearly doubled our Twitter followers in the last year – for the second year in a row! – and even boasted a trending topic ([#bigdataandhealthlaw](#)) during our May 2016 annual conference.

We also 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. We currently have nearly 5,000 subscribers to our list serve—up almost 25% over this time last year.

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.

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](#).

Bill of Health currently sees over 15,000 unique monthly users, and nearly 20,000 pageviews per month.

Events with Industry Participation

As noted above, Petrie-Flom hosted several events last 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:

Second Annual HLS-UCLA Food Law and Policy Conference: Drugs, Animals, and Food: Law & Policy of Antibiotics in the Food System

This one-day event examined the issue of antibiotic use in farm animals and their impact on human health. Speakers included scholars, policymakers, and representatives from the fast food industry.

Fourth Annual Health Law Year in P/Review

A highlight of this year's event was a debate, "Information Sharing or Misleading Promotion? Evolving Case Law on Pharmaceutical Company Statements," featuring HMS Professor Jerry Avorn and Pharmaceutical Research and Manufacturers of America (PhRMA) Executive Vice President and General Counsel, Mit Spears.

The Petrie-Flom Center's 10th Anniversary Conference Celebration: The Future of Health Law and Policy

To celebrate the Center's first 10 years, we invited many of our former Academic Fellows, a selection of other affiliates, and several eminent Harvard alumni to engage in candid discussion of what to expect in health law and policy – and from the Center – in the next decade. Noteworthy participants:

- **Neil Flanzraich** '65, JD '68, Cantex Pharmaceuticals, Inc.
- **Andrew Klaber** MBA '09, JD '10, Even Ground and Paulson & Co.
- **Dennis Langer** JD '83, Clinical Professor, Georgetown University School of Medicine and member of several corporate boards
- **John McGoldrick** '63, LLB '66, International AIDS Vaccine Initiative; Zimmer Biomet Holdings



Assessing the Viability of FDA's Biosimilars Pathway

This lunchtime panel discussion assessed the pathway to approval for biosimilar drugs created by the 2010 Biologics Price Competition and Innovation Act. Speakers included:

- **Donald R. Ware**, Partner, Foley Hoag LLP
- **Konstantinos Andrikopoulos**, Lead IP Counsel, Manufacturing, Biogen, Inc.



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 housed 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 and public conference](#)
- Our [Project on Law and Applied Neuroscience](#) with the Center for Law, Brain, and Behavior at Massachusetts General Hospital
- Our new [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:

- [American Society of Law, Medicine, and Ethics](#)
- [Animal Law and Policy Program](#) at HLS
- The [Berkman Klein Center for Internet & Society](#) at Harvard University
- [Boston University School of Law](#)
- The [Broad Institute](#) of MIT and Harvard
- 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)
- The [Criminal Justice Policy Program](#) at HLS



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- [Edmond J. Safra Center for Ethics at Harvard University](#)
- [Harvard Catalyst](#)
- [Harvard Food Law Lab](#)
- [Harvard Health Publications at Harvard Medical School](#)
- [Harvard Law School Project on Disability](#)
- [Harvard National Security Journal](#)
- [Harvard National Security & Law Association](#)
- [The Hastings Center](#)
- [Health Affairs](#)
- [The Health Ethics and Policy Lab, University of Zurich](#)
- [HLS Center for Health Law Policy and Innovation](#)
- [HLS Dean's Office](#)
- [HLS Human Rights Program](#)
- [HLS Library](#)
- [HMS Center for Bioethics](#)
- [The International Neuroethics Society](#)
- [Multi-Regional Clinical Trials Center at Harvard and Brigham and Women's Hospital](#)
- [The New England Journal of Medicine](#)
- [Public Responsibility in Medicine & Research \(PRIM&R\)](#)
- [92nd Street Y \(New York\)](#)



2016–17 Plans for Activities

(Fiscal Year 2017: July 2016–June 2017)

During the coming year, we plan to continue our ongoing sponsored research projects and other collaborations, host a compelling slate of public events and conferences, offer a range of opportunities for students and visitors, and contribute to the HLS teaching program.

Research, Scholarship, and Project Activities

Sponsored Research

As described above, we have three sponsored research projects that will continue for the next academic year:

- The Law and Ethics Initiative of the Football Players Health Study at Harvard University is slated to wrap all outstanding projects by the end of May 2017, the close of our third year on the Project. **I. Glenn Cohen** and **Holly Fernandez Lynch** expect to continue to provide legal and ethical guidance to the remainder of the Study thereafter, currently anticipated to run through 2021.
- 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, community engagement in research and research development, and other legal and ethical issues affecting clinical research.
- Our work on the Patient Centered Outcomes Research Oversight Study (PCOROS) will complete its first year in August 2016, with two additional years of collaboration anticipated through August 2018. Work in years 2 and 3 will focus on developing a whitepaper on the regulatory and ethical issues faced by Institutional Review Boards overseeing patient-centered research, generating a variety of policy recommendations, and engaging with key stakeholders for adoption and implementation, culminating in a large public conference at HLS.

In 2017, we will also conclude our work on the published volume generated through the Specimen Science collaboration, although funding for that project ended in February 2016.



Project Activities

Journal of Law and the Biosciences

Our collaboration on JLB will continue for the journal's fourth volume, with a new slate of Harvard contributors to the "Notes and Developments" section. Proposed contributions will be selected in Fall 2016, and published in early 2017. This year we have opened contributions to Harvard post-docs in addition to Harvard graduate students.

The Project on Law and Applied Neuroscience

Our collaboration with Massachusetts General Hospital's Center for Law, Brain and Behavior will continue for the third 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**. Senior Fellow in Law and Neuroscience **Robert Kinscherff**, PhD, JD, will remain with us for a second year and continue his work on juvenile justice, law, and neuroscience. This year, his work will build upon previous events, collaborations, and networking to include youth community violence as an important area of activity.

A schedule of events for FY17 is already underway, including:

- A September 2016 conference on pre-trial mental health and addiction diversion courts, sponsored by the Federal Judicial Center in collaboration with the Petrie-Flom Center, the Center for Law, Brain and Behavior at MGH, and the Criminal Justice Policy Program at HLS
- A panel discussion, developed based on contacts Dr. Kinscherff made at a recent meeting at the White House, on the neurodevelopmental impact of childhood adversity/trauma, its influence on juvenile crime, and public health approaches to youth and community violence
- A panel discussion on the challenges of using neurodevelopmental models of addiction, and developing opioid regulations that balance public health concerns about addiction with the need for access to medical pain management

In particular, the event on childhood adversity and youth violence will seek to build a movement to foster juvenile and criminal justice reforms. A July 12, 2016, initial working group meeting reviewed opportunities potentially leading to legal challenges to application of the felony-murder rule to juveniles. Other initiatives include comparison of legal theories of consent and waiver by juveniles across medical and legal contexts, and how to best provide "translational science" about developmental behavioral and neuroscience for



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public health approaches to violence or raising the age of juvenile jurisdiction past age 18.

The Project on Advanced Care and Health Policy

We look forward to our first full academic year engaging in our collaborative Project on Advanced Care and Health Policy. In response to our initial press release and inaugural event, we have been introduced to a number of academics, advocacy groups, and other stakeholders interested in working together to improve care models at the end-of-life; thus, an important component of our effort this year will be to build further collaborations and connections.

Mark Sterling, JD will continue as the Senior Fellow on this Project, leading the development of a research agenda that is expected to focus in particular on analyzing regulatory barriers to implementation of the advanced care model that cut across a variety of providers, payers, and other stakeholders, and developing appropriate recommendations for policy change. HLS students will likely be engaged to assist with background legal research and preliminary drafting.

This year, the Project is also contemplating events on the following topics, among others. Each of these events will focus on particular stakeholder groups, and be generative in the sense of developing recommendations, whitepapers, and reports:

- Policy recommendations to overcome barriers to the spread of an advanced care model (with leading national policymakers)
- Best practices in implementing an advanced care model (with for-profit and non-profit business leaders)
- Shared decision-making in advanced care (with patients, providers, and others)

Scholarship

Academic Fellows

For a variety of reasons, we have not accepted a new academic fellow to join the Center this year. Going forward, we are reconsidering our plans for the academic fellowship program and considering possible alternatives, including development of a policy or senior fellowship. We hope to relaunch the program when additional funding is secured.



Faculty

In the summer of 2016, the Center will once again provide research support to **Profs. Cohen and Elhauge**.

L. Glenn Cohen is working on the following projects:

- Editing the following books:
 - **THE OXFORD HANDBOOK OF U.S. HEALTH CARE LAW** (with Bill Sage and Allison Hoffman)
 - **LAW, RELIGION, AND HEALTH IN THE UNITED STATES** (with Holly Fernandez Lynch and Elizabeth Sepper)
 - **SPECIMEN SCIENCE: ETHICS AND POLICY IMPLICATIONS** (with Holly Fernandez Lynch, Barbara Bierer, and Suzanne Rivera)
 - **HEALTH CARE LAW AND ETHICS** (with Mark Hall, David Orentlicher, Mary-Anne Bobinski, and Nick Bagley)
- Several medical journal articles pertaining to In Vitro Gametogenesis, Mitochondrial Replacement Therapy, and Preembryo disposition disputes
- Several publications associated with the Football Players Health Study at Harvard University

Professor Cohen will also use his summer to complete work on an online course to be offered by **HarvardX** on reproductive technology, genetics, law, and ethics. This will be one of the first of five HLS-led courses to be offered on this platform, and the first on law, medicine, and ethics. It will launch in September 2016.

Einer Elhauge's summer funding is supporting the following work related to health law policy, biotechnology, and bioethics:

- Completion of two book projects
 - **MODERN ANTITRUST LAW AND ECONOMICS**
 - **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 2016–2017 academic year:

Kuei-Jung Ni, June–July 2016

Kuei-Jung Ni was a return visitor at the Center, having been a Visiting Scholar from August 2013 through July 2014. 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 his visit he was on leave from his role as Professor and Director at the Institute for Technology Law, National Chiao Tung University, Taiwan. His current project is to develop a book on comparative aspects of governmental food safety regulation in the United States, Europe, and Asia, which will also inform development of a suitable system for the Taiwanese government.

Peng Zhao, August 2015–August 2016

Peng Zhao will complete his visit at the Center in August 2016. His work is described at length above.

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 WGST department. Professor Hertz teaches courses on changing families and social policy, the social construction of gender, and women, work and the global economy. She also teaches a first-year seminar on “The Body.”

In broad terms, Professor Hertz researches families in a changing economy and how social inequality at home and in the workplace shape the experiences of women and men. Presently she is interested in the pivotal moments that influence certain kinds of women leaders. 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. During her time at the Petrie-Flom Center, Professor Hertz will work on two projects:



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- The Politics of Genes: This article will examine the influence of genetics in shaping public views, using data from both U.S. and Border-Crossing surveys about the politics of genes and health and social outcomes. Survey data will be used to interpret individual differences in a series of domains: major physical illness, serious mental illness, intelligence, personality and success in life.
- In addition, Professor Hertz will analyze qualitative data on the use of gray markets for giving away left over gametes or embryos by individuals to others through Internet sites and across state lines. She plans to use the data in a paper about related legal issues, particularly how state laws operate with regard to the transfer of gametes/embryos across state lines.

Frances Kamm, October–November 2016

Frances Kamm will return to the Center as Senior Fellow during Fall 2016 (she was previously Senior Fellow in 2007). 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 coming visit, Professor Kamm will be working on issues relating to end-of-life care and death. She will also present her current research to the Health Law, Policy, Bioethics, and Biotechnology Workshop.

Book Projects

Faculty Director **I. Glenn Cohen** and Executive Director **Holly Fernandez Lynch** continue to pursue edited volumes out of a variety of Petrie-Flom Center events and collaborations:

- We have completed all work on **NUDGING HEALTH: HEALTH LAW AND BEHAVIORAL ECONOMICS** (co-edited by I. Glenn Cohen, Holly Fernandez Lynch, and Christopher T. Robertson), which will be released by Johns Hopkins University Press in Fall 2016. This book stems from the Center's 2014 annual conference on behavioral economics, law, and health policy.
- We are in the manuscript editing stage for the book stemming from the Center's 2015 annual conference, **LAW, RELIGION, AND HEALTH IN THE UNITED STATES** (co-edited by Holly Fernandez Lynch, I. Glenn Cohen, and Elizabeth Sepper). The manuscript will be submitted in Fall 2016, for publication by Cambridge University Press in Spring 2017; the project was delayed in order to allow chapters to account for the Supreme Court's decision in *Zubik v. Burwell*, issued in May 2016.



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- In June 2016, we submitted the manuscript for **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. This volume will be published by MIT Press for release in Spring 2017, barring substantial revisions necessitated by finalization of proposed regulatory changes to the rules governing biospecimen research.
- Finally, we have submitted a book proposal (co-edited by I. Glenn Cohen, Holly Fernandez Lynch, Urs Gasser, and Effy Vayena) stemming from our 2016 annual conference, **BIG DATA, HEALTH LAW, AND BIOETHICS**, which has just been put under contract with Cambridge University Press. We will begin working on the manuscript shortly, in hopes of publishing the book within the next year.



Events Programming and Conferences

Over the 2016–2017 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 banner of the Projects on Law and Applied Neuroscience and Advanced Care and Health Policy:

Major Events/Conferences

Conference on pre-trial diversionary courts (invitation only) September 26–28, 2016

Sponsored by the Federal Judicial Center, the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, the Center for Law, Brain and Behavior at MGH, and the Criminal Justice Policy Program at Harvard Law School. Part of the Project on Law and Applied Neuroscience.

Advances in In Vitro Research and the 14 Day Rule: Examining the Ethical Underpinnings and Future Scope of the Rule November 7–8, 2016

Sponsored by the Harvard University Office of the Provost, the Harvard University Office of the Vice Provost for Research, the Edmond J. Safra Center for Ethics, 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 and Policy Program at Harvard Law School and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

Paying Research Participants: Ethical and Regulatory Parameters December 9, 2016

This event is 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 Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard.

Fifth Annual Health Law Year in P/Review January 23, 2017

The Law and Ethics Initiative of the Football Players Health Study March 2017 (exact date TBD)

Part of the Football Players Health Study at Harvard University



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HMS Center for Bioethics Annual Conference: The Ethics of Making Babies
April 6–7, 2017

2017 Petrie-Flom Center Annual Conference: Transparency in Health and Health Care: Legal and Ethical Possibilities and Limits
May 5, 2017

Lectures, Panels, and Other Events

2016 Petrie-Flom Center Open House
September 7, 2016

Battling Blood in the Streets: How Can Neuroscience Promote Public Health and Support Public Policy to Prevent Community Violence?
September 7, 2016

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

Health Care after the Election
October 24, 2016

Concurrent Surgeries: Medical, Legal, and Ethical Issues
October 27, 2016

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.

Book Event: FDA in the 21st Century
January 25, 2017
Hosted by the New York State Bar Association.

PORTAL Ethics and Health Policy Seminar: Returning Results to Research Participants
February 10, 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.



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 a new Massive Open Online Course (MOOC) 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](#) and the [Football Players Health Study](#), and **Holly Fernandez Lynch** will again teach a Spring [seminar on health policy, law, and bioethics](#) as part of the HMS Master's Program in Bioethics.

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

I. Glenn Cohen (HarvardX)

Starts September 6, 2016

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

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



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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.

Health Law, Policy, Bioethics, and Biotechnology Workshop

I. Glenn Cohen

Fall 2016 – Spring 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. This course meets 12 times total across the whole year, likely 6 times each semester. 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.

Law and Neuroscience

Nancy Gertner

Spring 2017

With frequent guest lectures and contributions to classroom discussion from Senior Fellow **Robert Kinscherff**, this course will again be offered as part of the Project on Law and Applied Neuroscience. The seminar will examine cutting edge and even controversial linkages between law and neuroscience. It will 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. It 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 to considerations of the relationship between law and science, more



generally, and neuroscience in particular. Speakers will provide insights into their work and research.

Reproductive Technology and Genetics: Legal and Ethical Issues

I. Glenn Cohen

Spring 2017

Should individuals be able to sell reproductive materials like sperm and ova, or reproductive services like surrogacy? Should the law require individuals diagnosed with diseases like Huntington's disease to disclose to family members that they too are at risk for the disease? Should prenatal sex selection be a crime? Should federal funds be used for stem cell research? Should law enforcement be able to bank DNA samples collected from suspects and perpetrators? Should doctors be able to patent cell lines developed from their patients' bodies?

Since Watson and Crick's discovery of the double helix structure of DNA in 1953, and the 1978 birth of Louis Brown, the first child conceived through in vitro fertilization, pressing questions like these have propagated. This course will cut across doctrinal categories to examine how well the law and medical ethics have kept up, and plot directions for fruitful development. Topics covered may include:

- Prenatal genetic screening and sex selection
- Genetic enhancement
- The sale of sperm and ova and access to reproductive technology
- Surrogacy
- Cloning
- Preembryo disposition disputes
- Wrongful birth, wrongful conception, and wrongful life torts
- The parentage and anonymity of gamete donors
- Imposition of criminal liability on mothers and third parties for harm to fetuses
- The use of genetic information by insurers and employers
- The collection of genetic information by the state and the criminal justice system
- Biobanking
- Chimeras (human-animal hybrids)
- The stem cell controversy
- The patenting of genes and their derivatives
- Research ethics issues involving fetuses and embryos
- Pharmacogenomics and Race



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 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 at the end of the summer.

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. In 2016, we also invited Harvard graduate students to serve as short-term summer bloggers, and selected two applicants who began posting in June.

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 September 2016 for publication in early 2017.



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

As we wrapped our first decade as a research program at Harvard Law School, we have been actively planning for our second. In addition to continuing elements of our existing portfolio, including fellowship programs, public events, interdisciplinary publications and collaborations, and various sponsored research projects, we are actively seeking funding to expand our capacity to influence policymaking in these fields.

Our goal is to establish several new Topical Programs within the Center 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 issues. If funded, these Topical Programs 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 aim is to initially launch the following three Topical Programs, which expand on work that has begun over the past decade:

- **Law and Bioethics**, covering such topics as human subjects research regulation and ethics, reproductive health and technology, organ donation policy, and end-of-life issues, among others, including expansion of the existing Project on Law and Applied Neuroscience.
- **Health Care Delivery and Finance**, covering topics including health insurance policy, industry consolidation, regulating medical professions, fraud and abuse, and the like.
- **Medical Innovation and Law**, focused on intellectual property and innovation policy as relevant to pharmaceuticals, devices, and other medical interventions.

Additional programs could be developed in other areas with a policy focus, such as empirical health law, mental health, race and health, health IT, adolescent and young adult health, and others.

We have also begun contemplation of whether to launch a formal Advisory Board to the Petrie-Flom Center, comprised of experts from a variety of fields and sectors related to health law, policy, and bioethics, to guide us most productively into the future.