



## **The Petrie Flom Center for Health Law Policy, Biotechnology, and Bioethics**

*Fiscal Year 2014*

*Annual Report*

August 15, 2014

### **Executive Summary**

We can easily say that this year was the Petrie-Flom Center's best yet. We launched two new sponsored research programs – one with Harvard Catalyst to address legal and ethical issues related to clinical and translational research, and one focused on resolving some of the most pressing legal and ethical issues that impact the health and welfare of professional football players – and we dramatically expanded our staff in order to keep up, welcoming two new Senior Associates and two part-time support staff. In addition, this year marked the beginning of our collaboration with Stanford and Duke to publish the JOURNAL OF LAW AND BIOSCIENCES, a peer-reviewed, open access interdisciplinary journal from Oxford University Press featuring world-class scholarship, responsive commentary, and student-written current event highlights. We are also pleased to welcome Professor Jacob Gerson's Food Law Lab under our umbrella as it got underway this year.

The Center unveiled an extensive new website featuring a range of resources for individuals interested in our fields, including news and announcements about our Center and its activities, a news feed of current health policy stories making headlines around the world, available job openings and other opportunities at Petrie-Flom and elsewhere, primers on key bioethics and health policy topics, and a compilation of curricular and other resources for individuals at Harvard. Our popular blog, Bill of Health, is stronger than ever with nearly two years under our belt, frequent contributions from leading scholars, about 12,000 visitors each month, and readers in nearly 200 countries around the world.



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Our bread-and-butter programs have also fared well. Each year, we host Academic Fellows (post-doctoral) who are preparing to enter the law school teaching market, several Harvard graduate student fellows and visiting scholars who are pursuing independent scholarly projects, and a number of student interns. We are also lucky to boast an impressive array of affiliated faculty from around the University. Our two departing Academic Fellows received tenure-track positions at the University of New Hampshire and the University of Cambridge, and produced world-class scholarship on innovation policy and anonymity. Several of our student fellows saw their papers published in leading outlets, and our visiting scholars made the most of their time through extensive networking, collaborative writing, and participation in Center events. And of course, our faculty leadership continued to be prolific scholars, publishing books and articles on topics ranging from medical tourism to reproductive technology to pharmaceutical patent policy and more. Center affiliates were published in leading journals, including *Health Affairs*; *The Harvard University of Chicago, UCLA, Fordham, and Boston College Law Reviews*; *The Journal of Law and Contemporary Problems*; *The Yale Journal of Health Policy, Law, and Ethics*; *The American Journal of Law and Medicine*; *The Journal of Law, Medicine, and Ethics*; *The New England Journal of Medicine*; *JAMA*; *The American Journal of Bioethics*, and more. Center affiliates were also routinely sought out by the media to offer commentary and guidance on news stories in our fields, especially the mounds of litigation related to the Affordable Care Act.

The Center's public events schedule was again packed and popular, from short panel discussions to conferences spanning several days. This year, we hosted events on behavioral economics, pharmaceutical policy, biopatent law, mental health, food law, animal ethics, reproductive rights, and health law and bioethics careers, to name a few. The edited volume from our 2012 annual conference, HUMAN SUBJECTS RESEARCH REGULATION: PERSPECTIVES ON THE FUTURE, was released by MIT Press in July 2014, and we are nearing submission of the manuscript for the volume from our 2013 conference on the Food and Drug Administration (to be published by Columbia University Press).

The Center's biweekly Health Law Policy Workshop once again featured the interdisciplinary scholarship of leading academics, and Center affiliates made important contributions to the Law School's health law curriculum, offering seminars on genetics and law, "ambiguous entities" in bioethics and law, and comparative professional responsibility for doctors and lawyers.

We anticipate that next year will be even better for the Center, save for the departure of our former Faculty Co-Director, Benjamin Roin, who is now at MIT Sloan. Professor Roin remains affiliated with the Center as a visiting scholar and affiliated faculty. We will launch a new collaboration with the Center for Law, Brain, and Behavior to host the Program on Law and Applied Neuroscience, and will continue our work on other sponsored research projects. Our current Academic



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Fellows are poised to do well on the law teaching market, we look forward to welcoming a new crop of student fellows and visitors, and our events schedule is already shaping up to feature a range of collaborations and commentary on everything from post-trial access to the legal and ethical issues faced by intersex individuals. We are nearing a contract with Johns Hopkins University Press on the book proposal stemming from our 2014 annual conference on Behavioral Economics, Law, and Health Policy, and already planning for next year's conference on Law, Religion, and Health Care.

We look forward to building and continuing our substantial collaborations with colleagues at the Schools of Medicine, Public Health, Government, and in particular, to working with the HMS Center for Bioethics to launch a new Master's degree in bioethics, featuring a health law and policy track run through the Petrie-Flom Center.

Our sincere thanks go out to everyone who supports our work. We can't wait to see what the next year will bring!

Sincerely,

I. Glenn Cohen

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

Faculty Director  
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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## ***2013-14 Report of Activities***

(Fiscal Year 2014: July 2013-June 2014)

### **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, with the goal of promoting interdisciplinary analysis and legal scholarship in these fields. The Center is a leading research program dedicated to the unbiased 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 – in other words, all of us.

The Center's work generally falls into the following categories: (1) academic, including our fellowship programs and curricular contributions; (2) public engagement, including our website, blog, numerous events, and media commentary; and (3) sponsored and other research.

During the 2013-14 academic year, the Center was led by faculty co-directors Professors **I. Glenn Cohen** and **Benjamin Roin**, with additional leadership from executive director **Holly Fernandez Lynch**.



## **Research, Scholarship, and Project Activities**

Since its founding as a research program at Harvard Law School (HLS), the Petrie-Flom Center and its affiliates have developed a strong reputation for the production of leading scholarship at the forefront of health law policy, biotechnology, and bioethics. This year our affiliates – including faculty, staff, fellows, and visitors – again published top-rate scholarship and served as commentators for major media outlets, as well as invited lecturers, panelists, and presenters in a wide variety of events. We also took several steps in new directions, including our first foray into sponsored research and launching a new peer-reviewed journal. These accomplishments are described in more detail below.

### **Sponsored Research**

This year, the Center commenced two major sponsored research projects that take advantage of the law and ethics expertise our affiliates have to offer, and provide the opportunity to expand the Center through new staff devoted entirely to these initiatives. We also submitted a number of funding proposals in collaboration with others around the university and elsewhere.

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

The Football Players Health Study (FPHS) at Harvard University is a research initiative established to improve and protect the health and well-being of professional football players. The project is funded through a contract between the National Football League Players Association and Harvard Medical School, and includes three main components: (1) a Players Health Study focused on the health and well-being of former National Football League players; (2) a Pilot Studies program focused on identifying and supporting innovative, high-return research studies that have a strong likelihood of impacting the health of football players; and (3) a Law and Ethics component, led by the Petrie-Flom Center.

The Law and Ethics Initiative seeks to promote understanding of the legal and ethical issues that may enhance or impede player health, and to this end, develop appropriate responsive strategies and recommendations. Key projects currently include:

- A qualitative research study (“listening tour”), conducted in collaboration with the Hastings Center. This study will catalogue the legal and ethical concerns of players and their families related to their health and wellbeing,



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- and will also be used to identify new priority projects for the Law and Ethics Initiative;
- A comparative legal and organizational policy analysis of various professional sports leagues to identify best practices in protecting player health and wellbeing, also conducted in collaboration with the Hastings Center;
  - Development of an ethical framework and accountability structure for various stakeholders that may influence player health and wellbeing, including recommendations about the responsibilities of relevant parties;
  - Public conferences, events, and publications to facilitate discussion of law and ethics issues, to solicit feedback from players and other stakeholders, and to influence change.

The Law and Ethics Initiative team also works to advise on legal and ethical issues that may arise in the clinical research portions of the Players Health Study.

The Law and Ethics Initiative is co-led by **I. Glenn Cohen** and **Holly Fernandez Lynch**. We welcomed **Christopher Deubert** as Senior Law and Ethics Associate at the end of May 2014, and will be welcoming a part-time Project Coordinator to support the project shortly. **Patrick Taylor** is also involved as an advisor.

In addition, we have established a Law and Ethics Advisory Panel (LEAP) to advise our work. The LEAP draws on scholarship and expertise across law, ethics, higher education, and professional football. Members will assist in the direction and execution of this Initiative by providing advice on the execution of planned projects; proposing additional priority law and ethics projects; providing input on draft reports, findings, recommendations, and other project output; facilitating connections to appropriate stakeholders and other experts; and serving as consultants when questions arise.

***Harvard Catalyst Clinical and Translational Science Award***

This winter, the Petrie-Flom Center joined the Regulatory Foundations, Ethics, and Law Program of Harvard Catalyst | The Harvard Clinical and Translational Science Center at Harvard Medical School. Harvard Catalyst 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 Harvard University, Harvard Medical School, Harvard School of Public Health, Harvard Law School, Beth Israel Deaconess Medical Center, Boston Children's





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Hospital, Brigham and Women's Hospital, Dana-Farber Cancer Institute, and Massachusetts General Hospital.

The Center's work on this project – the Ethics and Law Initiative – is initially focused on two priority areas: 1) participant recruitment to, and retention in, research studies, and 2) clinical data sharing for research purposes.

Clinical research cannot succeed without human research participants, but recruitment is a perennial challenge. Accordingly, our work aims to develop practical solutions to key barriers, focusing on such issues as the use of financial incentives, social media, demographic targeting, diversity, and engagement with vulnerable populations. Through exploration of international and comparative dimensions, engagement with critical stakeholders, and benchmarking current practices and concerns, this project will produce educational modules and guidance documents for IRBs, investigators, and recruitment managers, model policies and other toolkits, consensus statements, and the like.

In parallel, Petrie-Flom is examining the current landscape and challenges of sharing clinical data with qualified researchers. The project is designed to identify potential gaps in oversight, assess compliance demands, and craft recommendations about current and projected needs for the sharing of clinical data for research purposes.

We are also involved in various educational initiatives, including several recorded lectures for the Catalyst online course Fundamentals of Clinical and Translational Research (FaCToR), as well as lectures for Introduction to Translational Medicine (ITTM).

This Ethics and Law Initiative is co-led by **I. Glenn Cohen** and **Holly Fernandez Lynch**, in close collaboration with Program Director of the Regulatory Foundations, Law, and Ethics Program, Barbara Bierer, and Director of Regulatory Affairs Operations, Sabune Winkler. We welcomed **Robin Pierce** as Senior Law and Ethics Associate in March 2014, and part-time Project Coordinator **Yennifer Pedraza** in May 2014. **Patrick Taylor** has also been staffing this project, with a focus on data sharing.

***Additional Efforts***

In an effort to develop our sponsored research portfolio, this year Petrie-Flom participated in several additional grant applications, which were unfortunately unsuccessful. However, we may pursue funding of some of these projects through other avenues. Moreover, the application process allowed us to develop



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new collaborative relationships that have been fruitful in other ways, and to hone the Center's research agenda for the future.

**The John Templeton Foundation:** We collaborated with the Science, Religion, and Culture Program at Harvard Divinity School to propose a project on "Understanding Religion, Law, and Health Policy," as part of a larger proposal to create a Program on Health, Spirituality, and Religion at Harvard University. Had the project been funded, it would have created a post-doctoral fellowship program, several new cross-listed courses (e.g., Religion, Law, and Medicine; The First Amendment and Health Policy; and Public Discourse on Religion and Health Policy), a lecture series, and a graduate student research fund.

**The Greenwall Foundation:** We collaborated with the Multi-Regional Clinical Trials Center at Harvard (MRCT) to propose a project on "Clarifying and Implementing Post-Trial Access Obligations." The project aims were to identify legal barriers to and facilitators of post-trial access; offer recommendations to reduce identified barriers and encourage identified facilitators; clarify the current state of implementation of major national and international guidelines; uncover and articulate key features of successful and unsuccessful post-trial access policies and initiatives; generate recommendations to promote successful post-trial access policy implementation; develop practical tools for implementation; and engage policymakers. Although not funded, Petrie-Flom and MRCT are nonetheless pursuing work in this area, including a joint conference on "Post-Trial Responsibilities: Ethics and Implementation" in September 2014. In addition, MRCT will be creating a post-trial access working group, on which Petrie-Flom affiliates will participate.

**National Institutes of Health (NIH):** We collaborated with Rosamond Rhodes at Icahn School of Medicine at Mount Sinai to submit a proposal to NIH for a project on "Barriers to Research on Controlled Drugs for HIV-Related Treatment." Our work would have entailed overseeing law students to undertake a review of the current legal and regulatory constraints on research with controlled substances in order to provide an evidence-based foundation for developing ethical guidelines for the conduct of such research and a fact-based starting point for policy recommendations. Dr. Rhodes plans to resubmit this winter, including our work.

## **Journal of Law and Biosciences**

This year, we launched the first volume of the Journal of Law and Biosciences (JLB), a collaboration with colleagues at Duke and Stanford Universities, published by Oxford University Press. **I. Glenn Cohen** serves as co-Editor-in-Chief, alongside Nita



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Farahany (Duke) and Hank Greeley (Stanford); **Holly Fernandez Lynch** oversees the involvement of Harvard students.

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 “New Developments” for each issue, comprised of brief summaries of and commentary on recent legislation, regulation, and case law relevant to the biosciences.

The journal’s most recent table of contents is copied below:

*Volume 1 Issue 2 June 2014*

**Original Articles**

John A. Robertson, *Egg freezing and egg banking: empowerment and alienation in assisted reproduction*

Alan Wertheimer, *(Why) should we require consent to participation in research?*

**New Developments (Harvard students)**

Ashish M. Bakshi, *Gene patents at the Supreme Court: Association for Molecular Pathology v. Myriad Genetics*

Adriana Lee Benedict, *State-level legislation on follow-on biologic substitution*

Komal Karnik, *FDA regulation of clinical decision support software*

Nicholas Meyers, *Cook v. FDA and the importation and release of lethal injection drugs*

**Peer Commentary**

Mark S. Frankel, *Considering advances in neuroscience through the lenses of law and human rights*

Judy Illes, Jacqueline Davidson, and Ralph Matthews, *Environmental neuroethics: changing the environment — changing the brain,*



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*Recommendations submitted to the Presidential Commission for the Study of Bioethical Issues*

Owen D. Jones, Richard J. Bonnie, B. J. Casey, Andre Davis, David L. Faigman, Morris Hoffman, Read Montague, Stephen J. Morse, Marcus E. Raichle, Jennifer A. Richeson, Elizabeth Scott, Laurence Steinberg, Kim Taylor-Thompson, Anthony Wagner, and Gideon Yaffe, *Law and neuroscience: recommendations submitted to the President's Bioethics Commission, Comments of The MacArthur Foundation Research Network on Law and Neuroscience to The Presidential Commission for the Study of Bioethical Issues of the Department of Health and Human Services*

*Ethical considerations of neuroscience research and the application of neuroscience research findings for the Presidential Commission for the Study of Bioethical Issues*

## **Food Law Lab**

The Food Law Lab was founded in the Fall of 2013 by Professor **Jacob Gersen**, as a center for coordinated and directed research in the emerging field of food law. The Food Law Lab is currently situated within the Petrie-Flom Center, and works closely with the Harvard Food Law and Policy Clinic.

Jacob Gersen is Professor of Law at Harvard Law School and Director of the Food Law Lab. He holds a Ph.D. and J.D. from the University of Chicago, where he also taught prior to joining Harvard in 2011. He is co-editor of FOOD LAW AND POLICY (with Michael T. Roberts) (under contract) and is an expert in food law, administrative law, legislation, and constitutional law.

### ***Academic Approach***

Despite the prominence of food issues in current popular culture and policy debates, there is a comparative dearth of scholarship on food issues in legal academia. Historically, food law has typically been taught as a subset of Food and Drug Law, a course heavily focused on federal regulation. Partially as a consequence, there are still relatively few curricular offerings at most law schools and little modern scholarship being produced. The Food Law Lab hopes to remedy both these failings by creating the leading academic center for legal research on food that, beyond federal regulation, addresses the “law of everyday life” – or the regulations and issues that directly affect the dinner table experience



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Although the Lab focuses on legal problems, it supports a research agenda that is truly interdisciplinary, blending law with history, anthropology, philosophy, social science, and the humanities.

The Lab fosters a diverse range of methodological perspectives, incorporating aspects of culture and norms surrounding food. We will explore the ways in which these variances manifest themselves – for example, production and consumption of one animal as food is uncontroversial in one culture, while giving rise to potential legal claims in another. In this way, culture is sometimes enforced through legal and non-legal norms regarding food content, production, and labeling.

***Areas of Study***

The Lab's initial work will focus mainly on three current issue areas in the law of food: (1) Institutional Food, (2) Food Safety and Food Quality, and (3) Food Information Awareness.

- (1) *Institutional Food* explores the law and practice of food provision in institutional settings such as prisons, schools, and the military. At the turn of the century, such institutions tended to receive systematically lower quality food products. Today, given the combined proportion of the population in schools, prisons, and the military, much of the nations' diet is being supplied by institutional food. Yet, neither the law governing institutional food, nor the food practices of institutions, nor the consequence for individuals living in those institutions has been adequately evaluated.
- (2) *Food Safety & Food Quality* considers the relationship between food safety and food quality; we will approach the legal challenges and solutions affiliated with managing the food supply system for optimized output. The fundamental challenge of Food Safety is to identify potential intentional and unintentional contaminants in the food supply and either prevent them from entering the system or be able to find and remove them after entry. The challenge of Food Quality is to ensure that healthy, nutritious, and good-tasting foods are produced and consumed. These two problems are related, but they are also often in conflict as there is often a taste-safety tradeoff and the government regulators have strong incentives to favor safety. This decision process may be sensible, but it also has significant long-term consequences for what we eat and the way we eat it.
- (3) *Food Information Awareness*. The cornerstone of the United States food law system is information provision: people should know what they are eating. As a result, naming, labeling, and claiming are all heavily regulated by the Food and Drug Administration and by state tort law. More than fifty currently pending lawsuits involve challenges to food products names or labels, some brought by consumers, some brought by competitors. Yet, we



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know remarkably little about how information provision actually affects consumer beliefs and behavior. The Food Information Awareness project seeks to explain and ultimately improve the use of information policies in the law of food. As part of the Food Facts initiative, the Food Law Lab and the Resnick Program for Food Law and Policy at UCLA are co-sponsoring a conference on transparency in the food system in the Fall of 2014.

## **Faculty Leadership**

In 2013-2014, the Petrie-Flom Center continued to be ably led by our faculty co-directors, **I. Glenn Cohen** and **Benjamin N. Roin**, top scholars in their respective fields of bioethics and intellectual property law.

This summer, Professor Roin departed the Center and Harvard Law School to take up a position at the MIT Sloan School of Management. Going forward, Professor Cohen will continue to lead the Center as its sole Faculty Director.

In addition, we continue to enjoy the support of our founding faculty director, **Einer Elhauge**. Professor Elhauge was honored this year by the Tulsa Law Review, which published a symposium issue featuring his impact on health law policy: *Health Law Policy – Honoring the Work of Einer Elhauge*. The symposium featured contributions by Professor Elhauge, as well as I. Glenn Cohen and former Petrie-Flom student and academic fellow, Christopher T. Robertson; former academic fellows Abigail Moncrieff and Talha Syed gave oral comments in Professor Elhauge's honor.

## ***2013 Faculty Summer Research Support***

The Center supported several faculty research projects during the summer of 2013. Funding this research promotes one of our central goals, which is to encourage experts in health law policy, biotechnology, and bioethics to develop and promote creative solutions to persistent and new problems arising in these fields.

**I. Glenn Cohen** worked on a variety of research projects, including several articles and the following books:

PATIENTS WITH PASSPORTS: MEDICAL TOURISM, LAW, AND ETHICS (Oxford University Press, forthcoming October 2014)

HUMAN SUBJECTS RESEARCH REGULATION: PERSPECTIVES ON THE FUTURE (co-edited with Holly Fernandez Lynch) (MIT Press, 2014)

H2O FREE CIVIL PROCEDURE TEXTBOOK



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IDENTIFIED V. STATISTICAL LIVES: ETHICAL, LEGAL, AND MEDICAL PERSPECTIVES (Oxford University Press, forthcoming 2015) (co-edited with Nir Eyal and Norman Daniels and contributing a chapter)

NEW AND ENDURING CHALLENGES FOR FDA: SELECTED ESSAYS ON THE FUTURE OF THE AGENCY AND ITS REGULATION OF DRUGS AND NEW TECHNOLOGIES (co-edited with Holly Fernandez Lynch) (Columbia University Press, forthcoming 2015)

During his summer funded period, **Benjamin N. Roin** worked on a paper about how we can encourage pharmaceutical companies to develop new indications for older drugs and enable more efficient drug pricing by using e-prescribing and e-health records to facilitate differential drug pricing by indication. He also completed another paper entitled *Intellectual Property versus Prizes: Reframing the Debate*.

During his summer funded period, **Einer Elhauge** worked on a number of projects, including continued work on a book on Re-engineering Human Biology and an article on the Supreme Court's Medicaid expansion decision. Additional projects included work on the following articles:

- "Rehabilitating Jefferson Parish: Why Ties without a Substantial Foreclosure Share Should Not Be Per Se Legal"
- "The Welfare Effects of Metering Ties"
- "Gutting Private Antitrust Enforcement By Replacing It With Ineffective Forms Of Arbitration"

## **Academic Fellows**

Our Academic Fellowship is a full-time postdoctoral program specifically designed to identify, cultivate, and promote promising scholars early in their careers who are committed to pursuing publishable research that is likely to make a significant contribution to the fields of health law policy, innovation policy, or bioethics. Prior fellows are now employed as tenured or tenure-track professors at institutions such as Harvard, UC Berkeley, Boston University, UCLA, Cornell, the University of Illinois, the University of Arizona, and Union Graduate College. The two fellows who completed their fellowships this year, **Nicholson Price** and **Jeffrey Skopek**, will take up tenure-track faculty positions in law at the University of New Hampshire and the University of Cambridge, respectively.

In addition to their own independent research and writing, Academic Fellows advance the Center's mission by mentoring students, teaching seminars, presenting



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their work at Harvard and beyond, and planning and participating in a range of public events and closed workshops.

The Academic Fellowship program remains at present a cornerstone of the Petrie-Flom Center and its scholarly focus. However, as planned in response to the tightening of the teaching market in the recent past, we have begun to accept only one outstanding new fellow each year, and will taper the program off completely by Fall 2016.

The work of our fellows from the 2013-2014 academic year is summarized below.

***Jeffrey M. Skopek, 2011-2014***

Jeff has written two articles that explore how recognizing a key difference between the often-conflated concepts of anonymity and privacy reveals important insights into the legal issues at stake in many recent advances in the biosciences. In *Reasonable Expectations of Anonymity* (to be submitted), he develops the previously unrecognized distinction between anonymity and privacy in depth. His basic claim is that anonymity and privacy both protect the secrecy of our personal information, but that they do so in opposite ways: privacy hides the information, whereas anonymity hides what makes it personal. He then shows how understanding this difference reveals the ways in which emerging techniques of genetic identification, surveillance, and “big data” implicate constitutional values that have been overlooked by U.S. courts. In *Anonymity, the Production of Goods, and Institutional Design* (FORDHAM L. REV., 2014), he identifies and explores the complex ways in which legal institutions use anonymity rules to incentivize or control the production of public goods. Developing a taxonomy and theory of these rules, Jeff creates an institutional design framework that reveals innovative solutions to pressing challenges in the production of specific political and biomedical goods.

Jeff also designed and taught a seminar titled, “Rethinking the Legal and Ethical Status of Humans, Animals, and the Environment.”

Jeff will be joining the law faculty of the University of Cambridge in the fall. At Cambridge, Jeff will continue his scholarship on advances in the biosciences that destabilize fundamental concepts of law and ethics, play a leadership role in building a new center in Medical Law, Ethics, and Policy, and teach and supervise research in this area. His immediate research agenda consists of projects on personalized medicine, biobanking, and big data. These projects will build on the work he has done at the Petrie-Flom Center. Jeff is also excited to develop new interdisciplinary collaborations on law and the biosciences, including with old friends in the Department of the History and Philosophy of Science, where he received a M.Phil. and Ph.D. prior to coming to Harvard to study law.





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**W. Nicholson Price II, 2012-2014**

Nicholson focused his work on innovation in the life sciences, with a secondary focus on issues surrounding genetic testing. In the past year, he published two law review articles: *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing* (B.C. L. REV.) and *Patent Trolling—Why Bio & Pharmaceuticals Are at Risk* (STAN. TECH. L. REV. with Robin Feldman). He will submit two law review articles in the upcoming year: *Incentives, Intellectual Property, and Black-Box Personalized Medicine* and *Biosimilars and Manufacturing Trade Secrets* (with Arti Rai). Other co-authored works have been or will be published in *The Hastings Center Report*, *Pediatrics*, and *Genetics in Medicine*. One short article was published in the New England Journal of Medicine/Harvard Business Review Insight Center on High-Value Health Care, another is forthcoming in *IP Theory*, and a third, co-authored with Petrie-Flom Visiting Scholar Timo Minssen, is under review. Nicholson presented on these and other topics at 16 conferences and colloquia this year, including at Harvard, the Broad Institute, Yale, Columbia, UCLA, and the Munich Conference on Innovation and Competition. Nicholson also designed and taught a seminar entitled “Genetics and the Law” at Harvard Law School in Spring 2014.

Nicholson has joined the University of New Hampshire School of Law as an Assistant Professor. He will remain a Faculty Affiliate of the Petrie-Flom Center.

**Matthew J. B. Lawrence, 2013-2015**

Matt joined the Center this year, and spent his first year as an Academic Fellow unpacking how we value and distribute procedural rights in healthcare, in two law review articles. The first Article, *Mandatory Process*, is forthcoming in the INDIANA LAW JOURNAL in 2015. It began as a search for the market failure, if any, that justifies the Affordable Care Act’s mandate that private health insurance contracts offer beneficiaries a right to independent, external review of any decision denying coverage. The Article concludes that we should not presume that a market is superior to a government mandate for distributing procedural protections before a dispute has arisen, for two reasons. First, several classical and behavioral market failures can prevent claimants from taking the acceptance-promoting benefits of procedural protections into account when entering *ex ante* agreements that limit or waive procedural rights, such as agreements to arbitrate or to modify the rules of civil procedure. Second, rules that forbid enforcement of such contracts—process mandates—do not completely deprive the parties of the choice whether to forego procedural protections. Process mandates regulate only the timing of such a choice, not the



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ultimate decision, so they are not as normatively problematic as more run-of-the-mill mandates. Over the winter, Matt presented *Mandatory Process* at New York University School of Law and at the New England Regional Junior Faculty Workshop.

In his next Article, *Rationing Process*, Matt is addressing how Medicare should deal with a growing backlog of nearly a million coverage disputes. The work-in-progress, which Matt is preparing for job talks on the teaching market this fall, notes that because more claimants want hearings than Medicare can provide, Medicare has no choice but to ration procedural protections. Rather than ration by providing the same compromised procedural protections to all claimants, the paper argues that procedural protections should be rationed among claimants according to need. Specifically, it shows that hearings are not the most cost-effective way to resolve Medicare coverage disputes, and makes the case that large providers should be incentivized to waive their procedural rights in order to save scarce procedural protections for the small providers and beneficiaries who stand to derive most inherent benefit from having their “day in court.” The Article concludes by drawing from its study a framework to identify where and how other administrative and judicial processes should ration process.

In the spring, Matt presented *Rationing Process* at Harvard’s Health Law Workshop; the Petrie-Flom Center’s Annual Conference on Behavioral Economics, Law, and Health Policy; and at the ASLME Health Law Professors’ Conference in San Diego.

## **Visitors**

Although the Center does not solicit applications for Visiting Scholars, it is a sign of our success and 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 or projects 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.

This year, we hosted four outstanding visitors at different stages of their careers:

### ***Aziza Ahmed, January-August 2014***

Aziza Ahmed is Associate Professor of Law at Northeastern School of Law. She is an expert in health law, human rights, property law, international law, and development. Her interdisciplinary scholarship focuses on issues of both domestic and international law. She teaches Property Law, Reproductive and



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Sexual Health and Rights, and International Health Law: Governance, Development, and Rights. In addition to this work, Professor Ahmed also examines challenges facing Muslim minority communities post 9/11.

During her time as a Petrie Flom Visiting Scholar, Aziza worked on a range of issues impacting domestic and global health law. She completed a draft paper, “Medical Evidence and Expertise in Abortion Jurisprudence,” which will be submitted this fall. Further, she was invited to participate in a UN Expert Group Meeting in Addis Ababa, Ethiopia (following her work as an expert with the Global Commission on HIV and the Law) on the role of Property Law in the HIV Epidemic. A paper will be coming out of this gathering discussing feminism, property rights, and development in the context of HIV. This summer Aziza was invited to give a lecture during the Science and Technology Studies “summer camp” called Science and Government at the Frontiers of Life, which brings together scholars in the field of STS. This follows on an earlier presentation at a two-day workshop on STS at Harvard entitled Facts and Futures. The workshop was co-sponsored by the Harvard Law School Institute for Global Law and Policy. She will also be presenting her work on abortion and medical evidence and expertise in October 2014 constitutional law conference at Yale entitled “Public Health in the Shadow of the First Amendment” as part of a larger discussion on Science and Democracy.

***Kuei-Jung Ni, August 2013-July 2014***

Kuei-Jung 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. His research project explored the systems of governmental food safety regulation in the United States and Europe in order to develop a suitable system for the Taiwanese government. Ni’s visit to the Center was supported by a Fulbright grant and funding from the Top University Strategic Alliance (TUSA) of Taiwan.

Professor Ni collaborated with the Petrie-Flom Center and other faculty at Harvard Law School to host a conference on “New Directions for Food Safety: The Food Safety Modernization Act and Beyond.” The conference took place at Harvard Law School on February 21, 2014, and drew more than a hundred participants including scholars, practitioners, policymakers, regulatory officials, and farmers who engaged in a vigorous discussion of new developments in American and international food safety law.

Professor Ni also presented his work on the FDA’s current policy on antibiotics in food animals at the American Society of Law, Medicine, and Ethics 37<sup>th</sup> Annual



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Health Law Professors Conference in San Francisco on June 7, 2014. The PowerPoint file of his presentation can be viewed [online](#).

***Timo Minssen, January-March 2014***

Timo Minssen is Associate Professor of IP & Innovation Law at the University of Copenhagen (UCPH), Centre for Information & Innovation Law (CIIR), Denmark. Before joining UCPH, Timo graduated from law school in Göttingen (Germany) in 2001 and was trained in the German court system from 2002-2003. He also passed the Swedish "juris licentiate" (LL.Lic.) and "juris doctor" exams (LL.D.) and holds two IP- and Biotech- related masters degrees from the Universities of Uppsala and Lund (Sweden). He has worked for a life science company and for various law firms in Sweden and Germany.

While at Petrie-Flom, Timo focused on four main work areas. First, he used the three months for intensive networking with colleagues in the U.S. patent community, Harvard Law School, Harvard Medical School, MIT, the Broad Institute, Boston University, and Boston law firms. Second, he participated in a number of seminars and gave three presentations, including co-organizing and speaking at the Petrie-Flom Center event "Patents without Patents: Regulatory Incentives for Innovation in the Pharmaceutical Industry." Third, he published and wrote on a variety of articles (see below) and discussed future research and collaborative writing projects with Harvard and MIT scholars, mainly within the areas of pharmaceutical policy, regulation and patent law. Fourth, he worked extensively on an application for a major 5-10 years research grant in comparative US/European pharma policy.

Publications developed during Timo's time at the Center include:

***Standardization, IPRs & Open Innovation in Synthetic Biology***

in INNOVATION, COMPETITION AND COLLABORATION (Edward Elgar Publishing, forthcoming 2014)(with Jakob B. Wested)

***Book review: PHARMACEUTICAL INNOVATION, COMPETITION AND PATENT LAW***

EUROPEAN COMPETITION LAW REVIEW (2014)

***Legal aspects of biobanking as key issues for personalized medicine and translational exploitation***

PERSONALIZED MEDICINE (forthcoming September 2014)(with Jens Schovsbo)



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**George P. Smith, June 2014**

George P. Smith is Professor of Law at the Catholic University of America Columbus School of Law. He has had previous law teaching affiliations at the University of Michigan, Indiana University, Georgetown, George Washington and Notre Dame. His core teaching areas are property law, land use and environmental law. His areas of specialization are law, science and medicine - specifically bioethics and health law. He is the Founding Faculty Editor of THE JOURNAL OF CONTEMPORARY HEALTH LAW AND POLICY. He has held over 85 research appointments with institutions including: the medical schools at the universities of Chicago, Columbia, Indiana, Minnesota, Northwestern, Pennsylvania, Texas, Virginia and Washington, as well as the universities of Arizona State; Auckland; New Zealand; British Columbia; Cambridge; McGill; Oxford; Sydney, Australia; The Hoover Institution, The Max Planck Institute, Germany; The Rockefeller Foundation; Bellagio, Italy, Trinity College at Dublin University; Dartmouth College; The Free University of Berlin; Princeton Seminary and the divinity schools at Cambridge, Yale and Vanderbilt.

During his time at the Petrie-Flom Center, Professor Smith pursued research related to an ongoing project on the rationing of health care resources and distributive justice.

**2013-14 Affiliate Scholarship**

As has become the norm, our affiliates have once again enjoyed a prolific year, producing excellent scholarship in the areas of human subjects research, medical tourism, reproductive technology, health care reform, conscientious objection, predictive analytics, intellectual property and innovation policy, anonymity, 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.

**I. Glenn Cohen & Holly Fernandez Lynch**

**HUMAN SUBJECTS RESEARCH REGULATION: PERSPECTIVES ON THE FUTURE**  
(co-edited) (MIT Press, 2014)

**Streamlining Review by Accepting Equivalence**  
14 AM. J. BIOETHICS 11 (2014) (co-authored)

**When Religious Freedom Clashes with Access to Care**  
371 N. ENG. J. MED. 596 (2014) (co-authored with Gregory D. Curfman)



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**NEW AND ENDURING CHALLENGES FOR FDA: SELECTED ESSAYS ON THE FUTURE OF THE AGENCY AND ITS REGULATION OF DRUGS AND NEW TECHNOLOGIES** (co-edited)  
(Columbia University Press, forthcoming 2015)

**L. Glenn Cohen**

**PATIENTS WITH PASSPORTS: MEDICAL TOURISM, LAW, AND ETHICS**  
(Oxford University Press, forthcoming October 2014)

**What (If Anything) Is Wrong with Human Enhancement? What (If Anything) Is Right with It?**  
49 TULSA L. REV. 645 (2014) (festschrift honoring Einer Elhauge)

**Complexifying Commodification, Consumption, ART, and Abortion**  
42 J. L. MED. & ETHICS \_ (2014) (solicited commentary) (peer-reviewed)

**Plan B: Access to Emergency Contraception in the Legal and Political Cross Hairs**  
88 CONTRACEPTION 477 (2013) (co-authored with Eli Adashi and Lisa Sullivan)  
(peer-reviewed)

**Ethical and Legal Implications of the Risks of Medical Tourism for Patients: A Qualitative Study of Canadian Health and Safety Representatives' Perspectives**  
3 BRITISH MEDICAL JOURNAL OPEN e002302 (2013) (co-authored with Valorie A. Crooks, et al.) (peer-reviewed)

**Medical Tourism: Bioethical and Legal Issues**  
*in* ROUTLEDGE COMPANION TO BIOETHICS  
(John D. Arras et al. eds, Routledge, forthcoming 2014)

**Medical Tourism for Services Legal in the Home and Destination Country: Legal and Ethical Issues**  
*in* BODIES ACROSS BORDERS: THE GLOBAL CIRCULATION OF BODY PARTS, MEDICAL TOURISTS AND PROFESSIONALS  
(Brownyn Parry et al. eds, Ashgate, forthcoming 2014)

**Regulating The Organ Market: Normative Foundations for Market Regulation**  
77 LAW AND CONTEMP. PROB (forthcoming, 2014) (symposium)



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***Organs Without Borders? Allocating Transplant Organs, Foreigners, and the Importance of the Nation State***

77 LAW AND CONTEMP. PROB \_ (forthcoming, 2014) (symposium)

***Are All Abortions Equal? Abortion, Rape, and Incest***

42 J. L. MED. & ETHICS (2014) (solicited) (peer-reviewed)

***Clinical Trials and the Right to Remain Silent***

174 JAMA INTERNAL MEDICINE E1 (co-authored with Michelle Mello) (peer-reviewed) (solicited)

***Was the Medicaid Expansion Coercive?***

in THE AFFORDABLE CARE ACT DECISION: PHILOSOPHICAL AND LEGAL IMPLICATIONS 253 (Fritz Allhoff and Mark Hall, eds. 2014)

**H2O FREE CIVIL PROCEDURE TEXTBOOK**

***Make it Work! Breyer on Patents in the Life Sciences***

128 HARV. L. REV. \_ (forthcoming 2014) (festschrift for Justice Breyer)

***Physicians, Medical Ethics, and Execution by Lethal Injection***

311 JAMA 2375 (2014) (co-authored with Robert Truog and Mark Rockoff) (peer-reviewed)

***The Legal And Ethical Concerns That Arise From Using Complex Predictive Analytics In Health Care***

33 HEALTH AFF. 1139 (2014) (co-authored with Bernard Lo, Ruben Amarasingham, and Anand Shah) (peer-reviewed)

***FDA Regulation of Mobile Health Technologies***

370 N. ENG. J. MED. 372 (2014) (co-authored with Nathan Cortez and Aaron Kesselheim) (peer-reviewed)

***Reconsideration of the Lifetime Ban on Blood Donation by Men Who Have Sex With Men***

311 JAMA 337 (2014) (with E. Adashi and J. Feigenbaum) (peer-reviewed)

**IDENTIFIED V. STATISTICAL LIVES: ETHICAL, LEGAL, AND MEDICAL PERSPECTIVES**

(Oxford University Press, forthcoming 2015) (co-edited with Nir Eyal and Norman Daniels, and contributing a chapter)



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**Benjamin N. Roin**

***Do Fixed Patent Terms Distort Innovation?: Evidence from Cancer Clinical Trials***

Chicago Booth Research Paper No. 13-79

***Intellectual Property versus Prizes: Reframing the Debate***

81 U. CHI. L. REV. \_\_ 2014

***The Case for Tailoring Patent Awards Based on the Time-to-Market of Inventions***

UCLA L. REV. (forthcoming 2014)

**Einer Elhauge**

***Obamacare and the Theory of the Firm***

in THE FUTURE OF HEALTH CARE REFORM, Malani and Schill, eds. (U. Chicago Press, forthcoming 2014)

***Robust Exclusion and Market Division Through Loyalty Discounts***

(April 2, 2014)(with Abraham L. Wickelgren)

***Treating RAND Commitments Neutrally***

J. COMPETITION L. & ECON. (forthcoming 2014)

***I'm Not Quite Dead Yet—And Other Health Care Observations***

49 TULSA L. REV. 607 (2014)

**RESEARCH HANDBOOK ON THE ECONOMICS OF ANTITRUST LAW**

(Edward Elgar Publishing Ltd., 2013)

**Holly Fernandez Lynch**

***Protecting Human Research Subjects as Human Research Workers***

in HUMAN SUBJECTS RESEARCH REGULATION: PERSPECTIVES ON THE FUTURE (I. Glenn Cohen & Holly Fernandez Lynch eds., MIT Press 2014)

***Human Research Subjects as Human Research Workers***

14 YALE J. HEALTH POL'Y, L., & ETHICS 122 (2014)(peer reviewed)





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**Jeffrey M. Skopek**

***Anonymity, the Production of Goods, and Institutional Design***

82 FORDHAM L. REV. 1751 (2014)

**W. Nicholson Price II**

***Making Do in Making Drugs: Innovation Policy and Pharmacy Manufacturing***

55 B.C. L. REV. 491 (2014)

***Patent Trolling—Why Bio & Pharmaceuticals Are at Risk***

STAN. TECH. L. REV. (forthcoming 2014) (with Robin Feldman)

***Legal Implications of an Ethical Duty to Search for Genetic Incidental Findings***

13 AM. J. BIOETHICS 48 (2013)

***Problems of Innovation-Deficient Pharmaceutical Manufacturing***

HARV. BUS. REV. & NEW ENG. J. MED. INSIGHT CENTER: LEADING HEALTH CARE INNOVATION (2013)

***Informed Consent for Return of Incidental Findings in Genomic Research***

16 GENETICS MED. 367 (2013) (peer-reviewed) (co-authored with Paul S. Appelbaum et al.)

***Generic Entry Jujitsu: Innovation and Quality in Drug Manufacturing***

3 IP THEORY \_\_ (forthcoming 2014)

***Models of Consent to Return of Incidental Findings in Genomic Research***

44 HASTINGS CENTER REP. 22 (2014) (co-authored with Paul S. Appelbaum et al.)

**Robin Pierce**

***Broader challenges for Deep Brain Stimulation (DBS) in the treatment of Alzheimer's disease***

AM. J. BIOETHICS- NEUROSCIENCE (forthcoming, 2014)



## **2013-14 Affiliate Commentary**

Once again, our affiliates were highly sought after for their expert opinions on a number of pressing news items, including the Affordable Care Act and contraceptives coverage, reproductive technology, medical tourism, doctors' involvement in executions, the VA scandal, biobanks, patent law and innovation, stem cell therapies, the ban on blood donations by gay men, human enhancement, 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 [PrawfsBlawg.com](#) and [TheFacultyLounge.org](#).

These contributions to the media, lay press, and more informal online outlets are invaluable to garnering recognition for the Petrie-Flom Center and our community. Moreover, their focus on and engagement with the general public helps advance the Center's goal of reaching beyond academic circles on critical policy issues.

A full list of our extensive media commentary can be found [here](#), covering the gamut of leading press outlets, including ABC News, NBC News, CBS News, MSNBC, NPR, The Wall Street Journal, The Washington Post, The Los Angeles Times, The Washington Times, USA Today, The New Republic, Nature, Reuters, Business Insider, Fortune, Shape Magazine, Newsmax, FactCheck.org, PolitiFact.com, Vox, and more. Selected highlights are featured below:

### **I. Glenn Cohen**

**JAMA opinion piece calls for ending lifetime ban on blood donations by gay men: Hemophilia groups say policy must be based on science, not politics**  
THE WASHINGTON TIMES, July 19, 2014 (featuring Cohen's JAMA article)

**Some Insurance Companies Ask Their Customers to Cross the Border for Care: Is the practice going to spread?** (editorial with Adam Teicholz)  
THE NEW REPUBLIC, July 7, 2014

**Doctors pushed to reject role in executions**  
interview on The Rachel Maddow Show, June 17, 2014

**California Counties Sue 5 Narcotics Makers**  
interview on Here & Now, NPR, May 22, 2014

**Delaying Pregnancy and Parenthood: Risks and Rewards**  
interview with The Forum at Harvard School of Public Health, in collaboration with WGBH, May 21, 2014



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**Globalization and Healthcare Ethics**

online Twitter discussion, BioethxChat, May 19, 2014

**Proposed West Va. Ban on Abortions After 20 Weeks**

interview on Talkline radio show, February 27, 2014

**Will your clothing spy on you? A scholar warns of the potential for wearable technology to annihilate privacy for good**

FORTUNE, February 13, 2014 (featuring Cohen's Radcliffe Institute lecture)

**These two Americans want babies through Indian surrogates. It's not been easy**

THE NEW REPUBLIC, December 10, 2013 (featuring Cohen's book, PATIENTS WITH PASSPORTS)

**American Companies Sending Workers on Surgery Vacations**

interview with ABC World News, September 30, 2013 (also on Nightline)

**Holly Fernandez Lynch**

**After Hobby Lobby, ACA Exceptions May Become the Rule**

interview with Reuters Health Reform Watch, July 11, 2014

**Everything you need to know about the healthcare contraception mandate**

interview with SHAPE MAGAZINE, March 17, 2014

**W. Nicholson Price**

**Pharma manufacturing woes dog industry**

CHEMISTRY WORLD, October 23, 2013 (quote)

**Matthew Lawrence**

**States seek wiggle room on Obamacare deadline**

THE WASHINGTON TIMES, March 19, 2014 (quote)

**Few will use Obamacare hardship exemption, analysts say**

THE WASHINGTON TIMES, March 23, 2014 (quote)



## **Fellowship Alumni Update**

As indicated above, our Academic Fellowship program aims to promote first-rate scholarship in the areas of health law policy, biotechnology, and bioethics. Several of our past Academic Fellows have gone on to become prolific scholars and emerging leaders in these fields, allowing the Center's influence to expand far beyond Cambridge, particularly as these alumni train the next generation of health law scholars and practitioners.

Below are key updates from the past academic year on the scholarly activities of some of our fellowship alumni:

### **Allison Hoffman, Fellow 2008-2010**

Assistant Professor of Law, UCLA School of Law

#### **Health Care Spending and Financial Security after the Affordable Care Act**

92 N.C. L. REV. 101 (2014)

Featured on JOTWELL (The Journal of Things We Like Lots), July 23, 2014

#### **A Vision of an Emerging Right to Health Care in the U.S.: Expanding Health Care Equity through Legislative Reform**

in THE RIGHT TO HEALTH AT THE PUBLIC/PRIVATE DIVIDE: A GLOBAL COMPARATIVE STUDY (C. Flood & A. Gross eds., 2013, Cambridge University Press)

#### **An Optimist's Take on the Decline of Small-Employer Health Insurance**

98 IOWA L. REV. BULL. 113 (2013) (solicited response to Amy B. Monahan & Daniel Schwarcz, *Saving Small-Employer Health Insurance*, 98 IOWA L. REV. 1935 (2013))

#### **Retiree Out-of-Pocket Healthcare Spending: A Study of Consumer Expectations and Policy Implications**

39 AM. J. L. & MED. 62 (2013)

### **Frances Kamm, Fellow 2007-2008**

Littauer Professor of Philosophy and Public Policy, HKS and Professor of Philosophy, Department of Philosophy, Harvard University

#### **BIOETHICAL PRESCRIPTIONS; TO CREATE, END, CHOOSE, AND IMPROVE LIVES**

(Oxford University Press, 2013)

#### **Summary of Ethics for Enemies**

11(4) J. MORAL PHIL. 373 (2014)



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**Trolley Problem**

in *THE INTERNATIONAL ENCYCLOPEDIA OF ETHICS* (Wiley, 2013)

**Self Defense, Resistance, and Suicide: The Taliban Women**

Reprinted in *HOW WE FIGHT: ETHICS IN WAR* (Oxford University Press, 2014)

**Rationing and the Disabled: Several Proposals**

in *INEQUALITIES IN HEALTH: CONCEPTS, MEASURES, AND ETHICS*, Nir Eyal, Samia A. Hurst, Ole F. Norheim, and Daniel Wikler, eds. (Oxford University Press, 2014)

**Michelle N. Meyer, Fellow 2010-2013**

Assistant Professor and Director of Bioethics Policy, Union Graduate College-Icahn School of Medicine at Mount Sinai Bioethics Program

In April 2014, Michelle was named to the Board of Directors of PersonalGenomes.org, an organization incorporated in 2005 to support Harvard geneticist George Church's Personal Genome Project (PGP) and related projects, and to develop novel ways of managing the ethical, legal, and technical aspects of creating open access repositories of highly identifiable human genomic data.

In August 2013, Michelle was named to the Scientific Advisory Board of Making Science Less WEIRD, an academic effort to engage research participants beyond the traditional pool of those who are Western, Educated, Industrialized, Rich, and Democratic through the Internet, thereby making research results more applicable to non-WEIRD groups.

Health related publications this year include:

**Misjudgments will drive social trials underground: A Facebook study that manipulated news feeds was not definitively unethical and offered valuable insight into social behavior**

NATURE, July 16, 2014 (with John Lantos et al.)

**Everything You Need to Know About Facebook's Controversial Emotion Experiment**

WIRED, June 30, 2014

**Government: When Push Comes to Nudge**

LOS ANGELES TIMES, September 29, 2013 (with Christopher Chabris)



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**Three Challenges for Risk-Based (Research) Regulation: Heterogeneity among Regulated Activities, Regulator Bias, and Stakeholder Heterogeneity**

in HUMAN SUBJECTS RESEARCH REGULATION: PERSPECTIVES ON THE FUTURE (I. Glenn Cohen & Holly Fernandez Lynch eds., MIT Press 2014)

**Abigail R. Moncrieff, Fellow 2007-2009**

Peter Paul Career Development Professor; Associate Professor of Law; Boston University School of Law

**Beyond Payment and Delivery Reform: The Individual Mandate's Cost-Control Potential**

40 AM. J.L. & MED. 185 (2014)

**The Individual Mandate as Health Care Regulation: What the Obama Administration Should Have Said in NFIB v. Sebelius**

39 AM. J.L. & MED. 539 (2013)

**Will My Job Be Safe if I Defend My Patients?: When Patient Advocacy Collides with Employment Law**

144 CHEST 1106 (2013) (peer reviewed)(with Constantine A. Manthous)

**Christopher Robertson, Fellow 2008-2010**

Fall 2013 – Spring 2014: Visiting Professor, Harvard Law School  
Associate Professor, James E. Rogers College of Law, University of Arizona

This year, Chris served as a visiting professor at Harvard Law School, where he taught torts, health law, and the health law and policy workshop (with I. Glenn Cohen). Chris continued his affiliation with the Edmond J. Safra Center for Ethics Institutional Corruption Lab, and served as a visiting member of the methods core for the Robert Wood Johnson Foundation Public Health Law Program.

While at Harvard, Chris hosted a symposium with Aaron Kesselheim, titled "When Less Information Leads to Better Decisions: Blinding as a Solution to Bias." They now have a book contract to edit the contributions and other works into a single volume. He also spoke at a symposium at Tulsa College of Law in honor of Center founder, Professor Einer Elhauge.

Health related publications this year include:

**Cost-Sharing as Choice-Architecture (with David V. Yokum)**

in BEHAVIORAL ECONOMICS, LAW, AND HEALTH POLICY



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(I. Glenn Cohen, Holly Fernandez Lynch, and Christopher Robertson, eds., forthcoming 2016)

***Introduction to Part II: Transparency and Accountability and The FDCA as the Test for the Truth of Promotional Claims***

in *NEW AND ENDURING CHALLENGES FOR FDA: SELECTED ESSAYS ON THE FUTURE OF THE AGENCY AND ITS REGULATION OF DRUGS AND NEW TECHNOLOGIES* (I. Glenn Cohen and Holly Fernandez Lynch, eds., Columbia U. Press, forthcoming 2015)

***An Empirical Method for Materiality: Would Conflict of Interest Disclosures Change Patient Decisions?***

AM. J. L. & MED. \_\_ (forthcoming 2014) (with Roy Spece, David Yokum, Andrea-Gale Okoro)

***A Randomized Experiment of the Split Benefit Health Insurance Reform To Reduce High-Cost, Low-Value Consumption***

2 INNOVATION AND ENTREPRENEURSHIP IN HEALTH \_\_ (forthcoming 2014) (with David Yokum, Nimish Sheth, & Keith Joiner)

***Expert Witness Blinding Strategies to Mitigate Bias in Radiology Malpractice Cases: A Review of the Relevant Scientific, Professional and Legal Literature***

J. AM. COLL. RADIOLOGY \_\_ (forthcoming 2014) (with Dan Durand et al.)

***Perceptions of Efficacy, Morality, and Politics of Potential Cadaveric Organ Transplantation Reforms***

74 LAW AND CONTEMP. PROB \_\_ (symposium, forthcoming 2014) (with David V. Yokum, & Megan S. Wright)

***The Burden of Deciding for Yourself: The Disutility Caused by Out-of-Pocket Healthcare Spending***

IND. HEALTH L. REV. \_\_ (symposium, forthcoming 2014) (with David V. Yokum)

***Scaling Cost-Sharing to Wages***

14 YALE J. HEALTH POL'Y, L., & ETHICS \_\_ (forthcoming 2014)

***Heterogeneity in IRB Policies with Regard to Advertising Amounts of Compensation***

J. L., MED., & ETHICS \_\_ (forthcoming 2014) (with M.S. Wright)

***The Presumption Against Expensive Healthcare Consumption***

49 TULSA L. REV. 627 (2014)



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***When Truth Cannot Be Presumed: The Regulation of Drug Promotion  
Under an Expanding First Amendment***

94 B. U. L. REV. 551 (2014)

***The Problem of Biased Experts, and Blinding as a Solution: A Response to  
Professor Gelbach***

81 U. CHI. L. REV. DIALOGUE 61 (2014)

***Crowdsourcing Public Health Experiments: A Response To Jonathan  
Darrow's "Crowdsourcing Clinical Trials"***

98 MINN. L. REV. 2326 (2014) (with Ameet Sarpatwari, David V. Yokum &  
Keith Joiner)

***The Split Benefit: The Painless Way to Put Skin Back in the Healthcare  
Game***

98 CORNELL L. REV. 921 (2013)

***Melissa Wasserman, Fellow 2009-2011***

Assistant Professor; Richard and Anne Stockton Faculty Scholar; Richard W. and  
Marie L. Corman Scholar, University of Illinois College of Law

***The Changing Guard of Patent Law: Chevron Deference for the PTO***

54 WM. & MARY L. REV. 1959 (2013)





## **Public Events Programming and Conferences**

This year, the Petrie-Flom Center hosted a number of fantastic events, 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. This year, we hosted substantial conferences addressing major developments and key issues in the world of health law, food safety, behavioral economics and health policy, and regulatory biostatistics. We also hosted a number of smaller panels and lectures, addressing topics such as discrimination in health care, biotechnology and pharmaceutical patents, the globalization of healthcare, reproductive rights, animal ethics, pharmaceutical industry integrity, mental health, current legal issues in HIV/AIDS work, and more.

We continue to draw large audiences to these events from around Harvard's campus and beyond, and to expand our reach by posting video to our website 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.

### **Major Events/Conferences**

#### **Health Law Year in P/Review**

January 31, 2014

At our second Annual Health Law Year in P/Review event, the Petrie-Flom Center and the New England Journal of Medicine welcomed experts discussing major developments during 2013 and what to watch out for in 2014. The schedule of events is included below:

#### **Affordable Care Act**

- Exchanges – Wendy Mariner
- Medicaid Expansion – Abigail R. Moncrieff
- Q&A

#### **Medical malpractice**

- New developments – Michelle Mello
- Q&A



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**Food and Drug Administration**

- Drug/device liability and state law – [Peter Grossi](#)
- Breakthrough therapy – [Aaron S. Kesselheim](#)
- Stem cell regulation – [Patrick L. Taylor](#)
- Q&A

**Abortion/Contraception**

- Abortion regulation strategy – [I. Glenn Cohen](#)
- Contraceptives coverage mandate litigation – [Holly Fernandez Lynch](#)
- Q&A

**Life science IP**

- Recent cases and implications for industry – [Claire Laporte](#)
- Disclosure of FDA approval information – [W. Nicholson Price II](#)
- Q&A

**Public health policy**

- Tobacco, obesity, vaccination, and more – [Wendy E. Parmet](#)
- Organ donation and sale – [I. Glenn Cohen](#)
- Q&A

**Human subjects research**

- Data transparency and compensation for injury – [Mark Barnes](#)
- SUPPORT study, Common Rule and Helsinki revisions – [Greg Koski](#)
- Q&A

**Concluding remarks**

- [Martha Minow](#)

***New Directions for Food Safety: The Food Safety Modernization Act and Beyond***

February 21, 2014

This collaborative one-day conference was cosponsored by the Petrie-Flom Center; the [Food Law and Policy Clinic \(a division of the Center for Health Law and Policy Innovation\)](#); the [Food Law Lab](#); and the Food Law Society at Harvard Law School, with support from the [Top University Strategic Alliance](#) at Harvard University and the [Office of the Dean at Harvard Law School](#). It brought together experts in food law and regulation to discuss a range of issues including food safety, agriculture, risk regulation strategy, and international issues.



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**Welcome remarks/Keynote**

- The Food Safety Modernization Act in Historical Perspective - Peter Barton Hutt

**Panel 1 – FSMA and Risk Regulation Strategy**

- Political Economy & Political Psychology in Food Safety - Jacob E. Gersen
- The Regulation of Food Fraud Under FSMA: A Triggering of Obligations - Michael Roberts

**Panel 2 – Regulating Farm Production: From Zero to Sixty**

- Turning a Black Swan White: Questioning the Need for Regulation of Non-Industrial Agriculture - Denis Stearns
- FSMA and Farm Consolidation - Alli Condra
- FSMA and Sustainability - Margot Pollans
- Moderator – Robert Greenwald

**Panel 3 – Benefits, Challenges, and Gaps in FSMA's Approach**

- New Governance, New Challenges - Lewis Grossman
- FDA and Uncertain Health Risks: Regulating Veterinary Drugs in Feeding Food Animals - Kuei-Jung Ni
- Whole Foods: The FSMA and the Challenges of Defragmenting Food Safety Regulation - Stephanie Tai
- Moderator – Sheila Jasanoff

**Panel 4 – International Issues and Trade Implications**

- The FDA Perspective - Sharon Mayl
- The Role of Private Standards in the FSMA - Ching-Fu Lin
- Mandatory and Voluntary Programs for Importers - Marsha Echols
- Moderator – Joel Trachtman

**Concluding remarks**

- Jacob E. Gersen

**2014 Annual Conference: Behavioral Economics, Law, and Health Policy**

May 2 - May 3, 2014

Richard H. Thaler and Cass R. Sunstein's book *Nudge: Improving Decisions About Health, Wealth, and Happiness* brought behavioral economics to the masses, beginning a discussion of libertarian paternalism and the many ways that "choice architects" can help nudge people to make better choices for themselves without forcing certain outcomes on anyone. Some of their examples fall in the realm of health policy, as is also the case of Daniel Kahneman's recent book, *Thinking, Fast and Slow*, which examines various cognitive errors people



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make in their judgments, choices, and conclusions, as well as how we might correct them. But the conversation has only just begun.

Building on the success of the behavioral economics movement, this conference further developed the scholarly discussion by focusing on key issues in health law policy, bioethics, and biotechnology by addressing both broad conceptual questions and more specific policy applications.

**Welcome/Keynote**

- Choosing Not to Choose - [Cass Sunstein](#)

**Panel 1, The Ethics of Nudges in Health Care**

- Public Health Nudges and the Principle of the Least Restrictive Alternative - [Yashar Saghai](#)
- Incentives as “Nudges” for Childhood Vaccination in Rural India - [Jennifer Blumenthal-Barby](#),
- When Is Nudging Just Fine, and Why? [Nir Eyal](#)
- The Political Morality of Nudges - [Jonathan Gingerich](#)
- Moderator: [Holly Fernandez Lynch](#)

**Plenary**

- Introduction by [Martha Minow](#)
- Can Behavioral Economics Save Healthcare - [Alan M. Garber](#)

**Panel 2, Potential Problems and Limits of Nudges in Health Care**

- Nudges, Shoves, Pure Paternalism, or Leave Well Enough Alone? Applying Behavioral Economics to Health Law and Policy - [David A. Hyman](#)
- Bad Medicine: The Problems with Nudges in Health Care - [Mark D. White](#)
- Behavioral Economics and Food Policy: The Limits of Nudging - [Andrea Freeman](#)
- Moderator: [I. Glenn Cohen](#)

**Panel 3, Behavioral Economics and Healthcare Costs**

- Cost-Sharing as Choice Architecture - [Christopher T. Robertson](#) (with David Yokum)
- Active Choice and Health Care Costs: Evidence from Prescription Drug Home Delivery - [Brigitte Madrian](#)
- Behavioral Economics and Physician Prescribing Practices: Legal and Ethical Considerations in the Use of “Nudges” to Promote Generic Drug Use - [Ameet Sarpatwari](#) (with Nitesh K. Choudhry, Jerry Avorn, and Aaron S. Kesselheim)
- Asymmetric Responses to Increases and Decreases in Cost-Sharing for Breast Cancer Screening - [Anupam Jena](#) (with Jie Huang, Bruce Fireman,



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Vicki Fung, Scott Gazelle, Mary Beth Landrum, Michael Chernew, Joseph P. Newhouse, and John Hsu)

- Towards Behaviorally Informed Policies for Consumer Credit Decisions in Self-Pay Medical Markets - [Jim Hawkins](#)
- Moderator: [Matthew J. B. Lawrence](#)

**Panel 4, Crowding Out**

- Do Financial Incentives Reduce Intrinsic Motivation for Weight Loss? Evidence from Two Tests of Crowding Out - [Aditi Sen](#) (with David Huffman, George Lowenstein, David Asch, and Kevin Volpp)
- Crowd Control: Extrinsic Incentives, Intrinsic Motivation, and Motivational Crowding Out in Health Law and Policy - [Kristen Underhill](#)
- Moderator: [Neel T. Shah](#)

**Plenary**

- The Choice Architecture Problem and Health Care Decisions - [Russell Korobkin](#)

**Panel 5, Behavioral Economics and the Doctor-Patient Relationship**

- Affective Forecasting in Medical Decision-Making: What Do Physicians Owe Their Patients? [Jennifer Zamzow](#)
- Mobile Devices, Small Data, and Personal Healthcare Decisions: Behavioral Economics' New Frontier and the Law - [Alexander Capron](#)
- The Perilous Promise of Privacy: Ironic Influences on Disclosures of Health Information - [Ester Moher](#) (with Khaled El Emam)
- Moderator: [Robert D. Truog](#)

**Panel 6, Deciding for Patients and Letting Patients Decide for Themselves**

- Justice by Default: Solving Medicare's Backlog Problem - [Matthew J. B. Lawrence](#)
- Libertarians, Cognitive Failures, and Transaction Costs: The Behavioral Case for the Individual Mandate - [Abigail Moncrieff](#) (with Manisha Padi)
- Death Squads, Paternalism, and End of Life Care - [Sarah Conly](#)
- Improving Health Care Decisions Through a Shared Preferences and Values Approach to Surrogate Selection - [Nina Kohn](#)
- Preventing Harms to Patients Who Know Too Much About Their Own Genomes - [Barbara Evans](#)
- Moderator: [Christopher T. Robertson](#)

**Plenary**

- Applying Behavioural Insights in Theory and in Practice - Michael Hallsworth, [The Behavioural Insights Team](#)



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**Panel 7, Defaults in Health Care**

- Selection Effects Versus Default Power: The Choices of Terminated Medicare Advantage Clients - [Anna Sinaiko](#) (with Richard Frank and Richard Zeckhauser)
- Default Behavior as Social Inference - [David Tannenbaum](#) (with Peter Ditto)
- How Choice Architecture Can Define a New Era of Providing Mental Health Treatment - [Elliot Doomes](#) (with Aeva Gaymon Doomes)
- Presumed Consent to Organ Donation - [David Orentlicher](#)
- Moderator: [Gregory Curfman](#)

**Biostatistics and FDA Regulation: The Convergence of Science and Law**

May 20, 2014

Biostatistics is the application of statistics — the study of the collection, organization, analysis, interpretation and presentation of data — to a wide range of topics in life sciences. Biostatistics informs the Food and Drug Administration’s regulatory decision-making processes for premarket review of investigational drugs and devices and post-market surveillance of medical products, including decisions to require safety labeling changes and withdraw approval. Recent developments, such as Congress’s creation of a new federal infrastructure for the dissemination of comparative effectiveness information, point to the need for a fresh look at the way in which biostatistical principles inform federal health care policy, particularly at the FDA. This one-day symposium gave attendees the foundational knowledge they need to understand how biostatistics applies in FDA regulation, and also addressed closely related issues residing at the intersection of statistical analysis and life sciences litigation. It was a collaboration between the Petrie-Flom Center, the [Drug Information Association](#) (DIA), the [Food and Drug Law Institute](#) (FDLI), Harvard School of Public Health’s [Department of Biostatistics](#), and [Harvard Catalyst | The Harvard Clinical and Translational Science Center](#).

**Introduction to Statistics and Regulatory Law**

- Why biostatistics matters in regulatory law
- Establishing clinical effectiveness
- The limits of biostatistical analysis: risk-benefit assessments

Speakers:

Qi Jiang, [Amgen](#)

[Robert T. O’Neill](#), Office of Translational Sciences, CDER, FDA

Jerald S. Schindler, Merck Research Laboratories

Moderated by [Coleen Klasmeier](#), Sidley Austin LLP



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**Safety Issues**

- Safety Meta-Analysis
- CTTI Safety-related Efforts

Speakers:

Lee-Jen Wei, Harvard School of Public Health  
Geoffrey M. Levitt, Pfizer, Inc.  
Janet Wittes Statistics Collaborative  
Moderated by Qi Jiang, Amgen

**Statistics Disputes in Life Sciences Litigation**

- Recent *Daubert* developments
- *Matrixx, Inc. v. Siracusano*
- *US v. Harkonen*
- Avandia

Speakers:

Anand Agneshwar, Arnold & Porter LLP  
Christina L. Diaz, GlaxoSmithKline  
Nathan A. Schachtman, Ulmer & Berne LLP  
Lee-Jen Wei, Harvard School of Public Health

**Question Time with FDA Officials: Emerging Issues**

- Precision Medicine
- Next-Gen Statistical Analysis
- Affordable Care Act

Speakers:

Robert T. O’Neill Office of Translational Sciences, CDER, FDA  
Moderated by Christopher T. Robertson, Harvard Law School

**Can We Handle the Truth: Roundtable Discussion**

- Reconciling Regulatory Expectations and First Amendment Principles
- Broader Societal Shifts in Information Availability
- Relevance of FDA Premarket Review and Approved Labeling in New Media Era

Speakers:

Anand Agneshwar, Arnold & Porter LLP  
Jeffrey K. Francer, PhRMA  
Freddy A. Jimenez, Johnson & Johnson  
Moderated by Janet Wittes, Statistics Collaborative



## **Lectures, Panels, and Other Events**

### **Patient Discrimination against Medical Personnel**

September 17, 2013

We don't stand for doctors discriminating against patients on the basis of race, but what about when the tables are turned? At this event, Kimani Paul-Emile of Fordham Law School led a discussion of her article in the UCLA Law Review, Patients' Racial Preferences and the Medical Culture of Accommodation. Renee Landers of Suffolk Law School and Dr. Fidencio Saldana of Harvard Medical School and Brigham and Women's and Faulkner Hospitals served as discussants. I. Glenn Cohen moderated.

### **Gene Patenting, the Supreme Court's Myriad Decision, and the Future of Biotechnology: A Panel Discussion**

September 23, 2013

Moderated by Dean Martha Minow this hugely popular panel focused on the impact of the Supreme Court's decision in the *Myriad* case that naturally occurring DNA cannot be patented. Key questions included: Will this be a boon for patients and a burden for biotech companies? Will sufficient incentive remain for innovation? Will there be any practical change at all?

Panelists were:

- Eric S. Lander, Director of the Broad Institute of MIT and Harvard, Professor of Biology at MIT, and Professor of Systems Biology at Harvard Medical School
- I. Glenn Cohen, Professor of Law, Harvard Law School; Faculty Co-Director of the Petrie-Flom Center
- Benjamin N. Roin, Hieken Assistant Professor in Patent Law, Harvard Law School; Faculty Co-Director of the Petrie-Flom Center
- Claire Laporte, Partner, Foley Hoag LLP
- Tania Simoncelli, former Science Advisor to the ACLU

### **The Globalization of Health Care: Book Talk and Discussion by I. Glenn Cohen**

September 24, 2013

I. Glenn Cohen discussed his edited volume The Globalization of Health Care: Legal and Ethical Issues, published by Oxford University Press in March 2013. The book ties together the manifestation of health care globalization in four related subject areas – medical tourism, medical migration (physician "brain





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drain"), telemedicine, and pharmaceutical research and development – and integrates them in a philosophical discussion of issues of justice and equity.

The event also featured a panel discussion with Dr. Sue Goldie, Faculty Director of the Harvard Global Health Institute and Director of the Center for Health Decision Science at the Harvard School of Public Health, and Dr. Neel T. Shah, Founder and Executive Director of Costs of Care and Assistant Professor at Harvard Medical School and Beth Israel Deaconess Medical Center. Einer Elhauge, Petrie Professor of Law at Harvard Law School and Founding Director of the Petrie-Flom Center, moderated.

***Harvard Reception at the PRIM&R Annual Conference***

November 06, 2013

The Petrie-Flom Center and the Division of Medical Ethics at Harvard Medical School hosted a welcome reception at PRIM&R's 2013 Advancing Ethical Research Conference, held this year in Boston. Colleagues doing bioethics and policy work at Harvard and others in the broader research ethics community were invited to attend to connect and find out more about our events, conferences, and opportunities to get involved.

***Reproductive Rights around the Globe***

November 07, 2013

This event featured a discussion of selected topics in the field of international reproductive rights, moderated by Elizabeth Bartholet, Morris Wasserstein Public Interest Professor of Law and Faculty Director of the Child Advocacy Program at Harvard Law School. Our expert panelists addressed a range of issues, including:

- International trends in gamete donor identifiability v. anonymity – I. Glenn Cohen
- The politics of evidence and expertise in domestic and international abortion litigation – Aziza Ahmed
- Use of international fora, including courts and treaty bodies, to advance reproductive rights – Mindy Jane Roseman



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***Ethics and Animals: Where Are We Now? A lecture by Peter Singer***

November 08, 2013

In this very well-attended lecture by Professor Peter Singer, he argued that we owe animals equal consideration of interests as that provided to human beings. He elaborated on what that means and what changes would be required to implement such consideration, and discussed the progress that has been made towards that goal over the past 40 years.

Peter Singer is the Ira W. DeCamp Professor of Bioethics at the Princeton University Center for Human Values and Laureate Professor at the Center for Applied Philosophy and Public Ethics at the University of Melbourne. His book, *Animal Liberation: A New Ethics for Our Treatment of Animals* (Random House, 1975), has been described as the definitive classic of the animal movement, alongside his more recent book, *In Defense of Animals: The Second Wave* (Wiley-Blackwell, 2005).

***Livestream of Sessions from the 2013 International Neuroethics Society Annual Meeting***

November 08, 2013

The Petrie-Flom Center hosted a live webstream of sessions from the International Neuroethics Society's 2013 Annual Meeting. Sessions included:

- Can Neuroscience Inform Us About Criminality and the Capacity for Rehabilitation?
- The Science and Ethics of Moral Enhancement
- States of Consciousness: Neuroethics in impairments of consciousness, brain-machine interfacing and end of life decisions?

***Responsibility and Integrity in the Pharmaceutical Industry***

November 21, 2013

The Petrie-Flom Center hosted a lecture by Neil Flanzraich on responsible pricing strategy, access to care, clinical trial design, outsourcing, and other topics that raise thorny but crucial issues for pharmaceutical and biotechnology companies. Mr. Flanzraich graduated from HLS in 1968, and was appointed by Dean Martha Minow as an Expert in Residence at the Harvard Innovation Lab (i-lab) in fall 2012. He is the Executive Chairman of Kirax Corporation and the Executive Chairman of ParinGenix, Inc., both of which are privately owned biotech companies. He previously served as the Vice Chairman and President of



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Ivax Corporation, an international pharmaceutical company, which was sold to Teva in 2006 for an enterprise value of \$10 billion.

**Patents Without Patents: Regulatory Incentives for Innovation in the Drug Industry**

February 19, 2014

In the pharmaceutical industry, patents are the preeminent incentive for innovation in developing new drugs. But patents aren't the whole story; regulatory agencies also offer different forms of exclusivity—enforced by the agencies themselves—to encourage different forms of innovation in the industry. This panel discussed actual and potential roles for those rewards in the context of developing new drugs, new uses for old drugs, and new ways to make drugs, in both the United States and the European Union.

Panelists were:

- Benjamin N. Roin, Hieken Assistant Professor in Patent Law, Harvard Law School; Faculty Co-Director, the Petrie-Flom Center
- W. Nicholson Price II, Academic Fellow, the Petrie-Flom Center
- Timo Minssen, Associate Professor, University of Copenhagen Faculty of Law; Visiting Scholar, the Petrie-Flom Center
- Moderator, Aaron Kesselheim, Assistant Professor of Medicine, Harvard Medical School; Director of the Program On Regulation, Therapeutics, And Law (PORTAL), Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital

**Frances Kamm's Bioethical Prescriptions: Book Talk and Panel Discussion**

February 24, 2014

We hosted this book talk and panel discussion for Professor Frances Kamm's latest book, *Bioethical Prescriptions: To Create, End, Choose, and Improve Lives* (Oxford University Press, December 2013), which she worked on while a Senior Fellow at the Center in 2007. The book showcases Professor Kamm's articles on bioethics as parts of a coherent whole, with sections devoted to death and dying; early life (on conception and use of embryos, abortion, and childhood); genetics and other enhancements (on cloning and other genetic technologies); allocating scarce resources; and methodology (on the relation of moral theory and practical ethics).



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Panelists:

- Frances Kamm, Littauer Professor of Philosophy & Public Policy, Harvard Kennedy School of Government; Professor of Philosophy, Faculty of Arts & Sciences, Harvard University; Former Senior Fellow, Petrie-Flom Center
- Norman Daniels, Mary B. Saltonstall Professor of Population Ethics and Professor of Ethics and Population Health, Harvard School of Public Health
- Thomas (Tim) Scanlon, Jr., Alford Professor of Natural Religion, Moral Philosophy, and Civil Polity, Faculty of Arts & Sciences, Harvard University
- Moderator: Christopher T. Robertson, Visiting Professor of Law, Harvard Law School; Associate Professor, James E. Rogers College of Law, University of Arizona

***Evaluating the Revised Diagnostic and Statistical Manual of Mental Disorders (DSM-5)***

March 11, 2014

The DSM is the reference used by clinicians, researchers, and insurers to diagnose and classify mental disorders, with the intent to provide specific, objective criteria by which to assess symptoms and determine whether to pay for treatment. The American Psychiatric Association released the manual's fifth edition in May 2013, nearly twenty years after the fourth edition, to substantial public and professional criticism. This discussion examined the new revisions and their implications for patients, medical practice, research, and the law.

Panelists:

- Steven E. Hyman, Director of the Stanley Center for Psychiatric Research at the Broad Institute and Harvard University Distinguished Service Professor of Stem Cell and Regenerative Biology
- Anne Becker, Maude and Lillian Presley Professor of Global Health and Medicine, Harvard Medical School
- Nita Farahany, Professor of Law, Professor of Genome Sciences & Policy, and Professor of Philosophy at Duke University
- Moderator: I. Glenn Cohen, Professor of Law, Harvard Law School; Faculty Co-Director, Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics



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**Current Legal Issues in HIV/AIDS Work**

March 27, 2014

More than 30 years have passed since AIDS first appeared in the United States. Today the CDC estimates that 1.1 million Americans are living with HIV/AIDS, and each year 50,000 Americans are newly diagnosed. Despite great strides in education, awareness, prevention, and treatment, people affected by HIV/AIDS still face significant discrimination, including unequal treatment under the law. This panel explored some of the legal barriers faced by people living with HIV/AIDS in the United States, including FDA's ban on men who have sex with men donating blood and laws criminalizing HIV transmission.

Panelists:

- Felix Lopez, Director of the Legal Department, GMHC
- Jason Cianciotto, Director of the Public Policy Department, GMHC
- I. Glenn Cohen, Professor of Law and Faculty Co-Director of the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School
- Moderator: Aziza Ahmed, Visiting Scholar, Petrie-Flom Center; Associate Professor of Law, Northeastern University School of Law

**Hot Topics in European Bio-Patent Law: Stem Cells, Genes, and More**

April 2, 2014

This esteemed panel of leading patent experts, including members of the European Patent Office, addressed U.S. and European perspectives on patenting stem cells, genes, and medical uses, as well as other ethical and legal issues.

Panelists:

- Aliko Nichogiannopoulou, Director, Biotechnology, EPO
- Anja Schmitt, Examiner, EPO
- Maaïke van der Kooij, Examiner, EPO
- Tom Kowalski, US Patent Attorney

Moderator: Benjamin N. Roin, Hieken Assistant Professor in Patent Law, Harvard Law School; Co-Director, Petrie-Flom Center for Health Law Policy, Biotechnology & Bioethics; Associate Member, Broad Institute

This event was part of a larger series of events hosted by the Broad Institute. Other topics included:



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**March 31, 2014, Improving Lives: Using Intellectual Property to Create Opportunity Aligned with Mission**

*Biotech Innovation: Framework for success*

*Translation of innovation: Can patient outcome be improved?*

**April 1, 2014, Hot Topics in European and US Patent Law: Comparing, Contrasting, and Harmonizing Strategies**

*Post-grant proceedings: Comparing, contrasting, and synchronizing the US and European patent systems*

*Unitary Patent System*

*Biosimilars: An update and predictions*

*Trolls and patent misuse*

**April 2, 2014**

*Educational Seminar for Broadies: Patenting Basics*

**April 3, 2014**

*Educational Seminar for Broadies: Searching Strategies and Selection Inventions*

**Book Launch: The Witch-Hunt Narrative: Politics, Psychology, and the Sexual Abuse of Children**

April 10, 2014

This event focused on Professor Ross E. Cheit's new book *The Witch-Hunt Narrative: Politics, Psychology, and the Sexual Abuse of Children* (Oxford University Press, April 2014).

It has become widely accepted that a series of high-profile child sexual abuse cases from the 1980s and early 1990s were "witch hunts." That view first took hold in the media, then spread to the courts and academia. But purveyors of the witch-hunt narrative never did the hard work of examining court records in the many cases that reached the courts throughout the nation. Drawing on fifteen years of original trial research into these child sex abuse cases, Cheit challenges the accuracy of the narrative.

Panelists:

- Jacob E. Gersen, Professor of Law, Harvard University
- Jeannie Suk, Professor of Law, Harvard Law School



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**Hot Topics at the Presidential Commission for the Study of Bioethical Issues:  
Plus Q&A on Careers in Law and Bioethics**

April 11, 2014

This event featured an update from the Presidential Commission for the Study of Bioethical Issues delivered by Michelle Groman (HLS '05), Associate Director at the Bioethics Commission. Since its inception in 2009, President Obama's Commission has issued reports on synthetic biology, human subjects research, whole genome sequencing, pediatric medical countermeasure research, and incidental findings. Currently, the Commission is examining the ethical implications of neuroscience research and the application of neuroscience research findings as part of the federal government's BRAIN Initiative. The Commission also has developed educational materials to support teaching of bioethics ideas, principles, and theories in traditional and non-traditional settings.

The final half-hour of the event featured a discussion of career opportunities in law and bioethics, led by Ms. Groman and Holly Fernandez Lynch, Petrie-Flom Center Executive Director.

**Dallas Buyers Club: Free Film Screening and Panel Discussion**

April 16, 2014

Students from across Harvard were invited to view a free screening of the Academy-award winning film *Dallas Buyers Club* and participate in a panel discussion about issues addressed in the film related to access to health care for the HIV community. The panel discussion addressed the history of access to care and treatment for HIV; ongoing issues with fair pricing of HIV medications; the role of the FDA in access to experimental medicines; and the portrayal of HIV and LGBTQI individuals in the media as it impacts access to individual and public health resources.

Panelists:

- Robert Greenwald, Director, Center for Health Law & Policy Innovation; Clinical Professor of Law, Harvard Law School
- Grace Sterling Stowell, Executive Director, BAGLY: Boston Alliance of Gay, Lesbian, Bisexual and Transgender Youth
- Dr. Jean McGuire, Clinical Professor, Department of Health Sciences, Northeastern University; former MA Assistant Commissioner for Public Health; former Assistant Secretary of the MA Executive Office of Health and Human Services



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**Bill of Health/Petrie-Flom reception at the 2014 ASLME Health Law Professors Annual Conference**

June 5, 2014

The Petrie-Flom center hosted a reception for all Bill of Health bloggers and readers in attendance.

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

In addition to the events that the Petrie-Flom Center took the lead in organizing and hosting, we also collaborated on several other events organized by our Harvard colleagues:

**Compulsory License and Access to Medicine: The Indian Experience to Date**

Presented by the Program on the Legal Profession at Harvard Law School, with the Universities Allied for Essential Medicines - Harvard Chapter, the Harvard University South Asia Institute, the Harvard Law and International Development Society at Harvard Law School, and the Petrie-Flom Center.

September 16, 2013

**Open Access Week 2013: Promoting Access to Federally Funded Research**

Co-sponsored by the Universities Allied for Essential Medicines, HLS Advocates for Human Rights, Office for Scholarly Communication, Right to Research Coalition, Berkman Center for Internet and Society, and the Petrie-Flom Center.

October 21, 2013

**Conference: When Less Information is Better: Blinding as a Solution to Institutional Corruption**

Organized by the Edmond J. Safra Center for Ethics and co-sponsored by the Petrie-Flom Center.

November 01, 2013

**Conference: Bioethical Reflections in Honor of Dan Brock**

Sponsored by the Division of Medical Ethics, the Department of Global Health & Social Medicine at Harvard Medical School and the Petrie-Flom Center.

November 22, 2013

**Conference: Companies' Global Health 'Footprint': Could Rating Help?**

Organized by Nir Eyal, Associate Professor of Global Health and Social Medicine, and Jennifer Miller, Edmond J. Safra Lab Fellow.

December 9, 2013





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**Reforming Brazilian Pharmaceutical Patent Policy: Lessons from the Past  
and the Road for the Future**

Organized by the HLS Brazilian Studies Association, with support from the Petrie-Flom center.

April 23, 2014



## **Contributions to HLS Teaching Program**

This year, Petrie-Flom affiliates offered a compelling range of health law course offerings for Harvard graduate students, from our traditional workshop to new seminars designed by Academic Fellows.

### **Health Law Policy and Bioethics Workshop**

I. Glenn Cohen and Christopher Robertson  
Fall 2013-Spring 2014

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 2013-2014 workshop welcomed scholars on the following topics:

- **Dov Fox**, University of San Diego School of Law: *Interest Creep*
- **Kimani Paul-Emile**, Fordham University School of Law: *Beyond Title VII: Rethinking Race, Ex-Offender Status and Employment Discrimination in the Information Age*
- **Bernard S. Black**, Northwestern University School of Law: *The Effect of Health Insurance on Near-Elderly Health and Mortality*
- **Kimberly D. Krawiec**, Duke University School of Law: *Reverse Transplant Tourism*
- **Jennifer Prah Ruger**, University of Pennsylvania: *Global Health Justice and Governance*
- **Aaron Kesselheim**, Harvard Medical School: *Do March-In Rights Protect Public Interest in Medical Products Arising from Federally-Funded Research?*
- **Christopher Robertson**, University of Arizona: *Scaling Cost-Sharing to Wages and A Presumption against Expensive Healthcare Consumption*
- **Kevin Outterson**, Boston University: *New Business Models for Sustainable*



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- *Antibiotics*
- **I. Glenn Cohen**, Harvard Law School: *What (if anything) is Wrong with Human Enhancement? What (if anything) is Right With It?* and *This Is Your Brain On Human Rights: Moral Enhancement and Human Rights*
- **Hank Greely**, Stanford Law School: *The End of Sex: The Future of Humans Reproduction*
- **David Gamage**, UC Berkeley School of Law: *The Evolution of Health Care Reform: Should Risk Adjustment Become the Heart of Obamacare?*
- **Matthew J.B. Lawrence**, Petrie-Flom Center: *Rationing Justice*

## **Lawyers, Doctors, Ethics, and Professionalism**

I. Glenn Cohen and Rebecca Brendel (HMS)  
Reading Group, Spring 2014

This reading group, which cross-enrolled HLS and HMS students, explored the ways in which professional responsibility and ethical issues common to law and medicine are handled by the two professions.

Selected topics included:

- Rationing
- Fiduciary responsibilities
- Lawyering and doctoring in war
- Truth-telling and privileges (including duties to warn)
- Origins of professionalism
- Organizational form
- Self-dealing, referrals, and other financial conflicts of interest.

## **Rethinking the Legal and Ethical Status of Humans, Animals, and the Environment**

Jeffrey Skopek, Academic Fellow  
Seminar, Spring 2014

Cutting across issues in bioethics, animal rights, and environmentalism, this course explored the law's treatment of entities whose legal and ethical status is ambiguous or contested.

The first section of the course was devoted to human entities, such as embryos, the brain dead, and future persons. With respect to future persons, for example, students considered whether an activity can be considered harmful to a future person if it alters the person's genetics so much that it changes the person's identity; whether a law that prevents someone from coming into existence can



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be justified by reference to the best interests of that person; and if it can be justified, in what circumstances and on what grounds.

The second section of the course was devoted to animal entities, such as primates, farm animals, and chimeras. With respect to primates, for example, students considered whether animal protection statutes should be understood as granting rights to primates; how their status as property without legal standing to enforce these statutes shapes the answer to that question; and whether they should be granted standing or a functional alternative, such as equitable self-ownership.

The third section of the course was devoted to environmental entities, such as the climate, forests, and endangered plant species. With respect to the climate, for example, students considered whether cap and trade regimes create objectionable rights to impose harm by which they can be meaningfully distinguished from other regulatory regimes; how a cap and trade solution to the problem of global warming conceptualizes the harm of emissions; and what conception of the “good” of the environment underlies this conception of harm.

Across these categories, students also explored a broader set of common questions and issues. For example, students considered the relationship between legal and natural categories, as well as the nature of ethical and legal justification, asking whether rights and duties should be based on general categories (such as species membership), individual capacities (such as sentience or rationality), or a completely different type of criterion (such as the meaning of a form of treatment).

## **Genetics and the Law**

Nicholson Price, Academic Fellow  
Seminar, Spring 2014

Genetic technologies have advanced tremendously and are becoming commonplace; personal genome sequencing is getting cheaper and easier, and genetic analyses are increasingly used by public and private actors. These advances raise important issues for law and policy, for areas as diverse as family law, criminal law, torts, intellectual property, and of course health law. This seminar considered the law and policy implications of advances in genetics and the spread of genetic technology.

Selected topics included:

- Basics of genetics;
- Genetic screening of fetuses, newborns, children and adults;
- Liability for failure to detect or warn about genetic disorders;



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- Links between genetics, criminal responsibility, and punishment;
- Discrimination on the basis of genetic traits;
- Implications of genetics for family law;
- Public health implications of whole-genome sequencing; and
- Limits on genetic research and genetic manipulation of humans



## **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, availability of affiliates for mentoring and professional advice, and most importantly, our student fellowships and internships.

### **Student Fellowship Program**

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

Under the substantial mentorship 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 and Bioethics 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 blog twice each month 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.

Beginning this year and going forward, one of our students with a focus on food and drug law will be named the Peter Barton Hutt Student Fellow, in honor of our friend and colleague Peter Barton Hutt. A founding father of the field and a tremendous mentor to many, Professor Hutt has taught Food and Drug Law at HLS for more than 20 years. He has practiced at the Washington, DC law firm of Covington & Burling for more than five decades, and from 1971-1975, he was Chief Counsel for the Food and Drug Administration.

The Center's 2013-2014 student fellows and projects were as follows:



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**Matthew Baum**

**Harvard Medical School/MIT, MD/PhD candidate**

**Paper: "Off-Label Bioprediction of Alzheimer's Dementia"**

During his fellowship, Matthew was a second year MD-PhD student in the Health Science and Technology (HST) combined program of Harvard and MIT, through which he hopes to integrate his interests in clinical, scientific, and ethical aspects of mental health. He recently completed a DPhil at the Oxford Centre for Neuroethics where his doctoral work, supported by a Rhodes Scholarship, concerned the ethical implications of the development of predictive biomarkers of brain disorders. Matthew also completed an MSc in Neuroscience at Trinity College Dublin as a George Mitchell Scholar and holds a BS and an MS in Molecular Biology from Yale. During his medical and neuroscience training he hopes to maintain a strong engagement with neuroethics; he currently acts as the student representative to the International Society for Neuroethics and further explored the intersection of biological risk and disorder during his time at the Petrie-Flom Center.

**Nathaniel Counts**

**Harvard Law School, JD 2014**

**Paper: "Law and Understanding Mental Health"**

Nathaniel graduated from Harvard Law School in 2014 with a focus on behavioral disorders, including intersections with the criminal justice system. During his fellowship, Nathaniel focused on the role of law and lawyers in the treatment of mental health issues, and the use of a right to healthcare in human rights lawyering and international development. Nathaniel graduated from Johns Hopkins with a major in Biology and a minor in Entrepreneurship and Management. Prior to law school, he studied creative writing at Bar-Ilan University in Israel. His past research has focused on the federal government's response to marijuana legalization, including recommendations for public health initiatives; he has an article on this subject forthcoming in the GONZAGA LAW REVIEW in 2014.

**Jeremy Kreisberg**

**Harvard Law School, JD 2014**

**Paper: "Legislative Bargaining and the Administrative State"**

Jeremy graduated from Harvard Law School in 2014. He received his undergraduate degree from the University of Michigan, where he majored in Political Science. Prior to law school, Jeremy spent one year as a paralegal at Proskauer Rose LLP. Jeremy was a Notes Editor on the HARVARD LAW REVIEW, and



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previously served as the President of the HLS Democrats and the Secretary of the HLS Chapter of the American Constitution Society. He was also a semi-finalist in the Upper Level Ames Moot Court Competition. During his law-school summers, Jeremy has worked as an intern in the Medicare Branch of the Office of Management and Budget and as a summer associate at Williams & Connolly LLP. Jeremy has been published in the HARVARD LAW REVIEW, and he was the co-author of a policy brief that appeared in *Is U.S. GOVERNMENT DEBT DIFFERENT?*, a book published by the Wharton Financial Institutions Center. Jeremy is now a clerk for Judge Stephen R. Reinhardt of the United States Court of Appeals for the Ninth Circuit.

**Ching-Fu Lin**

**Harvard Law School, SJD candidate**

**Paper: "Public-Private Regulatory Interaction in Global Food Safety Governance"**

Ching-Fu, the 2013-2014 Peter Barton Hutt Student Fellow, received his LLM in 2010 from Harvard Law School, where he is currently a candidate for the SJD. He holds a double degree in law (LLB) and chemical engineering (BS) from National Taiwan University. He is currently Researcher and Associate Journal Editor at the Asian Center for WTO & International Health Law and Policy. His areas of research include food safety regulation, WTO law, international health law, and international relations theory. His legal scholarship has appeared in numerous journals and edited collections including *Global Food Safety: Exploring Key Elements for an International Regulatory Strategy* (VIRGINIA JOURNAL OF INTERNATIONAL LAW, 2011), *SPS-Plus and Bilateral Treaty Network: A "Global" Solution to the Global Food Safety Problem?* (WISCONSIN INTERNATIONAL LAW JOURNAL, 2012), and *Reassessing the Limits of the Codex Alimentarius Commission* (COLUMBIA SCIENCE AND TECHNOLOGY LAW REVIEW, forthcoming). His fellowship paper was published by the Food and Drug Law Journal and is available [here](#).

**Julián Urrutia**

**Harvard University, PhD candidate**

**Paper: "Cost-Effectiveness, DALYS and Measurement: On the Informational Base for Social Choice in Health and Medicine"**

Julián is a PhD candidate in Health Policy, Ethics Concentration, at Harvard University. He holds a BA in Philosophy, Politics, and Economics from the University of Pennsylvania. In 2009, Julián enrolled in the Medical School of the University of Los Andes in Bogotá, Colombia. Julián's interests lie in the intersection between ethics, constitutional law, and health policy, with a





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particular focus on disparities in health outcomes and health resource prioritization. Over the summer of 2013, Julián worked at the Colombian Ministry of Health and Social Protection as part of a team in charge of creating a regulatory framework for new medical procedures. He also served as Ad Hoc Secretary to the Bioethics Committee at the Colombian National Medical Academy, which was commissioned by the Ministry of Health to draft a law bill to update the Medical Code of Ethics. Additionally, Julián is coordinating a project to undertake a health needs assessment in Colombian national prisons, which is being funded by the Administrative Unit for Penitentiary Affairs of the Colombian Ministry of Justice and Law, and which will be implemented beginning in the summer of 2014.

**Michael J. Young**

**Harvard Medical School, MD 2016**

**Paper: "Medical Repatriation and the Ends of Healthcare"**

During his fellowship, Michael was a second-year medical student at Harvard Medical School. His current research examines the ethical dimensions and philosophical framework underlying standards of care in medicine and public health. Prior to arriving at Harvard, Michael completed an MPhil in philosophy at the University of Cambridge as a Gates Cambridge Scholar, where he focused on philosophical issues relating to medicine and the mind. In the past he has worked as a Patient-Family Advocate in the Emergency Department at Johns Hopkins Hospital and as a research assistant in the Division of Medical Ethics & Health Policy at the University of Pennsylvania, where he studied resource strain and decision procedures surrounding allocation of scarce resources in intensive care units. Most recently, Michael was awarded the Henry K. Beecher Prize in Medical Ethics from HMS. In addition to publishing his fellowship paper, Michael worked on the following projects over his fellowship year:

**Undocumented injustice? Medical repatriation and the ends of health care (based on fellowship paper)**

(with Lisa S. Lehmann) *New England Journal of Medicine*. February 2014.

**Ethics and Ontology in Deep Brain Stimulation**

*AJOB Neuroscience*. January 2014.

**Defining Mental Illnesses: Can Values and Objectivity Get Along?**

(with Dominic Sisti and Arthur Caplan) *BMC Psychiatry*. December 2013.

**Direct-to-patient laboratory test reporting: Balancing access with effective Clinical Communications**

*JAMA*. 2014;312(2):127-128



## **Internship Program**

The Petrie-Flom Center student internship program is open to all undergraduate and graduate students at Harvard, but particularly those studying health policy, philosophy, bioethics, law, medicine, business economics, and the sciences.

The internship involves two primary components: (1) attending the Center's events; and (2) assisting with various Center projects, for example:

- Advertising for Petrie-Flom events
- Drafting weekly news round-ups for blog
- Collating biweekly Twitter round-ups for blog
- Developing resource lists for our website
- Collating biweekly Health Law News for website
- Developing Harvard health law/bioethics curriculum lists for website and uploading of data to website
- Research projects as assigned

The internship program was created in response to popular demand from students interested in becoming more involved with the Center, and interns were selected after a competitive application process. Our 2013-2014 interns included:

Aleeza Hashmi (Fall 2013 only), College 2015  
Cole Carter (Spring 2014 only), HLS 2016  
Parker Davis, College 2015  
Fatima Mirza, College 2015  
Sara Providence, College 2014  
Chloe Reichel, College 2015  
Elizabeth Zhang (Fall 2013 only), HLS 2014

## **Research Assistants**

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



## **Journal of Law and Biosciences Student Contributors**

As described above, the Petrie-Flom Center collaborates on publication of the Journal of Law and Biosciences. The journal includes a New 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 New Developments for one issue per volume. This year's student contributors were:

Ashish M. Bakshi, HLS/HBS 2016: *Gene patents at the Supreme Court: Association for Molecular Pathology v. Myriad Genetics*

Adriana Lee Benedict, HLS 2014: *State-level legislation on follow-on biologic substitution*

Komal Karnik, HLS/HSPH 2014: *FDA regulation of clinical decision support software*

Nicholas Meyers, HLS 2014: *Cook v. FDA and the importation and release of lethal injection drugs*

## **Student Bloggers**

In addition to blogging by our student fellows, we also had several other student bloggers from HLS:

- [Deborah Cho](#)
- [Aditya Gupta](#)
- [Adriana Benedict](#)
- [Elizabeth Guo](#)

In addition, several of this year's student fellows plan to stay on as bloggers even after their obligations to do so have ended.



## **Faculty Participation**

As noted throughout this report, faculty participation in the Petrie-Flom Center is both strong and essential. In addition to the clear investment by the Faculty co-Directors **I. Glenn Cohen** and **Benjamin Roin**, and Founding Director **Einer Elhauge**, other faculty members from around the university have traditionally been informally involved 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](#).

In order to expand faculty involvement and build connections across campus, in May 2013 the Center undertook an initiative to build 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](#), but we also list those added over the 2013-2014 academic year below:

- **Anne Becker**, Ph.D., Maure and Lillian Presley Professor of Global Health and Social Medicine, Associate Professor of Psychiatry and Vice Chair, Department of Global Health and Social Medicine, Harvard Medical School
- **Judith Edersheim**, J.D., Co-Founder and Co-Director of the Center for Law, Brain and Behavior, Assistant Clinical Professor of Psychiatry, Harvard Medical School; Senior Consultant, Law and Psychiatry Service, Massachusetts General Hospital
- **Sue Goldie**, MPH, Faculty Director, Roger Irving Lee Professor of Public Health, Department of Health Policy and Management; Director, Center for health Decision Science, Harvard School of Public Health; Professor of Global Health and Social Medicine, Harvard Medical School
- **W. Nicholson Price, II**, J.D., Ph.D., A.B., Assistant Professor of Law, University of New Hampshire School of Law
- **Ahmed Ragab**, M.D., Ph.D, Richard T. Watson Assistant Professor of Science and Religion, Harvard Divinity School
- **Benjamin Roin**, J.D., Assistant Professor of Technological Innovation, Entrepreneurship, and Strategic Management, MIT Sloan School of Management; Associate Member, Broad Institute
- **Neel T. Shah**, M.D., M.P.P., Assistant Professor, Harvard Medical School; Associate Faculty, Ariadne Labs for Health Systems Innovation

We look forward to developing this opportunity of expansive 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 pressing policy issues and is open to the public/posted to our website, thereby reaching the community in a general way. In addition, our affiliates are regularly sought after to provide media commentary on news stories in our fields. However, every year the Center also endeavors to undertake more directed efforts to reach beyond the walls of academia. These efforts create opportunities not only to disseminate scholarship to influence policy, but also to inform Center affiliates' own scholarship.

In addition to our new sponsored research projects described above, which have clear policy implications for the health and welfare of professional athletes and the advancement of clinical and translational research, this year the Center pursued a number of additional projects and events that were intended to engage the broader community:

### **New Website**

In September 2014, Petrie-Flom unveiled a brand new redesigned website, with a beautiful, user friendly layout and a host of features for the Harvard community and others interested in health law policy, biotechnology, and bioethics.

Our new front page highlights a rotating slider of key announcements from the Center, alongside a running list of our most recent blog posts from Bill of Health. We are able to feature our upcoming events, as well as recent news and scholarship from our affiliates. Finally, we have begun posting selected health policy news headlines from major outlets twice a week in an effort to help drive traffic to our site. We have found that other websites with a similar news feed are a go-to source for people looking to quickly stay up to date on topical new stories.

On our "About" tab, we feature information on the Center's mission, staff, affiliated faculty, and programmatic affiliates. We also post prior annual reports for people looking for a more in-depth review of the Center's work, as well as an archive of our bi-weekly newsletter.

Our "Events" tab now breaks our massive events schedule down into smaller categories for easier searchability, including a list of all upcoming events, and subcategories for lectures/panels, conferences, and health law workshops. We also host an events archive, including slides and video of prior events whenever available.

Next, our "Research" tab features information on our various initiatives, including our work with Harvard Catalyst, the Football Players Health Study, the Program on



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Law and Applied Neuroscience, and the Food Law Lab. This portion of the site will eventually host the work product that results from each of these projects, such as whitepapers, articles, interviews, videos, etc.

Our “[Fellows](#)” tab includes information on the variety of fellowships offered by the Center: the Academic Fellowship, Student Fellowship, and Visitors program. Here we highlight information for individuals interested in these programs, as well as information about current and former fellows.

The “[Resources](#)” tab is a substantial new development, featuring a variety of resources related to health law policy, biotechnology, and bioethics, including:

- **Key Topics:** Topical primers independently developed by the Petrie-Flom Center and intended for beginners to the field on such topics as the Affordable Care Act, animal research, biospecimen research, conflicts of interest, conscientious objection in health care, enhancement, gene patenting, health information technology, human subjects research, international human subjects research, neuroscience and the law, physician-patient relationship, reproductive rights, and vaccines.
- **[Affiliate News](#):** This section of the site lists updates about Petrie-Flom ventures and those of our affiliates, including media coverage and other announcements.
- **[Affiliate Scholarship](#):** Our affiliates' scholarly work is announced and archived here.
- **[Opportunities](#):** In this section, which we anticipate driving substantial traffic to the site, we share job opportunities, fellowships, seminars, graduate programs, and other calls for applications and abstracts related to health law policy, biotechnology, and bioethics. This is intended as a clearinghouse for the interested community; posts are not limited to Petrie-Flom Center opportunities.

Finally, the “[For Students](#)” tab includes information about student fellowships and internships available to Harvard students, as well as information about the health policy curriculum at Harvard’s various schools, a list of relevant Harvard programs and groups, and a set of additional resources, such as a list of journals in the field.

The entire website is “taggable” which allows us to better categorize items and users to search for information across the entire site on a given topic in a more organized way.



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Since the new website launched, it has been viewed by more than 25,000 unique individuals, over more than 40,000 sessions. It has been viewed most often by users in the United States, United Kingdom, Canada, France, India, Australia, China, Germany, Brazil, and Italy, but has been seen by users in 161 countries.

### **Bill of Health**

We have just completed our second year hosting Bill of Health, our collaborative blog on health law policy, biotechnology, and bioethics co-edited by **I. Glenn Cohen** and **Holly Fernandez Lynch**, and it is 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 is incredibly active, with new bloggers being added at least weekly, and usually 2-3 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 numerous posts have resulted in follow up interviews and quotes.

We look forward to continuing to expand the blog in the years to come, ideally developing a more robust community of individuals who not only read the posts, but also comment on them to create conversation and dialogue.

The blog is hugely popular, and has been visited by users in nearly 200 countries around the world. Since it launched in 2012, it has seen nearly 200,000 unique visitors, and currently reaches about 12,000 users each month (an improvement over last year's reach of about 8,000 users per month).

### **Events with Industry Participation**

As noted above, Petrie-Flom hosted two events last academic year with industry participants:

- **Responsibility and Integrity in the Pharmaceutical Industry**, with Neil Flanzraich, Executive Chairman of Kirax Corporation and the Executive Chairman of ParinGenix, Inc., both of which are privately owned biotech companies. He previously served as the Vice Chairman and President of Ivax Corporation, an international pharmaceutical company.
- **Biostatistics and FDA Regulation: The Convergence of Science and Law**, with the Food and Drug Law Institute. This event involved presentations from leading law firms and pharmaceutical companies, as well as representation from the pharmaceutical industry trade organization and the government. Attendees reflected a similar mix of industry, academia, and private practice.



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Next year, we anticipate hosting several additional events that are likely to include industry participants:

- **Post-Trial Responsibilities: Ethics and Implementation** (with the Multi-Regional Clinical Trials Center at Harvard). This one day conference is intended to shed light on the issues surrounding responsibilities to clinical trial participants and host communities when a trial or trial participation is over. Responsibilities of investigators, industry sponsors, and governments will be examined.
- **Legal and Ethical Issues in Health Care Start Ups.** This event will feature successful former participants in the President's Innovation Challenge who have launched health care start-up companies through the Harvard Innovation Lab (iLab), as well as leaders from industry, HBS, and the iLab itself.
- **Emerging Issues and New Frontiers for FDA Regulation** (with the Food and Drug Law Institute). Although this event is intended to be more academic than our prior collaboration, we anticipate industry participation given FDLI's usual constituency.
- **Research Ethics Book Group Lunch and Meet the Authors: *Human Subjects Research Regulation: Perspectives on the Future*** (with PRIM&R). This event will be held at the annual conference of the major educational organization catering to human research protection professionals, and thus we expect substantial participation from both academic and industry representatives.





## **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:

- Launch of the JOURNAL OF LAW AND BIOSCIENCES with colleagues at Duke and Stanford
- Sponsored research projects with Harvard Catalyst (Football Players Health Study and work on the Clinical and Translational Science Award), including collaboration with The Hastings Center
- Sponsored research proposals with Harvard Divinity School, the Multi-Regional Clinical Trials Center at Harvard, and Mt. Sinai School of Medicine
- Co-teaching a reading group on Lawyers, Doctors, Ethics, and Professionalism with HLS and HMS faculty
- Book projects based on our conferences, with authors from a variety of institutions
- Work with the Multi-Regional Clinical Trials Center at Harvard, including co-sponsored events and membership on the MRCT Center's ethics working group
- Collaboration with the Harvard Medical School Center for Bioethics (formerly the Division of Medical Ethics) and University administrators to consider pursuit of a state-level bioethics task force

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

- American Health Lawyers' Association School Alliance
- The Broad Institute of MIT and Harvard (I. Glenn Cohen was appointed associate member of the [Broad Institute](#) in 2013)
- The Center for Law, Brain, and Behavior at Massachusetts General Hospital
- The Food and Drug Law Institute
- Harvard Global Health Institute
- The Hastings Center
- HLS Center for Health Law Policy and Innovation
- HLS Dean's Office
- HLS Food Law Society
- HMS Center for Bioethics
- Multi-Regional Clinical Trials Center at Harvard
- The New England Journal of Medicine



## ***2014-15 Plans for Activities***

(Fiscal Year 2015: July 2014-June 2015)

During the next year, we plan to continue our efforts to expand the Center's reach and influence through the development of stronger collaborations with colleagues at Harvard and elsewhere. Over the next several years, we hope to become a national leader not only in the realm of health law policy, biotechnology, and bioethics scholarship – an area in which we are already well on our way – but also to develop recognition and leadership among policymakers, industry leaders, students interested in pursuing careers in our fields, and the lay public.

## **Research, Scholarship, and Project Activities**

### **Sponsored Research**

As described above, we have two sponsored research projects that will continue for the next academic year: the **Football Players Health Study at Harvard University**, and our collaboration on **Harvard Catalyst's Regulatory Foundations, Ethics, and Law Program**.

We may also pursue other funding sources for the projects with Harvard Divinity School, the Multi-Regional Clinical Trials Center at Harvard, and Mt. Sinai School of Medicine.

Finally, at the end of June 2014, we applied for funding from the **Robert Wood Johnson Foundation New Clinical Scholars program** for a project called "Clinical Advocates: Training Clinicians to Advance a Culture of Health Through Law, Health Policy, and Social Science." Unfortunately, we were notified in mid-August that we were not selected for funding. However, we hope to pursue the project nonetheless, which would allow us to design an initiative to train and support cohorts of "Clinical Advocates," clinicians who would be motivated, prepared, and supported to serve as leading advocates to advance a culture of health through informed engagement with policymakers, the media, peers, and patients.

### **The Program on Law and Applied Neuroscience**

Beginning in Fall 2014, the Petrie-Flom Center will collaborate with the Center for Law, Brain, and Behavior (CLBB) at Massachusetts General Hospital to launch the Program on Law and Applied Neuroscience, including a Senior Fellow in residence, public events, and a curricular component. The Program will be led by **L**



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**Glenn Cohen; Hon. Nancy Gertner; Judith G. Edersheim**, co-director of CLBB; and **Bruce H. Price**, co-director of CLBB.

**Amanda Pustilnik, JD**, currently a Professor at the University of Maryland School of Law, will be the first Senior Fellow in Law and Neuroscience in 2014-2015. Professor Pustilnik will pursue original research (white papers, policy documents, and academic publications) that aim to advance law and neuroscience, mentoring, event and workshop planning, and public engagement. She will reside at the Petrie-Flom Center several times per month in Fall 2014 and full-time in Spring 2015.

The Program will also include expert symposia and public events. Finally, the Hon. Nancy Gertner, HLS Professor of Practice as well as a CLBB faculty member and Petrie-Flom affiliated faculty, will teach a Law and Neuroscience Seminar to introduce students to this complex and growing translational field. The course will draw on HLS and CLBB's interdisciplinary legal and scientific faculty.

Over the first several years of the Program, the focus will be on pain and addiction.

## **Academic Fellows**

This year, we are pleased to welcome **Rachel Sachs** to the Center as an Academic Fellow for the 2014-2016 fellowship term. In 2013, Rachel earned her J.D. *magna cum laude* from Harvard Law School, where she was the Articles Chair of the HARVARD LAW REVIEW and a student fellow with both the Petrie-Flom Center and the John M. Olin Center for Law, Economics, and Business. Rachel has also earned a Master of Public Health from the Harvard School of Public Health, during which she interned at the United States Department of Health and Human Services. She holds an A.B. in Bioethics from Princeton University. After law school Rachel clerked for the Honorable Richard A. Posner of the United States Court of Appeals for the Seventh Circuit. Rachel's primary research interests lie at the intersection of patent law and public health, with a particular focus on problems of innovation and access and the ways in which law helps or hinders these problems. Her past scholarship has examined the interactions between patent law and FDA regulation in the area of diagnostic tests, and explored the mechanisms behind the passage of patent-related legislation. Her current scholarship applies this focus on innovation and access to the intersection of patent law and drug reimbursement policies.

**Matthew J.B. Lawrence** will continue his fellowship, now in the second year at the Center. He is going on the entry-level teaching market this Fall.

Going forward, we will continue our recent practice of being highly selective in considering fellowship applicants in order to continue our record of strong placement, meeting fellows' expectations, and preserving our reputation for



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excellence. We are not actively soliciting applications for a new fellow for the 2015-2017 term. We are also currently considering whether to develop an alternative fellowship program on a different model.

## Faculty

The Petrie-Flom Center congratulates our former co-director, **Benjamin N. Roin**, who effective June 30, 2014 accepted an offer to join the faculty of MIT Sloan School of Management. As part of this transition Ben has given up his co-directorship of the Center (**I. Glenn Cohen** will remain as sole faculty director), but he will continue as a faculty affiliate and Visiting Scholar, and will remain involved with Petrie-Flom programs. We are extremely grateful for his role in helping to build the Center and its program, and take solace in the fact that while he is moving to MIT he will not be very far away.

In the summer of 2014, the Center once again provided research support to **Prof. Cohen** and **Elhauge**.

**I. Glenn Cohen** worked on the following projects, among others listed above in the publications section:

THE OXFORD HANDBOOK OF AMERICAN HEALTH LAW (co-edited with Allison Hoffman and William Sage, under contract, Oxford University Press)

IDENTIFIED V. STATISTICAL LIVES: ETHICAL, LEGAL, AND MEDICAL PERSPECTIVES (Oxford University Press, forthcoming 2015) (co-edited with Nir Eyal and Norman Daniels and contributing a chapter)

NEW AND ENDURING CHALLENGES FOR FDA: SELECTED ESSAYS ON THE FUTURE OF THE AGENCY AND ITS REGULATION OF DRUGS AND NEW TECHNOLOGIES (co-edited with Holly Fernandez Lynch) (Columbia University Press, forthcoming 2015)

**Einer Elhauge**'s summer funding supported the following:

- Completion of an article titled "The Welfare Effects of Metering Ties," with Barry Nalebuff
- Completion of an article titled "Rehabilitating Jefferson Parish: Why Ties without a Substantial Foreclosure Share Should Not Be Per Se Legal"
- Work on an article called "Gutting Private Antitrust Enforcement By Replacing It With Ineffective Forms of Arbitration"
- Work on an article on the Supreme Court's Medicaid expansion decision
- Work on an ongoing book project on human enhancement called "A Little Lower Than God: Redesigning Humans – What Limits?"



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## **Visitors**

The Petrie-Flom Center is a popular site for visiting scholars, both international and domestic. We expect to receive several inquiries this academic year, and to accept a number of stand-out candidates for short and longer-term stays.

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.

### ***Lydia Stewart Ferreira***

Petrie-Flom Center Visiting Scholar, July-August 2014

Lydia Stewart Ferreira is currently Adjunct Professor at the University of Toronto Faculty of Law and Osgoode Hill Law School. She earned an MPH at Boston University; and JD, LLM, and PhD degrees at Yorke University, Osgoode. She clerked at the Ontario Superior Court of Justice for Justice Casey Hill and assisted with numerous well-known cases including the Walkerton Insurance litigation. She was Called to the Ontario Bar in 2002. Lydia has taught Health Law, Medical Law and Public Health Law. She has also taught at the Windsor Faculty of Law, Queen's University Faculty of Law, and George Brown College. Lydia has worked as a Senior Policy Analyst and Manager with the Ministry of Health and Long Term Care (Canada). Her work in health law and health policy has included the Ontario West Nile Virus, Walkerton, Public Health Renewal following SARS, Tobacco Control, HIV/AIDS, emergency planning, consent and capacity, health information privacy, health promotion and the social determinants of health. She was the recipient of a Law Foundation of Ontario Grant which examined Access to Justice delivery and funding models for the Middle Class using the private sector and insurance models. She has also worked as Counsel for BLG, the Law Society of Upper Canada, and the Ministry of the Attorney General (Canada). She was Appointed by Orders in Council to the Health Services Appeal and Review Board and is currently Appointed to the Health Professions Appeal and Review Board. She served on the Research Ethics Board for the University of Toronto and is a Pro Bono litigator and legal advisor for clients of Law Help Ontario. For 10 years prior to law school, Lydia worked in the health sector at the municipal, provincial and national levels and, with the assistance of a World Health Organization/PAHO Fellowship, conducted research internationally into cardiovascular disease reduction strategies. Lydia is a member of the Advocates Society and the Society of Ontario Adjudicators and Regulators (SOAR) and previously on the Executive of Ontario Bar



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Association (OBA) Administrative Law Section, Health Law and Constitutional, Civil Liberties and Human Rights Section as well as on the Executive on the Canadian Bar Association Health Law Section.

As a visitor at the Petrie-Flom Center, Lydia has pursued work on medical tourism and clinical trials.

***Aziza Ahmed***

Petrie-Flom Center Visiting Scholar, January 2014-August 2014

See above, in the section of the report describing 2013-2014 activities, as Aziza's visit spanned academic years.

***Benjamin Roin***

Petrie-Flom Center Visiting Scholar, July 2014 -

As indicated above, Benjamin Roin has left HLS for MIT. However, he will remain engaged with the Petrie-Flom Center as a Visiting Scholar

## **Book Projects**

Faculty Director I. Glenn Cohen and Executive Director Holly Fernandez Lynch continue to pursue edited volumes out of the Petrie-Flom Center's annual conferences in order to provide a venue for publication of the excellent scholarship that is generated and to bring the conversation to a wider audience than was able to attend the event itself.

In July 2014, MIT Press released ***HUMAN SUBJECTS RESEARCH REGULATION: PERSPECTIVES ON THE FUTURE***, stemming from the Center's 2012 conference. From the book jacket:

The current framework for the regulation of human subjects research emerged largely in reaction to the horrors of Nazi human experimentation, revealed at the Nuremberg trials, and the Tuskegee syphilis study, conducted by U.S. government researchers from 1932 to 1972. This framework, combining elements of paternalism with efforts to preserve individual autonomy, has remained fundamentally unchanged for decades. Yet, as this book documents, it has significant flaws—including its potential to burden important research, overprotect some subjects and inadequately protect others, generate inconsistent results, and lag behind developments in how research is conducted. Invigorated by the U.S. government's first steps toward change in over twenty years, *Human Subjects Research Regulation* brings together the leading thinkers



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in this field from ethics, law, medicine, and public policy to discuss how to make the system better. The result is a collection of novel ideas—some incremental, some radical—for the future of research oversight and human subject protection.

After reviewing the history of U.S. research regulations, the contributors consider such topics as risk-based regulation; research involving vulnerable populations (including military personnel, children, and prisoners); the relationships among subjects, investigators, sponsors, and institutional review boards; privacy, especially regarding biospecimens and tissue banking; and the possibility of fundamental paradigm shifts.

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*Introduction, Nir Eyal*

*Chapter 2, De minimis Risk: A Suggestion for a New Category of Research Risk, Rosamond Rhodes*

*Chapter 3, Risk Level, Research Oversight, and Decrements in Participant Protections, Ana S. Iltis*

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*Chapter 5, Children as Research Partners in Community Pediatrics, Adam Braddock*

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*Part III, Redefining the Participant–Researcher Relationship and the Role of IRBs*

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Chapter 7, *Toward Human Research Protection That Is Evidence Based and Participant Centered*, Michael McDonald, Susan Cox, and Anne Townsend

Chapter 8, *Outsourcing Ethical Obligations: Should the Revised Common Rule Address the Responsibilities of Investigators and Sponsors?* Seema K. Shah

Chapter 9, *Subjects, Participants, and Partners: What Are the Implications for Research as the Role of Informed Consent Evolves?* Alexander Morgan Capron

Chapter 10, *Democratic Deliberation and the Ethical Review of Human Subjects Research*, Govind Persad

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*Part IV, Specimens, Data, and Privacy*  
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Chapter 12, *Biospecimen Exceptionalism in the ANPRM*, Ellen Wright Clayton

Chapter 13, *Biobanking, Consent, and Certificates of Confidentiality: Does the ANPRM Muddy the Water?* Brett A. Williams and Leslie E. Wolf

Chapter 14, *Mandating Consent for Future Research with Biospecimens: A Call for Enhanced Community Engagement*, Carol Weil, Hilary Shutak, Benjamin Fombonne, and Nicole Lockhart

Chapter 15, *Take Another Little Piece of My Heart: Regulating the Research Use of Human Biospecimens*, Gail H. Javitt

Chapter 16, *Reconsidering Privacy Protections for Human Research*, Suzanne M. Rivera

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Chapter 18, *What Is This Thing Called Research?* Zachary M. Schrag

Chapter 19, *What's Right about the "Medical Model" in Human Subjects Research Regulation*, Heidi Li Feldman

Chapter 20, *Three Challenges for Risk-Based (Research) Regulation: Heterogeneity among Regulated Activities, Regulator Bias, and Stakeholder Heterogeneity*, **Michelle N. Meyer**

Chapter 21, *Protecting Human Research Subjects as Human Research Workers*, **Holly Fernandez Lynch**

Chapter 22, *Getting Past Protectionism: Is It Time to Take off the Training Wheels?* Greg Koski

We are also nearing completion of the manuscript for our book on the Food and Drug Administration, stemming from our [2013 conference](#) (with some pruning and additions). The book, tentatively titled "**NEW AND ENDURING CHALLENGES FOR FDA: SELECTED ESSAYS ON THE FUTURE OF THE AGENCY AND ITS REGULATION OF DRUGS AND NEW TECHNOLOGIES**," is under contract with Columbia University Press, and is expected to be published next year. A brief description and table of contents follow:

While carrying out its fundamental mission of safeguarding public health by assuring the safety, efficacy, and security of a range of medical and other products, the Food and Drug Administration has faced perennial issues related to funding, relationships with industry, and striking the proper balance between consumer choice and consumer protection. These issues are as pressing and unresolved as ever, but are now compounded by distinctly modern challenges related to globalization, novel technologies, newly added responsibilities, and changing threats to the public health. This book aims to address both sets of challenges – the constant and the novel – through an approach that is diverse in terms of authorship, content, and scope.

Bringing together expert authors from academia, government, and private industry, the book offers insight into how one of the United States government's oldest consumer protection agencies is faring today, and how it ought to change moving forward. In order to focus the inquiry, the book uses the lens of drug products and new technologies to analyze selected questions about the agency and its future – in particular, institutional challenges facing the agency; unique issues in drug policy and innovation; and a handful of interesting questions raised by new technologies.



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Chapter 7, Genevieve Pham-Kanter, *Conflicts of Interest in FDA Advisory Committees: The Paradox of Multiple Financial Ties*

Chapter 8, Katrice Bridges Copeland, *The Crime of Being in Charge: Executive Culpability and Collateral Consequences*

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Chapter 11, **Christopher T. Robertson**, *The FDCA as the Test for the Truth of Promotional Claims*

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Chapter 25, Elizabeth Pike and Kayte Spector-Bagdady, *Device-ive Maneuvers: FDA's Risk Assessment of Bifurcated Direct-to-Consumer Genetic Testing*

Chapter 26, Andrew English, David Rosenberg, and Huaou Yan, *A New Regulatory Function for E-Prescriptions: Linking the FDA to Physicians and Patient Records*

Chapter 27, Jonathan Kahn, *Race and the FDA*

Finally, we are nearing a contract with Johns Hopkins University Press on the book proposal stemming from our 2014 annual conference on behavioral economics, law, and health policy, to be co-edited by **I. Glenn Cohen**, **Holly Fernandez Lynch**, and **Christopher Robertson**.



## **Events Programming and Conferences**

Over the 2014-2015 academic year, the Center is planning to host and co-sponsor a number of exciting public events, in addition to our annual Open House, including the following:

**September 18 – Post-Trial Responsibilities: Ethics and Implementation** (with the Multi-Regional Clinical Trials Center at Harvard)

**September 30 – A Conversation with the Department of Health and Human Services Offices of the Inspector General** (featuring Joyce Greenleaf, Regional Inspector General for the Office of Evaluations and Inspections in Boston, and Jessica Fagnoli, Program Analyst for the Office of Evaluations and Inspections, with Matthew Lawrence moderating)

**October 6 – Legal and Ethical Issues in Health Care Start Ups** (with the Harvard iLab, featuring former winners Vaxess and Virtudent, with commentary from Neil Flanzraich, Gordon Jones, and John Quelch)

**October 21 – Emerging Issues and New Frontiers for FDA Regulation** (with the Food and Drug Law Institute, in Washington, DC)

**October 22 – Human Subjects Research Regulation: Perspectives on the Future** (with the HLS Library, a book talk and discussion by co-editors I. Glenn Cohen and Holly Fernandez Lynch, with panelists Barbara E. Bierer and Michelle N. Meyer)

**November 5 – Global Reproduction: Health, Law, and Human Rights in Surrogacy and Egg Donation** (with Our Bodies Ourselves, featuring a screening of Can We See the Baby Bump, Please?, and discussion by Judy Norsigian, Shirley Shalev, and I. Glenn Cohen)

**November 6 – Law and Ethics of Non-Invasive Prenatal Testing** (a discussion with Vardit Ravitsky)

**November 19 – Patients with Passports** (with the HLS Library, a book talk and discussion with I. Glenn Cohen, Amitabh Chandra, Nir Eyal, and Alicia Ely Yamin)

**December 5 - Research Ethics Book Group Lunch and Meet the Authors: *Human Subjects Research Regulation: Perspectives on the Future*** (with PRIM&R, featuring I. Glenn Cohen, Holly Fernandez Lynch, and authors from the book)



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**January 31 – Health Law Year in P/Review** (with the New England Journal of Medicine)

**February 10 – Intersex, Third Gender, and Sex Change**

**March 18-20 – Families Matter: Clinically, Legally, and Ethically** (with the HMS Center for Bioethics)

**May 8-9 – Annual Petrie-Flom Conference: Law, Religion, and American Health Care**

We will also host a range of other public events, to be planned. In particular, we anticipate several events in collaboration with the Law and Applied Neuroscience Program, as well as collaboration with The Broad Institute on this year's Innovation and Intellectual Property Symposium.

Finally, the Petrie-Flom Center, in collaboration with Harvard Catalyst, has been awarded a grant by the Brocher Foundation in Geneva to host a workshop on ***Innovation in Recruitment to Clinical Trials***. The Petrie-Flom-Harvard Catalyst proposal was selected as one of 28 successful proposals from approximately 80 applications. The symposium will take place on January 19-21, 2015 in Geneva Switzerland and will bring together experts in the field of research ethics, along with representatives from industry, patient groups, and key governmental agencies. Collaborators on the application were Hans van Delden, Chair of CIOMS and Reidar Lie, a leading scholar in research ethics with NIH. The three day conference will explore innovation in recruitment to clinical trials, beginning with presentations on cutting edge issues in recruitment, including compensation in recruitment, use of clinical data in research, use of social media in recruitment, and demographic targeting. Among the confirmed participants are Otmar Kloiber, secretary-general of the World Medical Association; Bartha Knoppers, University of Montreal; Michael Parker, University of Oxford; Alex Capron, USC; Alan Wertheimer, NIH; and Barbara Bierer, MRCT. The Brocher Foundation is a non-profit foundation that supports scientific inquiry through the hosting of scientists and experts in the ethical, legal, and social implications of the development of medical research and biotechnologies.



## **Contributions to HLS Teaching Program**

Petrie-Flom affiliates will continue to make substantial contributions to the HLS health law curriculum, through workshops, seminars, and reading groups. **I. Glenn Cohen** and Rebecca Brendel may repeat their reading group from Spring 2014 next year, on medical and legal professionalism, although it remains tentative. In addition, affiliates will guest lecture on an ad hoc basis around the University; for example, Football Players Health Study Associate Chris Deubert may participate in sessions of Peter Carfagna's sports law courses. As we phase out our Academic Fellowship program, however, there will no longer be fellows available to teach seminars in their areas of focus, which is an important drawback of this plan.

### **Health Law Policy, Biotechnology, and Bioethics Workshop**

Fall 2014 and Spring 2015

This year's workshop will be co-taught by **I. Glenn Cohen** and **Einer Elhauge**. Confirmed presenters include:

- **Anup Malani**, University of Chicago Law School and Pritzker School of Medicine
- **Thomas McGuire**, Harvard Medical School
- **Ben Roin**, MIT Sloan School of Management
- **Matt Lamkin**, University of Tulsa College of Law
- **Leemore Dafny**, Kellogg School of Management, Northwestern University
- **Thomas Greaney**, St. Louis University School of Law
- **Liran Einav**, Stanford University, Department of Economics
- **Amy Kapczynski**, Yale Law School
- **Robert Truog**, Harvard Medical School
- **Nadia Sawicki**, Loyola University School of Law
- **Abbe Gluck**, Yale Law School
- **Rachel Sachs**, Academic Fellow, Petrie-Flom Center

### **Law and Medicine: The Affordable Care Act**

Spring 2015

This seminar will be offered by **Matthew Lawrence**, Academic Fellow. It will consider the package of reforms known as "the Affordable Care Act," first exploring the goals of the Act and then addressing the extent to which implementation and legal challenges have slowed or permanently limited the Act's success in meeting those goals.

Likely units and topics include:



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- Overview of our fragmented healthcare system
- The ACA's three-pronged reform plan
  - Insure the uninsured—the employer mandate, individual mandate, and Medicaid Expansion
  - Make insurance better—essential benefits requirements, medical loss ratios, external review, cost sharing, co-ops, and other market reforms
  - Make medicine better—pay-for-performance, fraud control, and primary care
- Implementation challenges
  - Website rollout and exchange enrollment
  - Employer mandate
  - Failed co-ops
- Legal challenges
  - Individual mandate (*NFIB v. Sebelius*)
  - Medicaid expansion (*NFIB v. Sebelius*)
  - Contraception mandate (*Hobby Lobby Stores v. Sebelius*)
  - Subsidy challenges (*Halbig v. Sebelius*)
  - Current developments
- The future of the ACA

### **Law and Neuroscience**

Spring 2015

This seminar, taught by **Nancy Gertner** with the support of **Amanda Pustilnik**, will be offered as part of the Project on Law and Applied Neuroscience. It examines cutting edge and even controversial linkages between law and neuroscience. The course seeks to highlight neuroscientific bases for behavior patterns with legal implications including how neuroscience intersects with criminal law, its normative assumptions and criminal punishment, evidentiary rules, memory bias and enhancement, lie and deception detection, adolescent brains and juvenile law. Students 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 students to consider the relationship between law and science, more generally, and neuroscience in particular.





## **Participation of HLS Students in Program Activities**

We plan to continue engaging students in a variety of ways, through our website resources (in particular, job announcements), 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.

### **Student Fellows**

We are pleased to welcome the following individuals to the Petrie-Flom Center as Student Fellows for the 2014-2015 academic year. They will pursue independent research under the supervision of Center faculty and fellows, regularly contribute to our blog, and enroll in the Health Law Policy and Bioethics Workshop.

#### **Christine Baugh, FAS**

**Proposed Research Topic: “Conflicts of interest in the athletic environment and their potential effects on athlete health”**

Christine is a first year student in the Ethics concentration of Harvard’s Health Policy PhD program. She received her BA in History and Science from Harvard College in 2010 and her MPH from Boston University School of Public Health in 2012 concentrating in Health Law, Bioethics, and Human Rights. Since her graduation in 2010, Christine has been studying the effects of brain trauma on contact sport athletes and military veterans. Broadly, Christine’s research interests involve the interaction between evolving science, policy, and society.

During her fellowship, she will examine conflicts of interest of stakeholders within the sports environment and how they may influence athlete symptom reporting and athletes’ overall health and wellbeing.

#### **Kelsey Berry, FAS**

**Proposed Research Topic: “Regulatory Flexibility at the FDA – Ethical Reasons and Effects of Regulatory Reform on Drug Access”**

Kelsey is a second year student in the Doctoral Program in Health Policy and Ethics at Harvard University. She completed her undergraduate work at Princeton University where she studied Political Philosophy and Neuroscience. Her undergraduate thesis traced the interactions of domination and servility in the republican theory of liberty expressed in Jean Jacques Rousseau’s philosophy. Kelsey has worked in health policy through various research fellowships: on a health service delivery project at an ophthalmological hospital in India; on an evaluation project in neonatal health at Children’s Hospital



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Boston; and on a technology development and clinical adoption project at a medical engineering research center. She is currently conducting empirical research in mental health policy.

During her internship, Kelsey will explore two topics related to the FDA's flexible regulatory approach. The first is a normative study of the ethical arguments underlying these regulatory reforms, and the second is an empirical study of the relationship between of FDA's flexible approval processes and insurer drug coverage policy as a key determinant of drug access.

**Emily Largent, FAS, HLS**

**Proposed Research Topic: "Forget Selling Your Soul: Skin and Bones Sales May Be More Beneficial"**

Emily is in her second year at Harvard Law School and is a PhD candidate in the Harvard Program in Health Policy. Emily has published articles on topics including emergency research without informed consent, IRB members' attitudes toward payment of research participants, access to orphan drugs, and research-care integration. She is a co-author of *CLINICAL RESEARCH ETHICS CONSULTATION: A CASEBOOK*, a collection of case studies in research ethics. Her current research interests include payment of research participants and markets for organs and tissues.

Although the National Organ Transplant Act, 42 U.S.C.A. § 274e, prohibits the sale of human organs, tissue banking is big business. Donor families are usually not aware of the commercial potential of tissue, nor are they compensated. Emily's fellowship project will seek to explore the legal, ethical, and practical arguments for compensating donor families.

**Zachary Shapiro, HLS**

**Proposed Research Topic: "Neuroimaging in American Criminal Law: Promises and Pitfalls"**

Zachary is in his second year at Harvard Law School. Zachary received his BA in Human Health and Medical Ethics from Brown University in 2009 and an MSc in Biomedicine, Bioscience, and Society in 2012 from the London School of Economics. He continued his studies in 2013 at Harvard Law School, in order to pursue his interest of the intersection of law, ethics, and biomedicine. He is a Legal Fellow at Harvard's Multi-Regional Clinical Trials Center, where his work focuses on projects related to returning clinical trial results, post-trial access, and the ethics of clinical trials. Zachary's current research interests in



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neuroimaging in criminal law build upon his prior publications in the field of neuroimaging and neuroethics.

During his fellowship, Zachary will focus on neuroimaging and its use in American Criminal Jurisprudence. The goals of his project are to assess the current state of neuroimaging in criminal law, inside and outside of the courtroom, and to explore promising future applications.

**Vadim Shteyler, HMS**

**Proposed Research Topic: "Ethically Informed Directions for the Future of Trans Health"**

Vadim is a fourth-year student at Harvard Medical School. He received his BS in Biology from Brooklyn College in 2011. His prior research and publications explored novel therapeutics and molecular pathways in Cancer Biology. His current research combines empirical research methods with analytic philosophy to answer medically relevant ethical questions. His interests include the ethical issues in transgender health, unique ethical challenges surrounding informed consent in obstetrics, and models of informed consent.

During his fellowship, Vadim will focus on the unique interactions trans people have with the healthcare system. Reviewing recent changes in law, insurance policy, and medical professional guidelines, he will write about how the evolving framework for theorizing trans affects their access to care

**Lauren Taylor, HDS**

**Proposed Research Topic: "How freely made is the choice to play?"**

Lauren is a Presidential Scholar and third year Master of Divinity Candidate at Harvard Divinity School (HDS). At HDS, she studies the ethics of health care delivery and serves as a Research and Development Director in the Science, Religion and Culture program. Prior to arriving at HDS, Lauren received a joint BA/MPH degree from Yale and worked for several years at the Yale Global Health Leadership Institute. Lauren's first book, co-authored with Elizabeth H. Bradley, PhD and titled "The American Health Care Paradox," was released by Public Affairs in November of 2013 and has since become required reading at several top-tier medical and public health schools across the country.

During her fellowship, Lauren will explore the duress involved in a football player's ability to choose to play by his own free will, including socio-economic pressures for those from disadvantaged backgrounds, lack of understanding in the health risks, and lack of opportunities for different careers.



## **Student Interns**

We have now run a successful internship program for two years. However, in order to improve the consistency of student engagement over time, this year we are planning to initiate a smaller program of paid interns. Interns will work on a range of projects for the Center, including:

- Blog maintenance at Bill of Health, and possibly weekly news round-ups or substantive posts;
- Management of social media accounts on Facebook and Twitter;
- Drafting of bi-weekly email newsletter;
- Website maintenance and content development, including identification of key topical resources for those interested in the field, career-related resources, and relevant programs, centers, courses, etc. around Harvard and beyond;
- Tracking news related to the Center and its areas of interest;
- Assistance with event coordination, advertising, and preparation.

Interns are encouraged but not required to attend Center events.

This Fall's interns are:

- [Audrey Zhang](#), College 2015
- [Virginie Chan](#), College 2015

## **Research Assistants**

As noted above, our Academic Fellows will utilize graduate student research assistants for their work, and RAs will also be engaged in our sponsored research programs, book projects, and other initiatives as needed.

## **Journal of Law and Biosciences Student Contributors**

Once again this year, Petrie-Flom will be responsible for populating the "New Developments" section for one issue of the annual JLB volume. New Developments will be written by Harvard graduate students, who will be selected this fall.



## **New Initiatives and Collaborations**

We are now entering the third year of our expansion at Petrie-Flom, and we have launched several new initiatives since 2012, expanding dramatically both in size and content. We wish to grow strategically and not too quickly, and so anticipate that after this initial push, our rate of expansion will begin to stabilize.

Nonetheless, we will continue to consider new programs and collaborations that meet our strategic vision of building the Center into the leading academic research program in our fields. In particular, we envision continuing to substantially develop our relationship with the Center for Bioethics at HMS, as well as other relevant Centers and Programs around the University. For example, both **I. Glenn Cohen** and **Holly Fernandez Lynch** have been named affiliated faculty at the Center for Bioethics, and we are working closely with our colleagues there on a large Spring conference focused on family decisionmaking, autonomy, and clinical ethics. Additional plans and possibilities include:

- Beginning in the 2015-2016 academic year, Petrie-Flom will contribute to the **Master's in Bioethics** being offered by the Center for Bioethics at Harvard Medical School. In particular, Petrie-Flom will help develop a Health Law and Policy track for Master's students, including particular course selections, directed mentoring, and practicum opportunities.
- We hope to pursue **additional educational initiatives**, including potentially training clinicians in key aspects of health law and policy (e.g., via the Robert Wood Johnson Foundation proposal described previously), as well as through more traditional Executive Education offerings.
- We will follow up on our collaboration with the Multi-Regional Clinical Trials Center at Harvard to host a Fall conference on post-trial access through participation in the **MRCT's new expert working group on post-trial access** that will be launched via the conference.
- We expect that our **collaboration with the Food and Drug Law Institute** will develop into an annual academic conference.