



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

Annual Report, Fiscal Year 2015

Executive Summary

This year marks the close of the Petrie-Flom Center's first decade of existence, and we are thrilled with what we have been able to accomplish in that time. The Center began with a focus on developing new scholars and scholarship in the fields of health law policy, biotechnology, and bioethics through fellowship programs for students and post-docs, as well as a handful of events and conferences. Since then, our goals have expanded dramatically to include not only these important academic pursuits, but also policy impact through sponsored research collaborations bridging legal, medical, and other disciplines. Most notably, we are no longer only a research program comprised solely of individuals working on their individual projects, but rather a true Center made up of collaborators working on Center-based research with high impact and visibility.

In terms of sponsored research, we have made substantial progress this year on our work leading the Law and Ethics Initiative of the Football Players Health Study at Harvard. In addition to providing guidance regarding legal and ethical issues that arise in other aspects of the study, we are drafting several reports and recommendations aimed at improving player health and well-being using the tools of law and ethics to complement clinical interventions. We have also continued our work with Harvard Catalyst's Regulatory Foundations, Ethics, and Law Program, hosting an international conference to develop a research agenda around improving recruitment to clinical trials, developing guidance for the use of social media in recruitment efforts, and conducting empirical research regarding perceptions of offers of payment to research participants. Work on both of these projects will continue through the next fiscal year.

We have also launched a new sponsored-research collaboration with colleagues at Case Western Reserve University and Harvard Catalyst, funded by the National



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Human Genome Research Institute at the National Institutes of Health (NIH). This project involves a conference slated for Fall 2015 and a subsequent edited volume examining the legal, ethical, and practical issues surrounding research with human biospecimens, a critical step for advancing precision medicine.

In September 2015, we will add another sponsored project to our repertoire, this one funded by the Patient-Centered Outcomes Research Institute (PCORI). Collaborating with colleagues elsewhere at Harvard, our work on this project will focus on developing guidelines and recommendations for Institutional Review Boards, investigators, and patient advisors to employ when designing or reviewing human subjects research aspects of patient-centered outcomes research and comparative effectiveness research.

With regard to programmatic collaborations, we are proud to have another volume of the Journal of Law and Biosciences under our belt, alongside our partners at Duke and Stanford. This peer-reviewed, open access interdisciplinary journal from Oxford University Press features world-class scholarship, responsive commentary, and "Notes and Developments" from graduate students at each of the collaborating schools. The first year of our Project on Law and Applied Neuroscience was a resounding success, with a prolific senior fellow and a wide range of well-attended events on the law's intersection with the neuroscience of pain. We look forward to welcoming a new senior fellow this fall, and turning the focus to neuroscience and juvenile justice. The Food Law Lab continues to grow, with important events and course offerings for students. And finally, we continue extensive collaboration with our friends at the Center for Bioethics at Harvard Medical School, co-organizing events and conferences, and most recently, the launch of their Master's of Bioethics in Fall 2015.

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 human subjects research, FDA regulation, law and pain, the role of the family in medical decisionmaking, the Affordable Care Act, reproductive technology, medical tourism, Ebola and measles outbreaks, food law and policy, neuroscience and responsibility, and gender reassignment, to name a few. Our 2015 annual conference addressed issues at the intersection of Law, Religion, and Health, and we have several book projects in the works from prior conferences including others on FDA law and applying behavioral economics to health policy.

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 comparative professional responsibility for doctors and lawyers, the Affordable Care Act, and law and neuroscience.



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Our Petrie-Flom affiliates have also fared well this year, with an impressive variety of publications and media commentary in leading outlets and collaborative volumes, covering such topics as medical tourism, the contraceptives coverage mandate, reproductive technology and freedom, blood donation regulation and organ markets, mobile health technologies, the Affordable Care Act, pharmaceutical pricing and innovation, procedural issues regarding Medicare claims, and the microbiome. Our departing Academic Fellow has returned to the Department of Justice to work on ongoing issues related to the Affordable Care Act and legal challenges to the Medicare Program, and our current Academic Fellow is poised to enter the law teaching market this fall. Although we do not plan to accept any additional Academic Fellows at this time, we are considering alternative ways to bring in promising post-doctoral and other fellows.

Our student fellowship continues to be an important component of the Center, and this year's fellows – representing HLS, HMS, HDS, and FAS – pursued projects on concussions in college sports, funding for global aid, regulation of tissue donation and payment, neuroimaging and criminal justice, transgender health, and vaccine exemptions. We also worked with several HLS students as research assistants on our sponsored research and other projects.

The Center's outreach has been expansive this year, reaching unprecedented numbers of interested people through our website, blog, social media outlets, and bi-weekly newsletter. In fact, Bill of Health – now entering its fourth year – has cemented its place as a leading source of commentary from health law scholars, with nearly 18,000 unique users each month.

In the 2016 Fiscal Year, we look forward to continuing our sponsored research projects, supporting our Academic Fellow on the teaching market, welcoming a new crop of student fellows and visitors, and hosting a range of exciting events and conferences. We have steadily expanded for the past three years, and currently plan to focus on stabilization and successful execution of our existing projects, as we gear up for a fundraising push to support our next phase of growth and development.

Our sincere thanks to everyone who supports our work. We look forward to what the next year – and decade – will bring!

Sincerely,

I. Glenn Cohen

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

Faculty Director and Professor of Law, HLS

Holly Fernandez Lynch

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

Executive Director



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2014-15 Report of Activities

(Fiscal Year 2015: July 2014-June 2015)

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 legal and ethical analysis of pressing questions facing health policymakers, medical professionals, patients, families, and others who influence and are influenced by health care and the health care system – in other words, all of us.

The Center's work generally falls into the following categories: (1) public engagement, including numerous events and conferences, extensive media commentary, our popular health policy and bioethics blog, and our resource-filled website; (2) sponsored research collaborations and independent scholarship; and (3) academic programs, including our fellowships and curricular contributions.

Leadership

During FY15, the Center was led by Faculty Director Professor **I. Glenn Cohen** and Executive Director **Holly Fernandez Lynch**.



Research, Project Activities, and Scholarship

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

Sponsored Research

This year, the Center continued two major sponsored research projects that take advantage of our expertise in law and bioethics, and added a third collaboration relating to a sponsored conference and book project.

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 in February 2014 to protect and promote 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, using funds allocated for research by the collective-bargaining agreement with the National Football League; the costs of the research program are shared with multiple Harvard-affiliated institutions.

FPHS includes three main components: (1) Player Studies, focused on defining the prevalence and severity of medical conditions that impact the quality and length of life of professional football players, in order to improve those outcomes; (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 research and understand legal and ethical issues that may enhance or impede player health, and to this end, develop appropriate responsive strategies and recommendations for change. In addition to serving in an advisory role on ethical and legal issues that may arise in the rest of FPHS, key Law and Ethics projects currently include:



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- An ethical framework and accountability structure for more than twenty stakeholders that may influence player health, ranging from players themselves to relevant medical staff to League and Union personnel and many others, including recommendations about the responsibilities of relevant parties;
- A qualitative research study (“listening tour”), conducted in collaboration with empirical researchers at the [Hastings Center](#). This study will catalogue the legal and ethical concerns of players and their families related to their health and wellbeing, 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, which will identify best practices for protecting player health, areas for improvement in the NFL, and aspects in which the NFL is leading the field;
- Legal and ethical assessment of the various predictive and evaluative tests and exams that professional players undergo to assess their health and skill;
- Evaluation of the legal protections available to protect the health and safety of professional athletes in the workplace;
- 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.

We are now about halfway through our initial three years of funding and have made strong progress on each of the projects listed above. We expect the first publications and reports from our work to be made available in the spring or summer of 2016.

The Law and Ethics Initiative is co-led by **I. Glenn Cohen** and **Holly Fernandez Lynch**. **Christopher Deubert** is the Senior Law and Ethics Associate on this project, which is supported by **Justin Leahey**, Project Coordinator. Our work is also guided by the [FPHS Leadership Team](#) and an independent panel of experts who comprise the [Law and Ethics Advisory Panel](#) (LEAP). We have also used this project to further student education at HLS; several HLS students have served as [research assistants](#) on this project, including students in the [HLS Sports Law Clinic](#).

**Harvard Catalyst Clinical and Translational Science Award
Regulatory Foundations, Ethics, and Law Program**

The end of FY15 marked the close of the Petrie-Flom Center’s first period of funding and collaboration with 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



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improve human health by enabling collaboration and providing tools, training, and technologies to clinical and translational investigators. It is funded by the National Institutes of Health (NIH) Clinical and Translational Science Award (CTSA) program (grant 1UL1 TR001102-01), and by contributions from a number of Harvard schools and affiliated institutions.

The Center's work on this project is initially focused on developing practical solutions to key barriers affecting participant recruitment to and enrollment in clinical research studies. In the initial funding period, primary projects included developing guidance materials for Institutional Review Boards (IRBs) and investigators regarding the use of social media to recruit to clinical studies, and conducting empirical research with IRB members, administrative officials, and investigators regarding their perspectives on the ethics of offering payment to research participants. In addition, we were awarded a competitive grant from the Brocher Foundation (one of 28 successful proposals out of approximately 80 applications) to host a three-day international closed-door workshop in Geneva in January 2015 focused on "Clinical Trial Recruitment: Problems, Misconceptions, and Possible Solutions." This meeting of international experts, including investigators, policymakers, academics, patient representatives, and industry professionals with representation from both the World Medical Association and the Council for International Organizations of Medical Sciences (CIOMS), spurred a number of collaborations and a research agenda for future work. Key plans for follow-up from this meeting include papers regarding the contours of the recruitment problem, whether mechanisms of prioritizing research studies may be available, and whether innovative trial designs might contribute to a solution; development of a recruitment "toolkit" for investigators and IRBs; and a number of empirical projects.

The Center has also been 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) and Harvard Catalyst's Master's Program in Clinical and Translational Investigation.

The Petrie-Flom Center's collaboration with Harvard Catalyst is co-led by **L. Glenn Cohen** and **Holly Fernandez Lynch**. **Robin Pierce** served as the Senior Law and Ethics Associate for the initial funded period, and **Yennifer Pedraza** served as the Project Coordinator. HLS student **Emily Largent** served as a critical research assistant, collaborating on the design, conduct, and analysis of the empirical research project regarding offers of payment to trial participants, as well as related publications. Plans for the next funding period, beginning in July 2015, will be described in the FY16 section of this report.



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

In Spring 2015, the Petrie-Flom Center joined forces with Suzanne Rivera, Principal Investigator of a grant from the National Human Genome Research Institute of the National Institutes of Health (Award Number R01HG005691) called “Advancing Collaborative Genetic Research: Ethical and Policy Challenges.” Dr. Rivera participated in our 2012 Petrie-Flom Center Annual Conference on “The Future of Human Subjects Research Regulation,” and the subsequent edited volume released from MIT Press in 2014, Human Subjects Research Regulation: Perspectives on the Future.

Building on the success of those endeavors, Dr. Rivera sought to revisit key topics related to research with biospecimens and their associated data, including important questions about consent, ownership, data-sharing, privacy considerations, group harms, and standards for responsible specimen stewardship. Accordingly, the Petrie-Flom Center has been awarded a subcontract to host a conference on these issues on November 16, 2015, followed by a published volume to be co-edited by Dr. Rivera, Barbara Bierer, Holly Fernandez Lynch, and I. Glenn Cohen. The project is also supported by Harvard Catalyst.

Additional Efforts

In an effort to develop our sponsored research portfolio, this year Petrie-Flom participated in additional grant applications, which were unfortunately unsuccessful. Nonetheless, the application process is always helpful to develop new collaborative relationships that have been fruitful in other ways, and to hone the Center’s research agenda for the future.

National Institutes of Health (NIH): We collaborated with Rosamond Rhodes, Icahn School of Medicine at Mount Sinai, to resubmit a proposal to NIH for a project on “Barriers to Research on Controlled Drugs for HIV-Related Treatment.” Our proposed work would entail 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. Despite scoring well, the project went unfunded in 2015 as not a priority for the particular Institute to which it was submitted. Upon further information and discussion, Dr. Rhodes has been encouraged to resubmit this winter, including our work, and we are actively considering whether to participate in a future resubmission.



Project Activities

The Petrie-Flom Center is involved with a number of projects that seek to advance cutting edge scholarship in our fields, including a collaborative, peer reviewed journal that offers a unique opportunity outside of traditional law reviews for publications at the intersection of law and bioscience, as well as programs on law and neuroscience and food law.

Journal of Law and Biosciences

This year, we launched the second 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 Farahany** (Duke) and **Hank Greely** (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 “**Notes and Developments**” for each issue, comprised of brief summaries of and commentary on recent legislation, regulation, and case law relevant to the biosciences. This year’s student contributions from Harvard are listed below, in the section of this report dedicated to Participation of HLS Students in Program Activities. Notably, student contributions are among the most downloaded pieces in each issue of JLB.

The journal has been a tremendous success, with more than 15,000 downloads in 2014, on track to exceed that in 2015. Nearly half of JLB’s readership comes from North America, with 20% located in Asia, and nearly another 20% in Europe.

Project on Law and Applied Neuroscience

In Fall 2014, the Petrie-Flom Center began the Project on Law and Applied Neuroscience, a new collaboration with the Massachusetts General Hospital Center for Law, Brain, and Behavior (CLBB). The collaboration includes a Senior Fellow in residence at the Petrie-Flom Center, public symposia at Harvard Law School, and a Law and Neuroscience Seminar (taught this past year by the Hon. Nancy Gertner).



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Amanda Pustilnik, JD, currently a Professor at the University of Maryland School of Law, was the first resident Senior Fellow in Law and Neuroscience for 2014-2015. Professor Pustilnik pursued original research, mentoring, and public engagement related to issues of pain and the law, exploring the ways in which new brain imaging science may have practical and theoretical applications for the law. For example, how should pain neuroimaging be handled as a matter of expert evidence in state, federal, and administrative proceedings? What doctrinal changes, if any, should occur in disability law to account for the ways in which chronic pain can become a central nervous system disorder? Tort law currently compensates physical and psychiatric or emotional injuries differently; if chronic pain is a subjective experience rooted in brain dysfunction, is the ongoing pain of an injury meaningfully different from a psychiatric harm?

During Spring 2015, Professor Pustilnik organized several expert symposia and two major public conferences that promoted focused discussion on questions at the intersection of pain, addiction, and the law:

- **Re-envisioning Pain: How Breakthroughs on the Science of Suffering Could Revolutionize Legal Understanding and Outcomes**, February 5, 2015
- **A Dialogue on Agency, Responsibility, and the Brain with Stephen Morse**, February 12, 2015
- **The Policeman at the Elbow: The Neuroscience of Addiction, Self-Control, and Criminal Responsibility**, March 4, 2015
- **Moral Decisions in the Law: What's the Brain Got to Do with It?**, April 8, 2015
- **Visible Solutions: How Neuroimaging Helps Law Re-envision Pain**, June 29-30, 2015

The “Visible Solutions” conference will result in an edited volume to be published by Oxford University Press.

Food Law Lab

The Harvard 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. While under its own leadership and funding, the Food Law Lab is currently situated within the Petrie-Flom Center, and works closely with the Harvard Food Law and Policy Clinic.

The Food Law Lab focuses on three key areas: (1) Promoting research, scholarship, and innovation in food law; (2) Supporting increased clarity in the



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legal regulation of food; and (3) Partnering with others in the field to develop new curricular offerings. The Lab works with faculty, students, and practitioners across various disciplines to foster innovation in the food law curriculum and the growth of modern scholarship.

Harvard Law School offers a seminar taught in conjunction with the Food Law program, allowing law students to engage directly with legal and policy debates by developing and publicly disseminating new research on food. The Lab partners with the UCLA School of Law Resnick Program to sponsor the annual Food Law and Policy Conference, and it sponsors additional events that increase awareness, spark dialogue, and support education around important food law issues. See more below in [Major Events/Conferences](#) and future [Events Programming and Conferences](#).

During the 2014-2015 year, the Food Law Lab launched a new [website](#) to facilitate communication about ongoing activities as well as fundraising efforts. Food Law Lab events continue to be hosted on the Petrie-Flom Center's website.

Scholarship

One of the founding principles of the Petrie-Flom Center was to support emerging, transitioning, and senior scholars making critical contributions to the ways in which the law can and should shape health policy, biotechnology, and bioethics. We promote this scholarship through programs for post-graduate fellows, visiting scholars, and other Petrie-Flom affiliates. Contributions to student scholarship are described [separately](#).

Academic Fellows

Our [Academic Fellowship](#) is a full-time postdoctoral program specifically designed to identify, cultivate, and promote promising scholars early in their careers. In addition to their own independent research and writing, Academic Fellows advance the Center's mission by mentoring students, teaching seminars, presenting their work at Harvard and beyond, and planning and participating in a range of public events and closed workshops. Prior fellows are now employed as tenured or tenure-track professors at institutions such as Harvard, UC Berkeley, Cambridge (UK), Boston University, UCLA, Cornell, the University of Illinois, the University of Arizona, the University of New Hampshire, and Union Graduate College.

The work of our fellows from the 2014-2015 academic year is summarized below.



Matthew J.B. Lawrence, 2013-2015

Matthew finished and published two law review articles this year: *Mandatory Process*, in the *Indiana Law Journal*, and *Procedural Triage*, in the *Fordham Law Review*, as well as a book chapter on Medicare's appeals backlog and section introduction on evidentiary challenges to using behavioral economics in healthcare forthcoming in the Center's edited volume, *NUDGING HEALTH*. Matt also presented on these and other topics at thirteen conferences, colloquia, and talks, including at Tulane University School of Law, DePaul Law School, the University of Chicago School of Law, West Virginia University College of Law, Harvard's Law and Economics Colloquium, and NYU Law School. In his teaching, blogging, and media commentary, Matt focused on the Affordable Care Act, developing and teaching a popular seminar on the landmark reform at HLS and co-organizing (with his co-fellow Rachel Sachs) a conference on *King v. Burwell*, the ACA subsidies challenge. He also continued to take an active interest in Medicare coverage issues, organizing and presenting at an HLS panel titled "Gender (re)assignment: legal, ethical, and conceptual issues."

At the conclusion of his fellowship in June 2015, Matt returned to work as a Trial Attorney at the United States Department of Justice, Civil Division, Federal Programs Branch, which is responsible for, among other matters, defending the Affordable Care Act and various legal challenges to Medicare Program issues.

Rachel E. Sachs, 2014-2016

Rachel joined the Center in Fall 2014 from a clerkship with Judge Richard Posner on the Seventh Circuit, and she spent the first year of her fellowship primarily developing a more capacious understanding of innovation policy in two law review articles. The first, *Innovation Law and Policy: Preserving the Future of Personalized Medicine*, 49 U.C. Davis L. Rev. __ (forthcoming 2016), presents a case study of the medical diagnostics industry, demonstrating the ways in which patent law, health law, and FDA regulation all interact, often synergistically, to affect incentives for innovation. During the year, Rachel presented this Article at the 2014 Intellectual Property Scholars Conference, the 2014 Boston University Law School Conference on Personalized Medicine and Intellectual Property, the 2014 University of New Hampshire Law School Intellectual Property Roundtable, and the 2015 Works-in-Progress Intellectual Property Colloquium.

Her second Article and job market paper, *Prizing Reimbursement: Prescription Drug Reimbursement as Innovation Incentive* (under submission), identifies in health law a solution to an innovation problem stemming from patent law. She explores a key practical case study of prescription drug reimbursement's potential by analyzing ways in which the Medicaid program in the United States



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could be altered to improve incentives for innovation into particular classes of pharmaceuticals. Specifically, Medicaid's complex system of mandatory drug rebates could be reframed as a prize system, which would reward companies who produce drugs primarily for Medicaid-eligible populations. Rachel has thus far had the opportunity to present *Prizing Reimbursement* at the Petrie-Flom Center's Health Law Workshop, the 2015 ASLME Health Law Professors' Conference, and the 2015 Intellectual Property Scholars Conference.

Rachel also co-authored a short Essay, *Ensuring the Safe and Effective FDA Regulation of Fecal Microbiota Transplantation*, just published in the peer-reviewed *Journal of Law and the Biosciences*, with the Director of Global Partnerships at a non-profit stool bank. Rachel has been invited to present the Essay to an NIH Working Group on the subject of microbiota transplantation this upcoming fall, as well as at the European Microbiome Congress in London.

Visitors

Although the Center does not actively 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 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.

In addition to **Benjamin Roin**, our former faculty co-director who transitioned to visitor when he moved to MIT in Fall 2014, we hosted three outstanding visitors this year:

Aziza Ahmed, February-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 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, Ahmed worked on the following papers:



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Trafficked?: Selling Sex in an Epidemic, UNIVERSITY OF MIAMI LAW REVIEW (2015)
(forthcoming)

Criminal Laws on Sex Work and HIV: A Mapping, DENVER UNIVERSITY LAW
REVIEW (2015) (forthcoming)

Medical Evidence and Expertise in Abortion Jurisprudence, 41 AMERICAN
JOURNAL OF LAW AND MEDICINE 84 (2015)

*Informed Decision Making on Abortion: Crisis Pregnancy Centers, Clinics, and
the First Amendment*, 43 JOURNAL OF LAW, MEDICINE, AND ETHICS 51 (2015)

*"Exploitation Creep" and Development: A Response to Janie Chuang and HIV,
Violence Against Women, and the Criminal Law Interventions*, CUNY LAW
REVIEW FOOTNOTES FORUM (2014)

Lydia Stewart Ferreira, July 2014-July 2015

Dr. Ferreira completed her doctorate at Osgoode Hall Law School in June 2014, and is publishing her doctoral research on quantitative legal analysis in two forthcoming journal articles. During her visit, she conducted empirical analysis of cross border health care in terms of delay accessing health care services and the role of physicians allocating health care resources. She is also undertaking quantitative legal research in biotechnology and genomics. Dr. Ferreira was recently appointed a deputy judge of the Superior Court of Justice in Ontario. In the spring, she was elected a member of the Board of Directors to the Ontario Deputy Judges Association.

Francis X. Shen, January-May 2015

During his visit, Dr. Shen explored topics at the intersection of neuroscience and law. His time at the Center allowed him to empirically study legal aspects of brain-based lie detection; neuroimaging and brain death; criminal mental states; the use of neuroscience in legislatures; the provision of mental health care to war veterans; and the influence of substance dualism in law's distinctions between mental and physical.

While a visiting scholar, he presented to the Neuroscience and Public Policy Program at the University of Wisconsin-Madison, as part of the Kavli



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Foundation Lecture series. He also presented research findings at the University of Chicago Public Law Workshop in June 2015.

Dr. Shen participated in a number of programs, both locally and nationally. At Harvard, he was a panelist at the April 2015 program *Does Brain-Based Lie Detection Belong in American Courtrooms?* and a participant in the June 2015 conference, *Visible Solutions: How Neuroimaging Helps Law Re-envision Pain*. Nationally, as Executive Director of Education and Outreach for the MacArthur Foundation Research Network on Law and Neuroscience, Dr. Shen traveled to North Dakota to introduce state judges to issues in law and neuroscience. He also participated in a San Francisco meeting of the Center for Responsible Brainwave Technologies, to discuss ethical and legal issues associated with wearable neuroscience technology. During this time, he also joined the National Courts and Science Institute, as a member of its Board of Scientific Advisors.

Dr. Shen is now extending the work he started at the Center, running new experiments on the topic of brain-based lie detection and further exploring the future directions of neuroscience and law. He continues to collaborate with the Center's Project on Law and Applied Neuroscience through his contributions to the forthcoming volume on pain, neuroscience, and the law.

Faculty Summer Research Support

The Center also contributes summer support for faculty research projects related to our areas of interest. In Summer 2014, we supported the following:

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

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

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

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

FDA IN THE TWENTY-FIRST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES (co-edited with Holly Fernandez Lynch) (Columbia University Press, forthcoming 2015)



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He also authored numerous medical and legal journal articles that he worked on during this period of summer funding.

Einer Elhauge, Petrie-Flom's founding faculty director, worked on several projects, including continued effort on a book on re-engineering human biology and an article on the Supreme Court's Medicaid expansion decision. His summer support also included a number of projects related to antitrust law and policy.

2014-15 Affiliate Scholarship

Petrie-Flom's Leadership, fellows, and other affiliates have once again enjoyed a prolific year, producing excellent scholarship in the areas of human subjects research, medical tourism, organ and blood donation, reproductive freedom and technology, health care reform, conscientious objection, intellectual property and innovation policy, and more. These publications (some of which remain pending) have generated academic conversation, invitations to events, inquiries from the press, and a great deal of positive attention to our Center.

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

I. Glenn Cohen & Holly Fernandez Lynch

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

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

FDA IN THE TWENTY-FIRST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES (co-edited) (Columbia University Press, forthcoming 2015)

NUDGING HEALTH: HEALTH LAW AND BEHAVIORAL ECONOMICS (co-edited, also with Christopher T. Robertson) (Johns Hopkins University Press, forthcoming 2016)

I. Glenn Cohen

Inbound Medical Tourism to Barbados: A Qualitative Examination of Local Lawyers' Prospective Legal and Regulatory Concerns 15 BMC HEALTH SERVICES



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RESEARCH 291 (July 2015) (co-authored with Valorie A. Crooks, Krystyna Adams, Rebecca Whitmore, and Jeffrey Morgan)

Navigating Physicians' Ethical and Legal Duties to Patients Seeking Unproven Interventions Abroad, 61 CANADIAN FAMILY PHYSICIAN 584 (2015) (co-authored with Jeremy Snyder, Krystyna Adams, Y.Y. Chen, Daniel Birch, Valorie A. Crooks, Judy Illes, and Amy Zarzeczny)

Medical Tourism for Services Illegal in Patients' Home Country, in HANDBOOK OF MEDICAL TOURISM AND PATIENT MOBILITY (Neil Hunt et al. eds, Edward Elgar Publishing, 2015)

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 (Bronwyn Parryet al. eds, Ashgate, 2015)

Medical Tourism, Access to Health Care, and Global Justice, 1 HEALTH LAW & HUMAN RIGHTS 1 (2015)

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

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

Las fronteras del Derecho sanitario: globalización y turismo médico, in LAS FRONTERAS DEL DERECHO BIO-SANITARIO, ANUARIO DE LA FACULTAD DE DERECHO DE LA UNIVERSIDAD AUTÓNOMA DE MADRID 21 (Pablo de Lora y Blanca Mendoza eds. 2014) (trans. Pablo de Lora)

This Is Your Brain on Human Rights: Moral Enhancement and Human Rights, 9 LAW AND ETHICS OF HUMAN RIGHTS 1 (2015)(peer-reviewed) (symposium, Human Rights and Human Minds)

Sperm and Egg Donor Anonymity: Legal and Ethical Issues, in OXFORD HANDBOOK OF REPRODUCTIVE ETHICS (Leslie Francis, ed., Oxford University Press, forthcoming 2015)

Are All Abortions Equal? Should There Be Exceptions to the Criminalization of Abortion for Rape and Incest?, 43 J. L. MED. & ETHICS 1 (2015)

"My Body, My Bank", 93 TEXAS L. REV. 953 (2015)



Complexifying Commodification, Consumption, ART, and Abortion, 43 J. L. MED. & ETHICS 2 (2015) (solicited commentary) (peer-reviewed) (2015)

Transatlantic Lessons in Regulation of Mitochondrial Replacement Therapy: Prospect of Disease-Free Children for Women Carriers through MRT, 348 SCIENCE 178 (2015) (co-authored with Julian Savulescu & Eli Y. Adashi) (peer-reviewed)

IDENTIFIED VERSUS STATISTICAL LIVES: AN INTERDISCIPLINARY PERSPECTIVE (Oxford University Press, 2015) (co-edited with Nir Eyal and Norman Daniels and contributing a chapter)

Hospital-Based Active Shooter Incidents: Sanctuary Under Fire, 313 JAMA 1209 (2015) (co-authored with Eli Y. Adashi and Hans Gao) (peer-reviewed)

Physicians, Medical Ethics, and Execution by Lethal Injection, 311 JAMA 2375 (2014) (co-authored with Robert Truog and Mark Rockoff) (peer-reviewed)

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

Reconsideration of the Lifetime Ban on Blood Donation by Men Who Have Sex With Men, 311 JAMA 337 (2014) (co-authored with Eli Adashi and Jeremy Feigenbaum) (peer-reviewed)

Regulating the Organ Market: Normative Foundations for Market Regulation, 77 LAW AND CONTEMP. PROB. 71 (2014) (symposium)

Organs Without Borders? Allocating Transplant Organs, Foreigners, and the Importance of the Nation State (?), 77 L. & CONTEMP. PROB. 175 (2014) (symposium)

Las recientes controversias sobre la tecnología reproductiva en los Estados Unidos, in DERECHO Y TECNOLOGIAS REPRODUCTIVAS FUNCACION COLOQUIO JURIDICO EUROPEO, MADRID 11 (2014) (trans. Pablo de Lora)

A Fuller Picture of Organ Markets, 14 AM. J. BIOETHICS 19 (2014)

FDA Regulation of Mobile Health Technologies 371 N. ENG. J. MED. 372 (2014) (co-authored with Nathan Cortez and Aaron Kesselheim) (peer-reviewed)



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Clinical Trials and the Right to Remain Silent (co-authored with Michelle Mello), 174 JAMA INTERNAL MEDICINE E1 (co-authored with Michelle Mello) (peer-reviewed) (solicited)

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)

Einer Elhauge (NB: The list below includes only scholarship related to health law policy, biotechnology, and bioethics.)

Resolving Reverse-Payment Settlements with the Smoking Gun of Stock Price Movements, 81 IOWA L. REV. _ (forthcoming 2016) (co-authored with Thomas G. McGuire, Keith Drake, Raymond S. Hartman, and Martha Starr)

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

Robust Exclusion and Market Division through Loyalty Discounts, HARVARD PUBLIC LAW WORKING PAPER NO. 14-12 (2015) (co-authored with Abe Wickelgren)

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

I'm Not Quite Dead Yet—And Other Health Care Observations, 49 TULSA L. REV. 607 (2014)

In addition, Professor Elhauge's paper, **The Scope of Antitrust Process**, 104 HARV. L. REV. 667, 672 (1991), was cited by Justice Kennedy's majority opinion in **North Carolina State Board of Dental Examiners v. Federal Trade Commission** (Feb. 25, 2015).

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)

Bosses in the Bedroom: Hobby Lobby, Religious Employers, and Moving Away from Employer-Sponsored Health Care (with Gregory Curfman), in LAW,



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RELIGION, AND HEALTH IN AMERICA (Holly Fernandez Lynch, I. Glenn Cohen, and Elizabeth Sepper eds., forthcoming, book proposal under review)

Matthew J. B. Lawrence

Procedural Triage, 84 FORDHAM L. REV. _ (forthcoming 2015)

Mandatory Process, 90 IND. L. J. (2015)

Rationing Process by Default: Solving Medicare's Backlog Problem, in NUDGING HEALTH: HEALTH LAW AND BEHAVIORAL ECONOMICS (I. Glenn Cohen, Holly Fernandez Lynch, and Christopher T. Robertson, eds.) (Johns Hopkins University Press, forthcoming 2016)

Rachel E. Sachs

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

Ensuring the Safe and Effective FDA Regulation of Fecal Microbiota Transplantation, J. L. & BIOSCIENCES (2015) (co-authored with Carolyn A. Edelstein) (peer reviewed)

The New Model of Interest Group Representation in Patent Law, 16 YALE J. L. & TECH. 344 (2014)

Francis X. Shen

Red States, Blue States, and Brain States: Issue Framing, Partisanship, and the Future of Neurolaw in the United States, 658 ANNALS AM. ACAD. POL. & SOC. SCI. 86 (2015)(with Dena B. Gromet)

* Dr. Shen's work was cited in The Presidential Commission for the Study of Bioethical Issues' Report, Gray Matters: Topics at the Intersection of Neuroscience, Ethics, and Society (Vol. 2)



2014-15 Affiliate Commentary

Our affiliates are 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 ban on blood donations by gay men, human subjects research, medical error, and more. Center affiliates also authored editorial pieces and gave extended interviews, and several are also regular bloggers at Petrie-Flom's collaborative blog, [Bill of Health](#), as well as other high-profile blogs, including Health Affairs. These contributions to the media, lay press, and more informal online outlets help advance the Center's goal of reaching beyond academic circles on critical policy issues.

A full list of our extensive media commentary can be found [here](#), covering the gamut of leading press outlets, including ABC News, 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, Newsmax, FactCheck.org, PolitiFact.com, Science, Vox, and more. Selected highlights in which Center affiliates authored commentary or were extensively interviewed are featured below:

I. Glenn Cohen & Holly Fernandez Lynch

Podcast, ***More than Meets the IRB: On Human Subjects Research and Regulation***, Washington Univ. School of Medicine in St. Louis, May 2015

Podcast, ***Science for the People: Research, Regulation, and Ethics***, July 2015

I. Glenn Cohen

New Blood-Donor Policy, Same Gay Stigma, NY TIMES (May 21, 2015) (editorial co-authored with Eli Y. Adashi)

Executions, Doctors, The U.S. Supreme Court, And The Breath Of Kings, HEALTH AFFAIRS BLOG (March 26, 2015)

Traveling patients, traveling disease: Ebola is just the tip of the iceberg, OUPBLOG (December 14, 2014)

An Interview with I. Glenn Cohen on Controversial Health Issues, PBS (September 9, 2014) (Tavis Smiley interviewing I. Glenn Cohen)

Big Data: The Conversation Continues (podcast), HEALTH AFFAIRS CONVERSATIONS (August 8, 2014) (Discussion between David Bates and I. Glenn Cohen)



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

Holly Fernandez Lynch

What Does Indiana's Religious Freedom Law Mean for Health Care?, HEALTH AFFAIRS BLOG (April 21, 2015)

After Hobby Lobby, ACA Exceptions May Become the Rule, interview with REUTERS HEALTH REFORM WATCH (July 11, 2014)

Matthew J. B. Lawrence

Exploring The Significant State-To-State Variation In Marketplace Enrollment, HEALTH AFFAIRS BLOG (April 29, 2015)

Rachel E. Sachs

The ACA Survives—But With a Note of Caution for the Future?, HEALTH AFFAIRS BLOG (June 30, 2015)

Happy About the Supreme Court's ACA Decision? Thank a Law Professor, THE CONVERSATION (June 26, 2015)

How Law Professors Helped the Supreme Court Understand the Affordable Care Act, THE CONVERSATION (June 16, 2015)

The Complex Effects of the FDA's Proposal to Regulate Laboratory-Developed Tests, HEALTH AFFAIRS BLOG (April 10, 2015)

FDA Proposal for Regulating Laboratory Diagnostics Could Improve Patient Care, THE HASTINGS CENTER BIOETHICS FORUM (September 4, 2014)

Francis X. Shen

Neuroscience is coming to the law. Can we keep politics out of it?, THE WASHINGTON POST (February 25, 2015)



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When Science and Politics Collide, online webinar featuring Dr. Shen and Dan Kahan (Yale Law) sponsored by SAGE Social Science Space and the American Academy of Political and Social Science (May 14, 2015)



Public Events Programming and Conferences

As has become the norm, the Petrie-Flom Center hosted a number of fantastic events this year, from major conferences to smaller panel discussions, some independently and some in collaboration with our colleagues from Harvard and elsewhere. In developing our substantive event agenda, we strive to plan events that are timely, interdisciplinary, and offer exposure to a variety of leading experts, from academics to policymakers to practitioners.

We continue to draw large audiences to these events from around Harvard's campus and beyond, with our average attendance increasing this year, 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.

Below is a list of our events from the past year, including hyperlinks for additional information regarding topics and speakers for each:

Major Events/Conferences

Post-Trial Responsibilities: Ethics and Implementation

Cosponsored with the Multi-Regional Clinical Trials Center at Harvard University, with support from the Oswald DeN. Cammann Fund
September 18, 2014

Emerging Issues and New Frontiers for FDA Regulation

Cosponsored with the Food and Drug Law Institute
October 20, 2014

- Held in Washington, D.C.

Clinical Trial Recruitment: Problems, Misconceptions, and Possible Solutions

Cosponsored with the Brocher Foundation and Harvard Catalyst
January 19-21, 2015

- Closed-door workshop held in Geneva, Switzerland



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Third Annual Health Law Year in P/Review

Sponsored with the New England Journal of Medicine; cosponsored by The Hastings Center, Health Affairs, the Center for Bioethics at Harvard Medical School, with additional support from the Oswald DeN. Cammann Fund

January 30, 2015

- Speakers at this event participated in a blog series run by the *Health Affairs Blog*. Contributions are available [here](#).

Re-envisioning Pain: How Breakthroughs on the Science of Suffering Could Revolutionize Legal Understanding and Outcomes

Part of the Project on Law and Applied Neuroscience

February 5, 2015

- Held at Massachusetts General Hospital

Families Matter: Ethically, Legally, and Clinically

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

March 18-20, 2015

- Held at Harvard Medical School

King v. Burwell and the Future of the Affordable Care Act

Supported by the Oswald DeN. Cammann Fund

April 1, 2015

- This event was organized by Petrie-Flom Academic Fellows **Matthew J. B. Lawrence** and **Rachel E. Sachs**. Speakers participated in a blog series run by the *Health Affairs Blog*. Contributions are available [here](#).

After Hobby Lobby: What Is Caesar's, What Is God's?

Cosponsored with the Ambassador John L. Loeb, Jr. Initiative on Religious Freedom and Its Implications at Harvard's Center for American Political Studies

May 7, 2015

2015 Annual Conference: Law, Religion, and Health in America

Supported by the Oswald DeN. Cammann Fund

May 8-9, 2015

Visible Solutions: How Neuroimaging Helps Law Re-envision Pain

Part of the Project on Law and Applied Neuroscience. Cosponsored with the Center for Bioethics at Harvard Medical School and the Mind Brain Behavior Interfaculty Initiative at Harvard University, with support from the Oswald DeN. Cammann Fund

June 29-30, 2015



Lectures, Panels, and Other Events

A Conversation with the HHS Office of the Inspector General

September 30, 2014

Legal and Ethical Issues in Healthcare Start-Ups

Cosponsored with the Harvard Innovation Lab, with support from the Oswald DeN. Cammann Fund

October 6, 2014

Petrie-Flom Center Annual Open House

October 6, 2014

A Conversation with Former Attorney General and Governor of Wisconsin Jim Doyle

Cosponsored with the Center for Health Law Policy and Innovation

October 15, 2014

Book Launch: Human Subjects Research Regulation: Perspectives on the Future

Cosponsored with the Harvard Law School Library

October 22, 2014

Global Reproduction: Health, Law, and Human Rights in Surrogacy and Egg Donation

Cosponsored with Our Bodies, Ourselves and the South Asia Institute at Harvard University, with support by the Oswald DeN. Cammann Fund

November 5, 2014

- Including a screening of the documentary *Can We See the Baby Bump, Please?*

Law and Ethics of Non-Invasive Prenatal Testing

Supported by the Oswald DeN. Cammann Fund

November 6, 2014

Book Launch: Patients with Passports: Medical Tourism, Law, and Ethics

Cosponsored with the Harvard Law School Library

November 19, 2014

Panel Discussion and Book Signing at the 2014 PRIM&R Advancing Ethical Research Conference: Human Subjects Research Regulation: Perspectives on the Future

December 5, 2014

- With a Petrie-Flom Center reception at the conference that evening



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Outbreak: Developing New Medical Products for Epidemics, A lecture by Peter Barton Hutt

January 15, 2015

A "Natural" Experiment: Consumer Confusion and Food Claims, a lecture by Efthimios Parasidis

January 29, 2015

A Right to Health? A lecture by John Tasioulas

Cosponsored with the Human Rights Program at Harvard Law School

February 5, 2015

A Dialogue on Agency, Responsibility, and the Brain with Stephen Morse

Part of the Project on Law and Applied Neuroscience

February 12, 2015

Measles, Vaccines, and Protecting Public Health

Supported by the Oswald DeN. Cammann Fund

February 25, 2015

The Policeman at the Elbow: The Neuroscience of Addiction, Self-Control, and Criminal Responsibility

Part of the Project on Law and Applied Neuroscience

March 4, 2015

Gender (Re)assignment: Legal, Ethical, and Conceptual Issues

Cosponsored with the Human Rights Program and Lambda at Harvard Law School

March 9, 2015

Book Launch: Identified v. Statistical Lives: An Interdisciplinary Approach

Co-sponsored with the Harvard Law School Library, with support from the Harvard Global Health Institute

March 11, 2015

Moral Decisions in the Law: What's the Brain Got to Do with It?

Part of the Project on Law and Applied Neuroscience

April 8, 2015

FDA's Impact on Pharmaceutical Innovation: A lecture by Neil Flanzraich

April 14, 2015

Petrie-Flom Center/ Harvard Medical School Center for Bioethics Reception at ASLME 38th Annual Health Law Professors Conference

June 4, 2015



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:

Film Screening: Fed Up

Sponsored by The Food Law Lab at Harvard Law School, Harvard School of Public Health, Food Law Society, Harvard Law Documentary Studio, and the Food Law & Policy Clinic

October 22, 2014

First Annual HLS-UCLA Food Law and Policy Conference: Transparency in the Global Food System: How Much Information and to What Ends?

Cosponsored by the Resnick Program for Food Law and Policy at UCLA School of Law and The Food Law Lab at Harvard Law School

October 24 - 25, 2014

Harvard Food+ Research Symposium

Hosted by the Weatherhead Center for International Affairs. For a full list of sponsors, see the website.

February 27, 2015

Just Food?: Forum on Justice in the Food System

A collaboration of the Harvard Food Law Society and Food Literacy Project as a part of Food Better. For a full list of sponsors, see the website.

March 28 - 29, 2015

Does Brain Difference Affect Legal and Moral Responsibility?

Cosponsored by the Center for Bioethics at Harvard Medical School

March 30, 2015

Documentary Screening: Just Eat It: A Food Waste Story

Sponsored by the Harvard Food Law and Policy Clinic, the Harvard Food Law Lab, and the Harvard Food Law Society

April 13, 2015



Contributions to the HLS Teaching Program

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

Health Law Policy and Bioethics Workshop

I. Glenn Cohen and Einer Elhauge
Fall 2014 – Spring 2015

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 2014-2015 workshop welcomed scholars on the following topics:

- Anup Malani, Lee and Brena Freeman Professor, University of Chicago Law School and Professor, Pritzker School of Medicine: *The Insurance Value of Medical Innovation*
- Thomas G. McGuire, Professor of Health Economics, Department of Health Care Policy, Harvard Medical School: *Do "Reverse Payment" Settlements of Brand-Generic Patent Disputes in the Pharmaceutical Industry Constitute an Anticompetitive Pay for Delay?*
- Benjamin N. Roin, Assistant Professor of Technological Innovation, Entrepreneurship, and Strategic Management, MIT Sloan School of Management and Associate Member of the Broad Institute of MIT and Harvard: *Solving the Problem of New Uses by Creating Incentives for Private Industry to Repurpose Off-Patent Drugs*
- Matt Lamkin, Assistant Professor of Law, University of Tulsa College of Law: *Regulating Identity: Medical Regulation as Social Control*
- Leemore S. Dafny, Professor of Management and Strategy and Herman Smith Research Professor in Hospital and Health Services, Kellogg School of



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- Management, Northwestern University: *More Insurers Lower Premiums: Evidence from Initial Pricing in the Health Insurance Marketplaces*
- Amy Kapczynski, Associate Professor of Law, Yale Law School and Director, the Global Health Justice Partnership: *Order Without Intellectual Property Law: The Flu Network as a Case Study in Open Science*
 - Robert D. Truog, Professor of Medical Ethics, Anaesthesiology & Pediatrics, Harvard Medical School, Director, Harvard Medical School Center for Bioethics, and Senior Associate in Critical Care Medicine, Children's Hospital Boston: *Defining Death: Getting It Wrong for All the Right Reasons*
 - Nadia A. Sawicki, Associate Professor of Law, Loyola University Chicago School of Law: *Modernizing Informed Consent: Expanding the Boundaries of Materiality*
 - Liran Einav, Professor of Economics, Stanford: *The Response of Drug Expenditure to Non-Linear Contract Design: Evidence from Medicare Part D*
 - Thomas L. Greaney, Chester A. Myers Professor of Law and Co-Director of the Center for Health Law Studies, St. Louis University School of Law: *Medicare Advantage, Accountable Care Organizations, and Traditional Medicare: Synchronization or Collision?*
 - Rachel E. Sachs, Academic Fellow, Petrie-Flom Center: *Rethinking the Incentives/Access Dichotomy: Prescription Drug Reimbursement as Innovation Incentive*

Lawyers, Doctors, Ethics, and Professionalism

I. Glenn Cohen and Rebecca Brendel (HMS)
Reading Group, Spring 2015

This reading group met for 6 two-hour blocks in the Spring semester, half of the time at HLS and half at HMS. It cross-enrolled students from both schools to explore the ways in which professional responsibility and ethical issues common to law and medicine are handled by the two professions. Topics covered 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.

Law and Medicine: The Affordable Care Act

Matthew J.B. Lawrence
Seminar, Spring 2015

This seminar, offered by our Academic Fellow Matthew J.B. Lawrence, considered 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



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challenges have slowed or permanently limited the Act's success in meeting those goals. Units and topics included the following:

- 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

Nancy Gertner (with support from Amanda Pustilnik)
Seminar, Spring 2015

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



Participation of HLS Students in Program Activities

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

Student Fellowship Program

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

Under the substantial guidance of Petrie-Flom affiliates, student fellows conduct independent research projects designed to lead to publishable articles, and are expected to produce at least one such paper by the end of the academic year. They are also expected to attend Center events and are required to enroll in the Health Law Policy 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.

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

The Center's 2014-2015 student fellows and projects were as follows:

Christine Baugh

Harvard University, PhD Candidate in Health Policy, Concentrating in Ethics

Paper: "Trust, Conflicts of Interest, and Concussion Reporting in College Football Players"

Kelsey Berry

Harvard University, PhD Candidate in Health Policy, Concentrating in Ethics



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Paper: "Rights and Duties against Conditional Funding Agreements in Global Aid" (not yet complete)

Emily Largent

Harvard Law School, JD 2016; Harvard University, PhD Candidate in Health Policy

Paper: "NOTA: No Good for Tissues"

* 2014-2015 Peter Barton Hutt Student Fellow

Zachary Shapiro

Harvard Law School, JD 2016

Paper: "fMRI, Neuroimaging, and Criminal Jurisprudence: A Case for Neuro-Realism"

Vadim Shteyler

Harvard Medical School, MD 2016

Paper: "Transgender Health: The True Eligibility Criteria for Transition-Related Medical Interventions" (not yet complete)

Lauren Taylor

Harvard Divinity School, MDiv 2015

Paper: "Re-conceptualizing the Religious Exemption from Childhood Vaccinations in the United States"

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.

During FY15 we have shifted our internship program toward employing paid interns who assist with various Center projects while gaining experience with the work of the Center. Intern projects included:

- Advertising and preparing materials for Petrie-Flom events;
- Drafting the biweekly newsletter;
- Updating the Affiliate News, Affiliate Scholarship, and Opportunities sections of the website as needed;
- Updating the Health Law News section of the website biweekly;
- Developing Harvard health law/bioethics curriculum lists for website and uploading of data to website;
- Collecting and formatting material for drafts of Center reports;
- Research projects as assigned.



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In addition to hiring Harvard students this year, we added two high school students hired through the Cambridge Housing Authority's WorkForce program. Our 2014-2015 interns were:

- Virginie Chan, Fall 2014, FAS '15
- Jose Lopez, Summer 2014, Cambridge Rindge and Latin '14 (CHA WorkForce)
- Alicia Morency, Spring 2015, Cambridge Rindge and Latin '18 (CHA WorkForce)
- Audrey Zhang, Summer-Fall 2014, FAS '14

Research Assistants

Petrie-Flom affiliates routinely work directly with Harvard graduate students as Research Assistants (RAs) on particular projects. We have engaged RAs to help research competitive works, develop book proposals, and edit 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.

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

Football Players Health Study:

- Thomas Blackmon, HLS 2016
- Laura Escalona, HLS 2016
- Louis Fisher, HLS 2016
- Elizabeth Guo, HLS 2016
- Elisa Hevia, HLS 2017
- Gabrielle Hodgson, HLS 2015
- Jason Joffe, HLS 2016
- Jose Lamarque, HLS 2017
- Jodie Liu, HLS 2015
- Sheila Meagher (Boston College Law School 2016)
- Jennifer Mindrum, HLS 2017
- Lauren Taylor, HDS 2015
- Russell Spivak, HLS 2017
- Scott Sherman, HLS 2017
- Valerie Wood, HLS 2017
- Additional students who participated via the Sports Law Clinic at HLS:
 - Daniel Ain, HLS 2015
 - Jay Cohen, HLS 2015



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- Nicholas Hidalgo, HLS 2016
- Jamie Smith-George, HLS 2015
- Samuel Stuckey, HLS 2015 (also FPHS RA)

Harvard Catalyst:

- Evelyn Chang, HLS 2015
- Emily Largent, HLS/FAS 2016
- Jaime McFarlin, HLS 2015
- Jessica Goodman, HLS 2017
- Alexandra Guest (Vanderbilt Law School 2012)
- Dorothy Hector, HLS 2017
- Sara Schaumburg, HLS 2016
- Russell Spivak, HLS 2017

Project on Law and Applied Neuroscience:

- Matthew Barno, HLS 2015

Specimen Science (book proposal):

- Victoria Hartmann, HLS 2017

Law, Religion, and Health in America (book proposal):

- Amal El Bakhar, HLS 2016

Nudging Health (edited volume):

- Evelyn Blacklock, HLS 2016
- Thomas Blackmon, HLS 2016
- Noah Marks, HLS 2016

FDA in the Twenty-First Century (edited volume):

- Thomas Blackmon, HLS 2016
- Louis Fisher, HLS 2016

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 “Notes and Developments”



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section, comprised of brief summaries and commentary on recent legislation, regulation, and case law written by graduate students at the collaborating schools. Petrie-Flom is responsible for providing the “Notes and Developments” for one issue per volume. This year’s student contributors were:

Christine Baugh, GSAS, and Zachary Shapiro, HLS 2016

Concussions and Youth Football: Using a Public Health Law Framework to Head Off a Potential Public Health Crisis

Nicholas J. Lennings, HLS LLM 2015

Forward, Gillick: Are competent children autonomous medical decision makers? New Developments in Australia

Ian V. McGonigle, GSAS 2019, and Lauren W. Herman, HLS/HDS 2014

Genetic Citizenship: DNA Testing and the Israeli Law of Return



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 Faculty Director **I. Glenn Cohen** and Founding Director **Einer Elhauge**, **Jacob Gerson** has pushed forward the work of his Food Law Lab under the Petrie-Flom Center's umbrella; **Peter Carfagna**, Lecturer on Law, has been active in coordinating student work on the Football Players Health Study through his Sports Law Clinic; **Barbara Bierer**, faculty at HMS, leads our collaboration with Harvard Catalyst; and **Judith G. Edersheim**, faculty at HMS, has been essential in launching our collaborative Program on Law and Applied Neuroscience.

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

- **Peter Barton Hutt**, HLS
- **Noa Ben-Asher**, HLS
- **Barbara Bierer**, HMS
- **Joshua Buckholtz**, FAS
- **Dan Carpenter**, HKS
- **Amitabh Chandra**, HKS
- **Gregory Curfman**, HMS
- **Fiery Cushman**, HMS
- **Norman Daniels**, HSPH
- **Alicia Ely Yamin**, HSPH
- **Nir Eyal**, HMS
- **Charles Fried**, HLS
- **Nancy Gertner**, HLS
- **Ashish Jha**, HSPH
- **Aaron S. Kesselheim**, HMS
- **Diane L. Moore**, HDS
- **Gerald L. Neuman**, HLS
- **Ahmed Ragab**, HDS
- **Millie Solomon**, HMS
- **Robert D. Truog**, HMS
- **Dyann Wirth**, HSPH

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

Several faculty members are also involved with our blog, **Bill of Health**:



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- Amitabh Chandra, HKS
- Dan Carpenter, HKS
- Gregory Curfman, HMS
- Nir Eyal, HMS
- Aaron S. Kesselheim, HMS

Beginning 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 2014-2015 academic year below:

- **Judith G. Edersheim**, JD, MD, Co-Founder and Co-Director of the Center for Law, Brain and Behavior, MGH; Assistant Clinical Professor of Psychiatry, HMS; and attending Psychiatrist in the Department of Psychiatry, MGH
- **W. Nicholson Price II**, JD, PhD, Assistant Professor of Law, University of New Hampshire School of Law; Petrie-Flom Academic Fellow, 2013 – 2015
- **Benjamin N. Roin**, JD, Assistant Professor of Technological Innovation, Entrepreneurship, and Strategic Management at the MIT Sloan School of Management (former Petrie-Flom Center faculty co-director)
- **Ameet Sarpatwari**, JD, PhD, Assistant Professor, HMS and Brigham and Women's Hospital
- **David Silbersweig**, MD, Chairman, Department of Psychiatry and Co-Director for Institute for the Neurosciences, Brigham and Women's Hospital; Harvard Medical School Dean for Academic Programs at Partners HealthCare; Stanley Cobb Professor of Psychiatry, HMS

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



Connections to the Community and Professions

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

In addition, our affiliates are regularly sought after to provide media commentary on news stories in our fields, to serve as expert witnesses and legal consultants, and perform other types of public service. For example, this year, Executive Director **Holly Fernandez Lynch** was appointed to government service as a member of the Secretary's Advisory Committee on Human Research Protections (SACHRP), U.S. Department of Health and Human Services. Academic Fellow **Rachel Sachs** has begun collaborating with non-profit industry groups and with scientists in her work on the microbiome, recently publishing a paper on the FDA regulation of fecal transplantation with the Director of Global Partnerships at a non-profit stool bank. She has been invited to present this paper to an NIH working group on the subject, as well as to the European Microbiome Congress.

Every year the Center also endeavors to undertake more directed efforts to reach beyond the walls of academia. These efforts, described below, create opportunities not only to disseminate scholarship to influence policy, but also to inform Center affiliates' own scholarship.

Sponsored and Other Research

The Center's sponsored research projects described above have clear policy implications for the broader community. Our work on the Football Players Health Study endeavors to develop practical recommendations to improve the health and welfare of professional athletes. Through our work with Harvard Catalyst, we are directly engaging with researchers, institutional policymakers, industry leaders, patients, and others to advance clinical and translational research through improved recruitment to clinical trials. We also regularly give lectures to junior investigators on the foundations of clinical research regulation and ethics. Our work on Specimen Science will help pave the way forward for medical advancement via biospecimen research, and our Project on Law and Applied Neuroscience is actively devoted to bringing together the professions of law and neuroscience so that each discipline can inform the other. Finally, the Journal of Law and Biosciences is an open-access online journal freely available to anyone with an interest in its contents, providing an important resource to both professional and lay communities.



Website and Social Media

Since the launch of the Center's redesigned website in September 2013, we have continued to develop and expand the site and its presence on various social media platforms to offer users easy access to a wide array of information about the Center's events, research, affiliate scholarship, fellowships, and other activities, as well as more general information about news, opportunities, and resources in the Center's major research areas at the intersection of health law and policy, biotechnology, and bioethics. The overarching goal is to make the Petrie-Flom Center's website a central resource for anyone looking to learn more about our fields of interest – from academics to students to journalists to interested members of the community.

Our **front page** continues to highlight a rotating slider of key announcements from the Center, alongside a running list of our most recent blog posts from **Bill of Health**. We feature our upcoming events, as well as recent news and scholarship from our affiliates. In keeping with our ongoing efforts to draw the health law and bioethics communities to our site, we now post selected health policy news headlines from major outlets twice a week.

In our **Events** section, we have revised the format to present a clean overview of past and upcoming events and to offer users a simpler interface to access video of past events. Most recently, we have adapted our presentation of videos so that users can link not just to an individual event or conference panel session, but to individual speakers.

Another key area of online growth is the **Opportunities** section. Here, 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. Over the last year, as people around Harvard and in the wider health law and bioethics communities have become aware of this resource, we have fielded increasing numbers of requests to share opportunities on our website. This is a critical resource for students and others interested in pursuing careers in these fields.

With increased staff, we have been able to dedicate more time to cultivating our social media presence, primarily on Facebook and Twitter, which we use to increase awareness of the Center and also to drive traffic to the website, the blog, and our event videos. The results have been impressive (all numbers compare April 2015 to April 2014 unless otherwise noted):

Website:

- Nearly 4,200 unique users in April 2015, up 38% over April 2014



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- Nearly 13,200 pageviews in the same period, up 30%
- Visitors from over 100 countries

Vimeo (video hosting site):

- Average weekly views in April 2015: 411, up 356% over the same period last year
- Particularly noteworthy: During the weeks of May 11 – week of June 1, when we were heavily advertising our newly available annual conference event video, we had average weekly views of 1,575, up nearly 2,000% over the same period last year

Twitter:

- Followers increased to 875 in July 2015, more than doubling in the last year
- Impressions (user views) up to nearly 96,000 in April 2015, compared to 650 in April 2014

Facebook:

- Followers up by 94%
- Total followers reached (daily) up 21%

These numbers demonstrate that we are successfully reaching the broader community through the various resources we have made available.

We also circulate an electronic newsletter every other week with information about upcoming events, recent blog posts, affiliate news and commentary, opportunities at Petrie-Flom and elsewhere, and other information relevant to our community. We currently have nearly 4,000 subscribers to our list serve.

Bill of Health

Bill of Health, our collaborative blog on health law policy, biotechnology, and bioethics co-edited by **I. Glenn Cohen** and **Holly Fernandez Lynch**, continues to be a resounding success. We have bloggers from all over Harvard, as well as the leading health law scholars at universities around the country and internationally. The site is incredibly active, with new bloggers joining us regularly, 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.



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We continue to actively developing new bloggers, including Harvard students involved with the Journal of Law and Biosciences and the Harvard Health Law Society, and have begun hosting blog series based on selected Petrie-Flom events.

The blog is hugely popular. Since it launched in 2012, it has seen nearly 350,000 unique visitors from more than 200 countries. In the last year, as we have improved the blog's visibility by sharing on our website and social network platforms, we saw significant growth:

Bill of Health (April 2015 vs. April 2014):

- Nearly 18,000 unique monthly users, up 30% in one year
- Over 27,000 pageviews, up 25%

Events with Industry Participation

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

- **Post-Trial Responsibilities: Ethics and Implementation** (with the Multi-Regional Clinical Trials Center at Harvard). This one-day conference explored 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 were examined.
- **Legal and Ethical Issues in Health Care Start Ups**. This event featured 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.) This event featured several academic presentations, with moderators from leading law firms with pharmaceutical company clients. It was co-sponsored by the Food and Drug Law Institute, a non-profit organization that serves as a network for pharmaceutical industry counsel.
- **Research Ethics Book Group Lunch and Meet the Authors: *Human Subjects Research Regulation: Perspectives on the Future*** (with PRIM&R). This event was held at the annual conference of the major educational organization catering to human research protection professionals, with attendance by members of academic and for-profit Institutional Review Boards.



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- **Clinical Trial Recruitment: Problems, Misconceptions, and Possible Solutions** (with the Brocher Foundation and Harvard Catalyst). This closed-door workshop included a variety of participants, including industry leaders, as well as investigators, patient advocates, international policymakers, and academics.
- **Third Annual Health Law Year in P/Review** (with the New England Journal of Medicine, The Hastings Center, and the Center for Bioethics at Harvard Medical School). This year's event included a number of academic presentations, as well a discussion of CVS/Pharmacy's decision to no longer sell tobacco products by **Andrew J. Sussman, M.D.**, CVS/minuteclinic and CVS Health, and key life science intellectual property cases of 2014 by **Claire Laporte**, Foley Hoag.
- **FDA's Impact on Pharmaceutical Innovation**, with Neil Flanzraich, Executive Chairman and CEO of Cantex Pharmaceuticals, Inc. Mr. Flanzraich previously served as the Executive Chairman of Kirax Corporation, the Executive Chairman of ParinGenix, Inc., and the Vice Chairman and President of Ivax Corporation, an international pharmaceutical company.



Collaborations

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

This year, our major collaborative efforts included:

- Our blog, Bill of Health;
- Sponsored research projects primarily housed at Harvard Medical School: the Football Players Health Study at Harvard University and Harvard Catalyst, including collaboration with The Hastings Center, the Brocher Foundation, several of Harvard's affiliated hospitals, the HLS Sports Law Clinic, and various consultants;
- Work with Case Western Reserve University (PI: Suzanne Rivera) on the Specimen Science book project and public conference;
- A sponsored research proposal with Mt. Sinai School of Medicine;
- Our Project on Law and Applied Neuroscience with the Center for Law, Brain, and Behavior at Massachusetts General Hospital;
- Support of Professor Gersen's Food Law Lab;
- Work with the Multi-Regional Clinical Trials Center at Harvard, including cosponsored events and membership on the MRCT Center's ethics working group;
- Work on the Journal of Law and Biosciences with colleagues at Duke and Stanford
- 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;
- Collaboration with the Harvard Medical School's Center for Bioethics on events, conferences, and their Master's program in bioethics.

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

- American Health Lawyers' Association School Alliance
- American Society of Law, Medicine, and Ethics
- The Broad Institute of MIT and Harvard
- The Brocher Foundation
- The Center for Law, Brain, and Behavior at Massachusetts General Hospital
- The Food and Drug Law Institute
- Harvard Catalyst



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- Harvard Center for American Political Studies (Ambassador John L. Loeb, Jr. Initiative on Religious Freedom and Its Implications)
- Harvard Global Health Institute
- Harvard i-Lab
- The Hastings Center
- Health Affairs
- HHS Office of the Inspector General
- HLS Center for Health Law Policy and Innovation
- HLS Dean's Office
- HLS Food Law Lab
- HLS Food Law Society
- HLS Human Rights Program
- HLS Lambda
- HLS Library
- HMS Center for Bioethics
- Multi-Regional Clinical Trials Center at Harvard
- The New England Journal of Medicine
- Our Bodies, Ourselves
- Public Responsibility in Medicine & Research (PRIM&R)



2015 – 16 Plans for Activities

(Fiscal Year 2016: July 2015 – June 2016)

After three years of expansion and rapid growth beginning with Holly Fernandez Lynch's tenure as Executive Director, the Petrie-Flom Center is precisely where we hoped to be at this stage. We have cemented the Center's place as a national leader in the realm of health law policy, biotechnology, and bioethics scholarship, and have also developed recognition and leadership among policymakers, industry leaders, students interested in pursuing careers in our fields, and the lay public.

During the next fiscal year, we plan to continue our priority efforts related to sponsored research, public events and conferences, independent scholarship, opportunities for students, and communications (website and blog). Given our current capacity and commitments, we will be very selective about pursuing new opportunities and projects. We will also slightly downsize, with only one academic fellow (rather than our usual two), and with a full-time project coordinator, rather than our prior two part-time positions. Because academic fellows play an important mentoring role to our student fellows, we will likely accept fewer students into that program this year to ensure that each fellow receives adequate attention.

Research, Scholarship, and Project Activities

Sponsored Research

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

The Football Players Health Study will continue on its current trajectory, with its current staffing. We expect to publish our first reports and recommendations in spring and summer 2016, and also to host public events related to our work.

We will be submitting our book proposal on SPECIMEN SCIENCE to publishers in late summer 2015, and will host the accompanying conference on November 16, 2015. The remainder of the year will be spent putting together the book manuscript with our various contributors, for likely submission in summer 2016.

The project that will change most substantially is our work with Harvard Catalyst. This year, the Center's collaboration will continue to be co-led by **I. Glenn Cohen** and **Holly Fernandez Lynch**, but due to a reorganization and funding changes, we



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will no longer have a Senior Law and Ethics Associate or Project Coordinator. Instead, in August 2015, we will be joined by **Luke Gelin**, the first Petrie-Flom Center/Harvard Catalyst Fellow in Clinical Research Ethics. Our work will continue to focus on improving recruitment to and retention in clinical trials, through the development of guidance documents, conceptual analysis, and empirical research. **Emily Largent** will continue on the project as Research Associate.

We also have a new sponsored research project that will begin in September 2015, “**Research Ethics in Patient-Centered Outcomes Research.**” This grant is funded by the Patient-Centered Outcomes Research Institute (PCORI), and is led by Joel Weissman at Brigham and Women’s Hospital. Its primary aims are to: (1) describe the human subject-related challenges posed by Patient-Centered Outcomes Research (PCOR) and Comparative Effectiveness Research (CER) and learn how, if at all, Institutional Review Boards (IRBs) in major research institutions are responding to those challenges; and (2) develop guidelines and recommendations for IRBs, investigators, and patient advisors to employ when designing or reviewing human subjects research aspects of PCOR and CER. **I. Glenn Cohen** and **Holly Fernandez Lynch** will serve as Co-Investigators on the project, and **Emily Largent** will serve as Research Associate, sharing project direction responsibilities with staff at the Brigham. We will also be hiring at least one HLS student research assistant to contribute to the work. The Petrie-Flom Center will advise on the composition of study protocols for empirical research with IRBs, take the lead on drafting a white paper with recommendations and guidelines, and host a public symposium. The project is slated to last for three years.

Finally, there are several possible grants that we are considering applying for or collaborating on this year. These include resubmission for NIH funding of our project with Rosamond Rhodes on “Barriers to Research on Controlled Drugs for HIV-Related Treatment,” as well as new proposals to collaborate on an application to the Robert Wood Johnson Foundation New Clinical Scholars Program and applications related to the role of “Physicians of Confidence” in the Muslim faith. Of course, none of these projects are confirmed, and our involvement will depend on capacity, progress, and Center goals.

The Program on Law and Applied Neuroscience

Our collaboration with Massachusetts General Hospital’s Center for Law, Brain, and Behavior will continue this year, for the second year of the Project on Law and Applied Neuroscience. The Project will again include expert symposia and public events, as well as a Law and Neuroscience seminar taught by the **Hon. Nancy Gertner**, HLS Professor of Practice as well as a CLBB faculty member and Petrie-Flom affiliated faculty.



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We will also be joined by a new Senior Fellow in Law and Neuroscience, **Robert Kinscherff**, PhD, JD. Given Dr. Kinscherff's expertise, the project will focus on juvenile justice, law, and neuroscience this year.

Dr. Kinscherff is a forensic and clinical psychologist and an attorney who has been on the faculty at William James College since 1999, where he is Associate Vice President for Community Engagement with oversight of key service-providing programs. He is also Teaching Faculty in the Doctoral Clinical Psychology Program and for the Doctoral School Psychology Program. Dr. Kinscherff is Faculty at the Center for Law, Brain and Behavior at Massachusetts General Hospital and Senior Associate for the National Center for Mental Health and Juvenile Justice. He is a member of the Massachusetts Governor's Juvenile Justice Advisory Committee and the Special Commission on Sexual Offender Recidivism. Dr. Kinscherff has previously served as Assistant Commissioner for Forensic Mental Health (MA Department of Mental Health), Director of Juvenile Court Clinic Services (MA Trial Court), and Director of Adult Forensic Services (Psychiatry and Law Program, MGH). For over a decade, he taught classes at the intersection of law and psychology at Boston University Law School. For the American Psychological Association, he is a current member of the Board of Professional Affairs, and has served as Chair of the APA Gun Violence Policy Review Task Force, a past two-term Chair of the Ethics Committee (EC), Chair of the Committee on Legal Issues (COLI) and Member of the Committee on Professional Practices and Standards (COPPS). His research and professional practice areas include ethical and professional practice issues in clinical and forensic mental health practice, violence risk assessment and management, juvenile homicide, aggressive and sexually problematic behaviors among youth and adults with developmental or mental disorders, and severe and unusual forms of child maltreatment. His many publications include the co-authored book *APA ETHICS CODE: COMMENTARY AND CASE ILLUSTRATIONS* (Washington, DC: American Psychological Association Press, 2009) and more recent publications on topics including mental health practice in juvenile justice contexts, special ethical and practice considerations in work with offenders, and international human rights law implications for forensic psychologists of the 2012 US Supreme Court case of *Miller v. Alabama* regarding mandatory life imprisonment without possibility of parole for offenses committed as a juvenile.

Other Projects

Our work on the Journal of Law and Biosciences will continue this year, which will be the Journal's third volume. The Center will continue to collate student contributions for the section on "Notes and New Developments."

We will also continue our collaboration with Professor Gersen's Food Law Lab.



Academic Fellows

Rachel E. Sachs will continue her fellowship in 2015-2016, her second year at the Center. This fall, she will be going on the entry-level teaching market, aiming to secure a law faculty position. She also plans to continue her research, focusing on projects involving coordination between administrative agencies and on the innovation policies surrounding emerging technologies. Next spring, she will teach a seminar at HLS, Innovation in Medical Technologies: Law and Policy.

For a variety of reasons – most notably the decreased demand for entry-level law professor hiring due to the decrease in law school applications across the U.S., but also budgeting – we have not accepted a new academic fellow to join the Center this year, nor are we actively soliciting applications. An unfortunate consequence of this approach is that it limits the Center’s ability to mentor students, and eliminates an HLS seminar related to our areas of focus, as Petrie-Flom Center Academic Fellows traditionally work closely with student fellows and offer seminars related to their work. Going forward, we are reconsidering our plans for the academic fellowship program and considering possible alternatives, including development of a policy or senior fellowship. We will also revisit the program if we can secure a new funding source.

Faculty

In the summer of 2015, the Center once again provided research support to **Prof. Cohen** and **Elhauge**.

I. Glenn Cohen is working on the following projects:

- Editing the books **NUDGING HEALTH: HEALTH LAW AND BEHAVIORAL ECONOMICS** (with Holly Fernandez Lynch and Christopher T. Robertson) and **THE OXFORD HANDBOOK OF AMERICAN HEALTH LAW** (with Bill Sage and Allison Hoffman)
- Several medical journal articles pertaining to the personhood movement and abortion regulation, In Vitro Gamatogenesis, and Mitochondrial Replacement Therapy
- Several law review articles and book chapters relating to sperm donor anonymity, travel abroad to access assisted suicide, and a number of other projects

He has also used his summer to film multiple segments of an online course to be offered by **HarvardX** on reproductive technology, genetics, law, and ethics. This will be one of the first of five HLS-led courses to be offered on this platform, and the first on law, medicine, and ethics.



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

- Finalizing ***Contrived Threats v. Uncontrived Warnings***, 83 U. CHICAGO L. REV. (forthcoming 2016), which covers the Medicaid Expansion decision and the recent King v. Burwell case
- Continued work on a book tentatively titled "A Little Lower Than God: Redesigning Humans – What Limits?"

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. All visits are of limited duration.

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.

So far, we have accepted the following visitors for the coming year:

Zhao Peng

September 2015 – August 2016

Zhao Peng is Associate Professor at the China University of Political Science & Law. He has published extensively on issues in food law including GMOs, environmental safety, risk assessment, and food safety in China. As a visitor at the Petrie-Flom Center, he will pursue work on regulating the risk of new technologies.

Mary Anne Bobinski

August – September 2015; February – March 2016

Mary Anne Bobinski has been at the Allard School of Law at the University of British Columbia since 2003 and served as Dean from 2003 to 2015. She previously served as the John and Rebecca Moores Professor of Law and Director of the Health Law and Policy Institute at the University of Houston Law



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Center in the United States. Professor Bobinski's research and teaching interests include torts, health law, health care finance and bioethics, legal aspects of HIV infection, and reproductive health law issues. She is a co-author of two leading law school casebooks in the United States, *Health Care Law & Ethics* and *AIDS Policy and Law*; the co-author/co-editor of a two volume set on medical ethics; and has authored a number of law review articles and book chapters on health law topics. Professor Bobinski has participated extensively in academic and professional service activities, and recently completed service as the President of the American Society of Law, Medicine and Ethics and as a member of the Canadian Public Health Officer's Ethics Advisory Committee. She is a frequent presenter to academic and other groups in the U.S. and Canada on topics ranging from health care finance to public health care law and ethics. During her visit, Professor Bobinski will work on U.S. health care issues and broadening the comparative base of her research covering the U.S. and Canada.

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 Fall 2015, Columbia University Press will release the volume from our 2013 conference: **FDA IN THE TWENTY-FIRST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES** (co-edited by Holly Fernandez Lynch and I. Glenn Cohen). The book's description is provided below, and a table of contents is available [here](#).

In its decades-long effort to assure the safety, efficacy, and security of medicines and other products, the Food and Drug Administration has struggled with issues of funding, proper associations with industry, and the balance between consumer choice and consumer protection. Today, these challenges are compounded by the pressures of globalization, the introduction of novel technologies, and fast-evolving threats to public health. With essays by leading scholars and government and private industry experts, *FDA in the Twenty-First Century* addresses perennial and new problems and the improvements the agency can make to better serve the public good.

The collection features essays on effective regulation in an era of globalization, consumer empowerment, and comparative effectiveness, as well as questions of data transparency, conflicts of interest, industry responsibility, and innovation policy, all with an emphasis on pharmaceuticals. The book also intervenes in the



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debate over off-label drug marketing and the proper role of the FDA before and after a drug goes on the market. Dealing honestly and thoroughly with the FDA's successes and failures, contributors rethink the structure, function, and future of the agency and the effect policy innovations may have on regulatory institutions in other countries.

Earlier this summer, we submitted the manuscript for **NUDGING HEALTH: HEALTH LAW AND BEHAVIORAL ECONOMICS** (co-edited by I. Glenn Cohen, Holly Fernandez Lynch, and Christopher T. Robertson) to Johns Hopkins University Press, where it is under contract. This book stems from our 2014 annual conference on behavioral economics, law, and health policy, and should be released in Fall 2016. We will be working with the Press to finalize the manuscript this year.

We have also recently submitted a book proposal stemming from our 2015 annual conference on **Law, Religion, and Health in America**, and we expect to do the same with a book proposal on **Specimen Science: Ethics and Policy Implications**, as described above, shortly. Given prior experience, we expect these volumes to be released in 2017, with the work this year focused on curating and editing chapters from our conference participants.



Events Programming and Conferences

Over the 2015-2016 academic year – our tenth! – the Center will continue to host and co-sponsor a variety of exciting public events dealing with issues at the intersection of health law policy, biotechnology, and bioethics. The following are confirmed to date:

September 28 – From Troubled Teens to Tsarnaev: Promises and Perils of Adolescent Neuroscience (part of the Project on Law and Applied Neuroscience)

September 28 – 2015 Petrie-Flom Center Annual Open House

September 30 – Non-Human Primates in Research: Legal and Ethical Considerations (with the Animal Law Program at HLS)

October 8 – Synthetic Biology: Science, Policy, and Ethics

October 15 – Is Professional Football Safe? Could We Make It Safer? Perspectives from Neuroscience, Law, and Ethics (part of the International Neuroethics Society Annual Meeting)

October 20 – Law and Moral Enhancement: A Lecture by Julian Savulescu (part of a series of events cosponsored by the Center for Bioethics at HMS and Edmond J. Safra Center for Ethics at Harvard University)

October 23 – Second Annual HLS-UCLA Food Law and Policy Conference: Drugs, Animals, and Food: Law & Policy of Antibiotics in the Food System (sponsored by the Food Law Lab at Harvard Law School and the UCLA School of Law Resnick Program for Food Law and Policy, with support from the Harvard Food Law and Policy Clinic and the Animal Law Program at Harvard Law School)

October 26 – Project on Law and Applied Neuroscience event

October 28 – Book Launch: FDA in the 21st Century (cosponsored by the Harvard Law School Library)

November 4 – Reflections in Honor of the Life and Influence of Professor Alan Wertheimer

November 13 – Lecture by Dr. Laurence Steinberg (part of the Project on Law and Applied Neuroscience)



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November 13 - Petrie-Flom Reception at 2015 PRIM&R Annual Conference
(cosponsored by the Center for Bioethics at HMS)

November 16 - Specimen Science: Ethics and Policy Implications (This event is a collaboration between The Center for Child Health and Policy at Case Western Reserve University and University Hospitals Rainbow Babies & Children's Hospital; the Petrie-Flom Center at Harvard Law School; the Multi-Regional Clinical Trials Center at Harvard; and Harvard Catalyst | The Harvard Clinical and Translational Science Center. It is supported by funding from the National Human Genome Research Institute.)

January 29 - Fourth Annual Health Law Year in P/Review

February 10 - Project on Law and Applied Neuroscience event

February 23 or 24 - Lecture by Visiting Scholar Mary Anne Bobinski

March 29 - Petrie-Flom Center 10th Anniversary Celebration

April 5 - The National Security Implications of the Genetics Revolution
(cosponsored by the Harvard National Security Journal and the Harvard National Security and Law Association)

April 13 - Project on Law and Applied Neuroscience event

May 6 - 7 - Annual Petrie-Flom Conference: Big Data, Health Law, and Bioethics

June 2 - Petrie-Flom Center pre-conference session, American Society of Law, Medicine & Ethics annual conference (cohosted by the Boston University School of Law)

We will also working to organize a range of other public events, including a lecture by former FDA Commissioner Margaret Hamburg and a symposium related to our work on the Football Player Health Study at Harvard University.



Contributions to HLS Teaching Program

Petrie-Flom affiliates will continue to make substantial contributions to the HLS health law curriculum this year, through workshops and seminars. In addition to the courses below, affiliates will guest lecture on an ad hoc basis around the University. For example, Football Players Health Study Senior Associate **Christopher Deubert** will participate in sessions of Peter Carfagna's Sports Law Clinic, and **Holly Fernandez Lynch** will co-teach a course in the new HMS Master of Bioethics program on Health Law, Policy, and Bioethics, as well as offer a variety of lectures related to research ethics and regulation as part of Harvard Catalyst.

Professor Cohen will launch his **HarvardX** course on reproductive technology, genetics, law, and ethics in Spring 2016.

Health Law Policy, Biotechnology, and Bioethics Workshop

Fall 2015 and Spring 2016

This year's workshop will be taught by **I. Glenn Cohen**. Confirmed presenters include:

- **Robert Cook-Deegan**, Research Professor in the Sanford School of Public Policy, Duke
- **Michael Frakes**, Associate Professor of Law, Northwestern Law
- **Adam Kolber**, Professor of Law, Brooklyn Law School
- **Jaime S. King**, Professor of Law, UC Hastings College of the Law and Associate Director of the UCSF/UC Hastings Consortium on Science, Law and Health Policy
- **Michelle Mello**, Professor of Law and Professor of Health Research and Policy, Stanford Law School and School of Medicine
- **Amanda C. Pustilnik**, Professor of Law, University of Maryland Carey School of Law
- **Jessica L. Roberts**, Associate Professor of Law and Director, Health Law & Policy Institute, The University of Houston Law Center
- **Julian Savulescu**, Professor and Director, Oxford Uehiro Centre for Practical Ethics
- **Seema Shah**, faculty member, Clinical Center Department of Bioethics and Division of AIDS, National Institutes of Health
- **Nicolas Terry**, Hall Render Professor of Law and Executive Director of the William S. and Christine S. Hall Center for Law and Health, Robert H. McKinney School of Law, Indiana University



Innovation in Medical Technologies: Law and Policy

Spring 2016

This seminar will be offered by **Rachel E. Sachs**, Academic Fellow. The course will consider the ways in which different areas of law contribute to the broader innovation ecosystem in the context of healthcare technologies such as drugs and medical devices, examining the relationships between legal doctrines and innovation incentives. Beginning with a focus on intellectual property law, the classic locus of innovation incentives, the course will then take a broader view that includes not only lesser-known incentive levers but also their interactions and the roles of the institutional actors that administer them.

Likely units and topics include:

1. Overview of the innovation process in the context of healthcare technologies, particularly for drugs, medical devices, and diagnostic tests
2. Types of innovation levers:
 - Intellectual property law (patent law and trade secrecy)
 - Grant-based funding from the NIH for basic research
 - Regulatory exclusivity periods from the FDA
 - Prize systems implemented by various actors
 - Exploration of lesser-studied levers (such as insurance reimbursement and tax credits)
3. Intersystemic analyses of innovation levers:
 - Consideration of the interactions between the various levers in practice
 - Examination of the negative spaces left behind by each lever, and the ways in which they can be combined into complementary units
 - Analysis of the institutional actors involved in each system
 - Potential policy solutions and interventions
4. Case study: developing an ideal innovation solution for certain types of neglected diseases

Law and Neuroscience

Spring 2016

This seminar, taught by **Nancy Gertner** with the support of **Robert Kinscherff**, will be offered as part of the Project on Law and Applied Neuroscience. It will be largely similar to the course offered in 2015.



Participation of HLS Students in Program Activities

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

Student Fellows

This year, we will welcome a new crop of Student Fellows who will pursue independent research under the supervision of Center faculty and fellows, regularly contribute to our blog, and enroll in the Health Law Policy and Bioethics Workshop. For the first time, we have decided to delay the deadline for applications to August (rather than May) in order to offer students in one-year programs the opportunity to apply and participate in the fellowship. We expect to accept up to four fellows this year, to ensure that each has sufficient mentorship in light of consolidated Center staffing.

Research Assistants

We will continue to work with graduate student research assistants on our many sponsored research projects, as well as to support the work of our Academic Fellow, 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 “Notes and Developments” section for one issue of the annual JLB volume. Contributions will be written by Harvard graduate students, who will be selected in September 2015.

Collaboration with Harvard Health Law Society

We have been in discussions with the student leadership of the Harvard Health Law Society about a variety of possible collaborations. To date, we plan to pursue the following:

- Work with HHLS to identify 2-4 regular graduate student bloggers for Bill of Health
- Co-organize public events



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- Develop a dedicated section of the Petrie-Flom Center’s bi-weekly newsletter FOR HHLS announcements
- Work with HHLS to develop substantive resources on health law policy, biotechnology, and bioethics for the Petrie-Flom Center website

Student Interns

The shift to a program of paid interns succeeded in improving the consistency of student engagement over time. This year we will continue to work with a smaller number of paid interns, both Harvard undergraduates and graduate students, who will contribute to a variety of Center projects (see [Internship Program](#) section above for details). Interns are encouraged but not required to attend Center events.



New Initiatives and Collaborations

As indicated above, the Petrie-Flom Center has been steadily expanding for the past three years. We are now focused on stabilization and successful execution of our current portfolio of projects. 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 on their new Masters program in Bioethics, launching in 2015. Eventually, the Petrie-Flom Center will help develop a Health Law and Policy track for Master's students, including particular course selections, directed mentoring, and practicum opportunities.

Other possible projects include a HarvardX course for legislative staffers working in health policy and new sponsored research projects, as described above. We would also like to pursue dissemination of our event recordings as podcasts, in addition to streaming videos.