



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

*Fiscal Year 2013
Annual Report*
October 4, 2013

Executive Summary

Once again, we have had a great year at the Petrie-Flom Center, continuing several of our successful programs, and initiating a variety of new projects and collaborations.

As in the past, we hosted a full schedule of events relating to pressing issues in health law policy, biotechnology, and bioethics, including health care reform, the NIH public access policy, advances in HIV prevention, legal responses to human rights violations in clinical research, stem cell therapy and medical tourism, definitions of personhood, personalized medicine patenting, and informed consent in managed care settings, as well as career events for students and a celebration in honor of our colleague, Peter Barton Hutt. Our annual spring conference brought together leading academics, practitioners, and policymakers concerned with the plight of the Food and Drug Administration in the 21st Century, and we also hosted conferences, workshops, and meetings on institutional financial conflicts of interest, key developments in health law, life sciences industry compliance, evidence-based policymaking, and clinical trial data sharing. As has become tradition with our annual conferences, we are nearing completion of the edited volume from our 2012 conference on the future of human subjects regulation, to be published by MIT Press, and are in the process of seeking a publisher for a volume stemming from this year's conference on the FDA.

The Health Law Policy and Bioethics Workshop continues to provide a forum for premier scholars from a variety of disciplines to present and develop new scholarship in the field, while exposing students to cutting-edge ideas and leading academics from around the country. Further, Petrie-Flom affiliates continue to contribute to the HLS health law curriculum through seminars and reading groups for students interested in the field.

Students also have the opportunity to engage more directly with the Center through our graduate student fellowship program, which offers substantial mentorship in the development of publishable scholarship, as well as our newly launched student internship program. The Center's 2012-2013 student fellows tackled topics as varied as biotechnology patents, clinical research, cyber-attacks on medical devices, health worker brain drain, and research misconduct, and enjoyed success placing their articles in law journals. Our interns helped us develop several new resources for students, including compilations of related programs around Harvard and new substantive materials for our website.

Petrie-Flom faculty and Academic Fellows continue to proliferate leading scholarship and commentary, placing their work in prestigious law reviews (*Journal of Empirical Legal Studies*, *Journal of Legal Analysis*, *Administrative Law Review*, *Minnesota Law Review*, *Cornell Law Review*, *UCLA Law Review*, *Fordham Law Review*,

Boston College Law Review, Yale Journal of Health Policy, Law, and Ethics, Journal of Law, Medicine, and Ethics); top medical, bioethics, public health, and science journals (*American Journal of Bioethics, New England Journal of Medicine, British Medical Journal, Journal of the American Medical Association, Science, Hastings Center Report, Reproductive Biomedicine, Ethical Perspectives*); and leading presses (Oxford University Press, MIT Press). They were also called on by nearly every major media outlet to offer their perspective on policy issues and news items, and did so through a host of interviews and Op-Eds. Their published work in the past year covered topics including human subjects research, biotechnology patents and intellectual property, reproductive technology, medical tourism, the globalization of health care, rationing and resource allocation, medical training, health care reform, stem cell research, conscientious objection, discrimination in health care, genetics, incidental research findings, evidence-based policymaking, pharmaceutical manufacturing, and anonymity.

Ongoing faculty projects include work on medical tourism, organ markets, human subjects research, resource allocation, incentivizing pharmaceutical innovation, health care reform, and the FDA. Meanwhile, the Center's Academic Fellows are currently working on projects related to health insurance disputes, anonymity, biotechnology and surveillance/identification, intellectual property incentives, and personalized medicine. Two of our fellows will be on the entry-level law teaching market this fall.

In addition to these stable activities, the Center undertook a variety of new initiatives in the past academic year. We launched a new collaborative blog, Bill of Health, which has had nearly 85,000 unique hits since going live in September 2012 and is enjoying success as a destination for discussion of issues related to health law policy, biotechnology and bioethics. We also began the process of launching a new peer-reviewed, open access journal with Duke and Stanford Law Schools, *Journal of Law and Biosciences*, which will have some student contributions in the form of "new developments" and is set to launch in the next several months. And we worked with collaborators at Harvard Medical School to pursue two new sponsored research projects that should begin shortly and will allow for expansion of the Center and its policy work: a Clinical and Translational Science Award from the National Institutes of Health to reduce barriers to engagement and conduct of clinical and translational research, and a contract with the National Football League Players' Association to advance the health and welfare of professional football players. We may also pursue additional grant funding as opportunities arise.

Our Faculty Co-Director, I. Glenn Cohen, received tenure effective July 2013 and is now a full professor of law at HLS. We look forward to his continued leadership as we maintain our current programs, further implement these new initiatives, and work to build the Center and its influence through a variety of additional projects. For example, in the coming year, we plan to cultivate a group of affiliated faculty around Harvard doing work in our areas of focus (full list below), welcome additional scholarly visitors to the Center, launch a brand new website that will

endeavor to become a leading resource in the field, and embark on several new collaborations related to state-level health policy, food and drug law, and neuroscience.

This report describes the past year's accomplishments in greater detail, and briefly outlines plans for next year's programming and potential areas of expansion.

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2012-13 Report of Activities

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 not an advocacy organization, but rather is dedicated to the unbiased scholarly analysis of pressing questions facing health policymakers.

The Center is currently led by faculty co-directors Professors [I. Glenn Cohen](#) and [Benjamin Roin](#), with additional support from executive director [Holly Fernandez Lynch](#). Each year, we host Academic Fellows who are preparing to enter the law school teaching market, as well as several Harvard graduate student fellows who are pursuing independent scholarly projects. For the first time in 2012, we launched a student internship program open to Harvard undergraduates and graduate students.

The Center organizes several events each year, ranging from individual speakers and panel discussions to academic workshops and major conferences. Our 2012 annual conference focused on the future of human subjects research regulation (proceedings will be released as an edited volume by MIT Press in 2014), and this year's conference addressed the Food and Drug Administration in the 21st Century. The Center has also hosted recent events on institutional financial conflicts of interest, compliance issues facing the life sciences industry, key cases in the realm of health law, personalized medicine patents, definitions of personhood, stem cell therapy and medical tourism, advances in HIV prevention, research ethics, open access to health research, and of course, the Affordable Care Act.

The Center has recently entered a phase of expansion in which we will be pursuing a variety of Center-based research projects, in addition to the high-quality individual academic work already done by our faculty and fellows. These projects will involve substantial collaboration with our colleagues at the Schools of Medicine, Public Health, Government, and elsewhere, and will include grant-funded research, collaboration with policymakers, and the launch of a new peer-reviewed academic journal focused on law and the biosciences.

We also host a collaborative blog – [Bill of Health](#) – offering expert commentary on the range of issues falling under the umbrella of health policy and bioethics.

Research, Scholarship, and Project Activities

Since its founding as a research program at HLS, the Petrie-Flom Center and its affiliates have developed a strong reputation for the production of leading scholarship at the forefront of health law policy, biotechnology, and bioethics. This year was no exception; our affiliates – including faculty, fellows, and visitors – continued to publish top-rate scholarship and serve as commentators in the national media. We also took several steps in new directions, including our first foray into sponsored research and development of a new peer-reviewed journal.

Sponsored Research

Beginning this year, the Center has taken steps toward involvement in a variety of sponsored research projects that will take advantage of the law and ethics expertise our affiliates have to offer, and also provide the opportunity to expand the Center through new staff that will be devoted entirely to these initiatives.

Harvard Integrated Program to Protect and Improve the Health of Professional Football Players

In Summer 2012, the Petrie-Flom Center was approached by the leadership of Harvard Catalyst to seek our involvement in responding to a Request for Proposals issued by the National Football League Players' Association (NFLPA). The Association was interested in funding scientific exploration of new and innovative ways to protect, treat, and improve the health of NFL players, and its call for applications listed medical ethics as a specific area of interest.

In January 2013, it was announced that the NFLPA planned to award the Harvard team \$100M for a 10-year research initiative; the Association made the announcement publicly at the 2013 Super Bowl. The Petrie-Flom Center's involvement in this project will focus on law and ethics, and will be led by Professor **I. Glenn Cohen** and **Holly Fernandez Lynch**.

We look forward to collaborating with a variety of interested and expert parties around Harvard and elsewhere when this project ultimately launches. Additional information is available [here](#) and [here](#).

Harvard Catalyst Clinical and Translational Science Award

In 2012, the Harvard Catalyst team also approached the Petrie-Flom Center for involvement in its proposal for a second [Clinical and Translational Science](#)

[Award](#) from the National Center for Advancing Translational Sciences at the National Institutes of Health. With its first award, spanning 2008-2013, the Harvard Catalyst developed an academic home, resources and services, and workforce development for the Harvard community of clinical and translational researchers. Among a variety of other efforts, it launched the “Regulatory Knowledge and Support Program” to foster institutional dialogue and develop and implement innovative approaches to facilitate regulatory compliance, efficient protocol approval, and engagement and protection of human research subjects.

In this new proposal, to span 2013-2018, the Petrie-Flom Center would be added to the existing (but renamed) Regulatory Foundations component, in order to launch a novel Ethics and Law component led by Professor **I. Glenn Cohen**, with additional support from **Holly Fernandez Lynch**. Together, the goal is to continue work to reduce barriers to engagement and conduct of clinical and translational research across all domains by forging local cross-institution teams and national collaborations that will identify opportunities to reduce regulatory burdens and address ethical challenges.

We anticipate additional information on this initiative to be available in Fall 2013.

Journal of Law and Biosciences

In January 2013, in collaboration with colleagues at Duke and Stanford Law Schools, Prof. **I. Glenn Cohen** and the Petrie-Flom Center submitted a proposal to Oxford University Press to publish a new peer-reviewed journal called the **Journal of Law and Biosciences**. Oxford offered a publishing contract in May 2013, which is currently in the process of finalization and should be signed shortly. Upon launch, **Prof. Cohen** will serve as co-Editor-in-Chief, alongside Nita Farahany (Duke) and Hank Greeley (Stanford); Petrie-Flom Center Executive Director **Holly Fernandez Lynch** will oversee the involvement of Harvard students.

The journal will be the first truly peer-reviewed, interdisciplinary academic legal journal focused exclusively on the intersection of law and advances in the biosciences. We plan to publish both original, mid-length articles and shorter response pieces, as well as “new development” pieces written by graduate students at each of the sponsoring schools, offering brief summaries of and commentary on recent legislation, regulation, and case law relevant to the biosciences in order to provide a resource to readers looking to stay up-to-date in the field. The journal will be Open Access, and in most cases, articles will be published immediately online once they have completed the editorial process.

More specifically, we seek to develop a conversation among lawyers, bioscientists, and other disciplines (e.g., philosophy, sociology, history, etc.) regarding cutting-edge developments in the biosciences, their implications for the law, and the law's implications for them, as well as persistent, unresolved problems or issues at the intersection of law and the biosciences. The journal will welcome theoretical, empirical, comparative, and/or international scholarship. Additionally, with topical input from the editorial board (comprised of leading academics from the US and abroad), we plan to publish a group of symposium articles each year.

With regard to scope, our plan is to cover the whole range of issues where law and the biosciences come together. For example:

- Behavioral genetics and neuroscience in criminal law
- Reproductive technology and family law
- Genetic and genomic testing, diagnosis, and results return
- Intellectual property in the biosciences
- The conduct and regulation of clinical research
- Bioscience funding and policy
- Food and drug law
- Human enhancement
- Regulation of stem cell research and practice
- Fetal development and abortion policy
- Science and public health
- Synthetic biology
- Chimeras
- Biobanks
- Bioterrorism/biological warfare
- Science of addiction

We hope to launch the journal in Fall/Winter 2013.

Faculty Leadership

The Petrie-Flom Center continues to be ably led by our dedicated faculty co-directors, **I. Glenn Cohen** and **Benjamin Roin**, top scholars in their respective fields of bioethics and intellectual property law. In addition, we enjoy the continued support and guidance of our founding faculty director, Professor **Einer Elhauge**.

Tenure Announcement/Awards

We are pleased to announce that our faculty co-director **I. Glenn Cohen** has been promoted from assistant professor to tenured professor of law, effective July 1, 2013, in recognition of his excellent scholarship, teaching, and commitment to the law school. During his time at HLS, Professor Cohen has taught courses in bioethics,

health law, and civil procedure. His current projects relate to reproduction and reproductive technology; comparing the way law and medicine deal with similar ethical issues facing the professions; and medical tourism – the travel of patients who are residents of one country, the "home country," to another country, the "destination country," for medical treatment. His past work has included projects on end-of-life decision-making, FDA regulation, research ethics and commodification.

“Having been a student, fellow, and assistant professor at HLS, I am incredibly grateful for the opportunities the school has given me and the mentorship and support from the Dean and my colleagues,” Professor Cohen said. “Harvard remains one of (if not the) key hubs for doing work on health care and bioethics, so I am incredibly excited to continue to mentor students, connect with colleagues, and launch new projects at the law school and across the university.”

Professor Cohen was also selected by the Radcliffe Institute for Advanced Study at Harvard University to be a [Radcliffe Institute Fellow](#) for the 2012-2013 year, with a focus on medical tourism. In addition, in September 2012, he was selected by the Greenwall Foundation to receive a [Faculty Scholar Award in Bioethics](#). The award allows recipients to conduct extensive independent research to help set public policy and standards of clinical practice.

2012 Faculty Summer Research Support

In the summer of 2012, the Center supported several faculty research projects. Funding this research promotes one of the central goals of the Petrie-Flom Center, which is to encourage experts in health law policy, biotechnology, and bioethics to develop and promote creative solutions to persistent and new problems arising in these fields.

During the summer, **I. Glenn Cohen** continued work on several major research projects. On the reproductive technology front, he completed a co-authored empirical paper, *Can you Buy Sperm Donor Identification? An Experiment*, 10 J. EMPIRICAL LEG. STUDIES __ (co-authored with Travis Coan) (forthcoming Dec. 2013), on whether people can be induced into donating sperm non-anonymously through increased compensation. Professor Cohen also published *Burying Best Interests of the Resulting Child: A Response to Professors Crawford, Alvaré, and Mutcherson*, 97 MINN. L. REV. HEADNOTES 1 (2012), which was a response to comments on his earlier paper made by Bridget J. Crawford, *Authentic Reproductive Regulation*, 96 MINN. L. REV. HEADNOTES 31 (2012), Helen M. Alvaré, *A Response to Professor I. Glenn Cohen’s Regulating Reproduction: The Problem with Best Interests*, 96 MINN. L. REV. HEADNOTES 8 (2012), and Kimberly M. Mutcherson, *In Defense of Future Children: A Response to Cohen’s Beyond Best Interests*, 96 MINN. L. REV. HEADNOTES 46 (2012).

In terms of medical tourism and the globalization of health care, Professor Cohen began work on a paper on transplant tourism, which was published this year as *Transplant Tourism: The Ethics and Regulation of International Markets for Organs*, 41 J. L. MED. & ETHICS 269 (2013) (peer-reviewed) (solicited), as well as a book, PATIENTS WITH PASSPORTS: MEDICAL TOURISM, LAW, AND ETHICS (under contract Oxford University Press). He also completed final edits on his edited volume, THE GLOBALIZATION OF HEALTH CARE: LEGAL AND ETHICAL CHALLENGES (Oxford University Press 2013) (editor, and contributing introduction and chapter).

Professor Cohen began a new project on comparative professional responsibility between medicine and law, with a paper on *Rationing Legal Services*, 5 J. L. ANALYSIS 221 (2013). In addition, he worked on several health policy papers, including *The Taxing Power and the Public's Health*, 367 NEW ENG. J. MED. 1777 (2012) (peer-reviewed) (co-authored with Michelle Mello) and *Conscientious Objection, Coercion, the Affordable Care Act, and U.S. States*, 19 ETHICAL PERSPECTIVES 163 (2013) (peer-reviewed) (solicited).

Finally, Professor Cohen began work on two new edited volumes that are now underway: THE FUTURE OF HUMAN SUBJECTS RESEARCH REGULATION (under contract MIT Press) (co-editor with Holly Fernandez Lynch), and IDENTIFIED V. STATISTICAL LIVES: ETHICAL, LEGAL, AND MEDICAL PERSPECTIVES (under contract Oxford University Press) (co-editor with Nir Eyal and Norman Daniels).

During his summer funded period, **Benjamin Roin** wrote a paper entitled *The Case for Tailoring Patent Awards based on Time-to-Market*, which is forthcoming in the UCLA LAW REVIEW, Volume 61. This paper argues that we should tailor patent awards (including duration) based on the amount of time it takes to develop inventions. The paper focuses on pharmaceuticals, medical devices, diagnostics, software, and semiconductors.

Finally, **Einer Elhauge** used his summer funding to work on an e-book, OBAMACARE ON TRIAL, which compiled his commentary on the constitutional challenges to the Affordable Care Act and offered some additional analysis. He also completed a co-authored paper with Alex Krueger on “reverse payment” patent settlements and antitrust law, *Solving the Patent Settlement Puzzle*, 91 TEX. L. REV. 283 (2012), and worked on two papers with Abraham L. Wickelgren on loyalty discounts, *Robust Exclusion through Loyalty Discounts with Buyer Commitment*, and *Anticompetitive Market Division through Loyalty Discounts without Buyer Commitment*. In addition, Professor Elhauge completed a chapter, “Introduction and Overview to Current Issues in Antitrust Economics,” for the RESEARCH HANDBOOK ON THE ECONOMICS OF ANTITRUST LAW (Edward Elgar Publishing Ltd. 2012).

Academic Fellows

Our Academic Fellowship is a full-time postdoctoral program specifically designed to identify, cultivate, and promote promising scholars early in their careers who are committed to pursuing publishable research that is likely to make a significant contribution to the field of health law policy, medical innovation policy, or bioethics. Prior fellows have found employment as tenure-track law professors at institutions such as Harvard, UC Berkeley, BU, UCLA, Cornell, the University of Illinois, and the University of Arizona.

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.

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

The work of our fellows from the past academic year is summarized below.

Michelle N. Meyer, 2010-2013

In addition to several publications listed below and in progress focused on human subjects research regulation and ethics, Michelle has been working on two ongoing empirical projects:

- Effects on Public Health of Legal Variables in Vaccine Mandates and Medical, Religious, and Philosophical Exemptions (collaborative empirical research in progress; epidemiological data collection complete, currently concluding legal data collection)
- Defining and Measuring IRB Quality (collaborative normative and empirical project in planning stages with colleagues at the Petrie-Flom Center and Harvard Medical School)

In the past year, she organized a major workshop and an online symposium:

- [“Legal Experimentation: Legal and Ethical Challenges to Evidence-Based Practice in Law, Medicine, and Policymaking”](#) (organizer of workshop held at Harvard Law School on March 1, 2013; book proposal in progress)
- Organizer and contributor, [Online Symposium: The Law, Ethics, and Science of Re-Identification Demonstrations](#), *Bill of Health Blog*, May 20-27, 2013

Michelle also gave several talks and lectures, and has another upcoming:

- Guest speaker on “Research Participation: Is There a Better Way?” in Prof. Misha Angrist’s class, Genome Sciences and Society, Duke University, March 27, 2013
- “The Ethics of IRB Risk-Benefit Analysis.” Harvard Medical School, Cambridge, MA, April 4, 2013
- “Defining and Measuring IRB Effectiveness.” Organizer, moderator, and panelist (with Christine Grady, Carl Coleman, and David Hyman), American Society of Law, Medicine, and Ethics (ASLME), Seton Hall Law School, Newark, NJ, June 6-8, 2013
- “Neither Duty Nor Prohibition: Using Private Ordering to Transcend ‘One-Size-Fits-All’ in Large-Scale Sequencing of Human Beings.” Panelist (with Ellen Wright Clayton, James Evans, and Misha Angrist) on panel, “Does the Increasingly Blurry Distinction Between Research and Clinical Care Create an Obligation to Actively Search for Secondary Findings in Genomic Research or Otherwise Change the Relationship Between Researchers and Participants?,” American Society of Human Genetics (ASHG) Annual Meeting, Boston, MA, Oct. 23, 2013

Finally, Michelle had a number of additional projects and responsibilities last year including co-teaching “Law and Bioethics” in the Union Graduate College-Icahn School of Medicine at Mt. Sinai Bioethics Program, serving as consultant to Union Graduate College-Icahn School of Medicine at Mt. Sinai Bioethics Program to design and seek New York State approval of curriculum for the Program’s new M.S. policy track, and continuing to serve on the Advisory Board of [Social Science Genetic Association Consortium \(SSGAC\)](#).

Michelle’s fellowship ended in June 2013, and as of this Fall, she is Assistant Professor and Director of the Policy Specialization in the Union Graduate College-Icahn School of Medicine at Mt. Sinai Bioethics Program, where she teaches Law and Bioethics, [Advanced Bioethics Policy: Philosophical, Economic, and Psychological Foundations](#), and a survey of contemporary policy issues in the biosciences. She is also Adjunct Faculty at Albany Law School (Fall 2013) and a Visiting Scholar at the [Institute for Advanced Study in Toulouse](#) (December 2013).

Jeffrey M. Skopek, 2011-2014

During his fellowship to date, Jeffrey has worked on two papers concerning the place of anonymity in our law, both of which start from the same conceptual move of differentiating anonymity from privacy.

In the first paper, *Anonymity, the Production of Goods, and Institutional Design* (forthcoming in the *Fordham Law Review*), he explores the ways in which anonymity is used to facilitate and control the production, rather than the seclusion, of public goods. He develops a taxonomic analysis of anonymity rules; proposes a theory of the functions that they serve; and demonstrates how this taxonomic and theoretical framework reveals innovative solutions to difficult problems in the production of specific political and biomedical goods.

In the second paper, *Anonymity, Secrecy, and Surveillance* (a work in progress), he argues that his analysis of the distinction between privacy and anonymity reveals a pervasive confusion in privacy law that has caused courts to mistakenly reject an important set of viable interests in the secrecy of personal information, including the Fourth Amendment interests that are implicated by new biotechnologies of surveillance and identification, such as biometric tracking and familial searching in DNA databanks.

W. Nicholson Price II, 2012-2014

Nicholson spent the first year of his fellowship exploring innovation and innovation policy in the understudied area of pharmaceutical manufacturing. His project, entitled *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, forthcoming in the *Boston College Law Review*, focuses on the significant problems that arise from the lack of innovation in manufacturing, including the economic costs of inefficiency, drug recalls and contamination events linked to drug quality, and drug shortages. The project considers the regulatory and intellectual property causes of this lack of innovation, and proposes several solutions, including both pure regulatory solutions and solutions which leverage regulatory change to alter intellectual property incentives. He has presented this work at Harvard and Seton Hall, as well as at the National Institute for Pharmaceutical Technology and Education's conference, *The Future of Pharmaceutical Manufacturing*, in June 2013, and at the Cardozo Intellectual Property Scholars Conference in August 2013.

In addition to this primary project, Nicholson's other work has revolved around genetic testing and gene patents. He has examined whole genome sequencing in the light of gene patents; legal implications of a potential ethical duty of researchers to search for genetic incidental findings; and informed consent for the return of genetic incidental findings, as part of a team including Wendy Chung and Paul Appelbaum at Columbia Medical School and Erik Parens at the Hastings Institute.

Visitors

Although the Center does not have an official program for visitors, nor do we solicit applications, it is a sign of our success and international influence that we receive a number of requests to visit with us each year. When a potential visitor has demonstrated academic success in our areas of interest, has a current project or projects that would benefit from collaboration with our affiliates, and has a perspective that may be of value to our students, fellows, and faculty, we have welcomed visitors to our Center through a variety of flexible arrangements.

This year, we hosted two outstanding visiting fellows at different stages of their careers:

Cansu Canca

Visiting Fellow, January 2012-December 2013

Cansu received her Ph.D. (2012) in philosophy from the National University of Singapore with a thesis on the ethics of buying and selling organs from the living. She earned her B.A. (2005) and M.A. (2007) in philosophy from Boğaziçi University (Istanbul). She was a visiting researcher at the Medical Ethics Department of Osaka University and at the [Program in Ethics and Health](#) at Harvard University, and an intern at the [World Health Organization](#).

During her visit at the Petrie-Flom Center, she has focused on two projects: a Kantian defense of a kidney market, and a fundamental critique of research ethics. Her first project is in its final stages, while the second is finding its form. While a visiting fellow, she was also involved in the [Fogarty International Research Ethics Initiative](#) in Turkey and Central Asia as project coordinator for Low and Middle Income Countries and as tutor to the fellows.

This summer, Cansu taught at the Philosophy Department at [Koc University](#).

Daniel Sperling

Short-Term Visiting Fellow, March 21-April 22, 2013

Daniel Sperling is a senior lecturer at the Federmann School of Public Policy and Government and Braun School of Public Health & Community Medicine, the Hebrew University of Jerusalem where he teaches courses on bioethics, public health law, and health policy. He holds an LL.B. and B.A. (Philosophy) from the Hebrew University of Jerusalem and LL.M. (Collaborative Programme in Bioethics) and S.J.D. from the University of Toronto. His current main research interests are reproductive ethics, organ transplantation, and issues involving equity and justice in the health system.

While visiting the Petrie-Flom Center, Daniel reviewed recent legal changes to the requirement of informed consent in the new era of privatization, managed care, and affordable care organizations (ACOs), and discussed their broader implications for bioethics. These changes refer to limiting the extent of physicians' duty to disclose information material to the patient's decision-making, including but not limited to physician financial interests, and subordinating the principle of informed consent to new factors such as the treatment setting, source of payment, financial incentives impinging on the physician, cost and time constraints, and the larger context of the healthcare system. His visit will result in several publications in this vein.

2012-13 Affiliate Scholarship

As has become the norm, our affiliates have once again enjoyed a prolific year, producing excellent theoretical and empirical scholarship in the areas of human subjects research, medical tourism, reproductive technology, conscientious objection, the doctor-patient relationship, anonymity, pharmaceutical innovation, and evidence-based practice. These publications (some of which remain pending) have generated academic conversation, invitations to events, inquiries from the press, and a great deal of positive attention to our Center.

I. Glenn Cohen & Holly Fernandez Lynch

THE FUTURE OF HUMAN SUBJECTS RESEARCH REGULATION
MIT Press (co-edited, forthcoming Spring 2014)

I. Glenn Cohen

[Can you Buy Sperm Donor Identification? An Experiment](#)

10 J. EMPIRICAL LEG. STUDIES _ (co-authored with Travis Coan) (forthcoming Dec. 2013)

[Of Modest Proposals and Non-Identity: A Comment on The Right to Know Your Genetic Parents](#)

13 AM. J. BIOETHICS 45 (2013) (peer reviewed)

[Made-to-Order Embryos for Sale - A Brave New World?](#)

368 N. ENGL. J. MED. 2517 (2013) (co-authored with Eli Adashi) (peer-reviewed)

[Burying Best Interests of the Resulting Child: A Response to Professors Crawford, Alvaré, and Mutcherson](#)

97 MINN. L. REV. HEADNOTES 1 (2012)

[**When Potential Does Not Matter: What Developments in Cellular Biology Tell Us About the Concept of Legal Personhood**](#)

13 AM. J. BIOETHICS 38 (2013) (co-authored with Jonathan Will and Eli Adashi) (peer reviewed)

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

[**THE GLOBALIZATION OF HEALTH CARE: LEGAL AND ETHICAL CHALLENGES**](#)

(Oxford University Press 2013) (editor, and author of introduction and chapter)

[**Circumvention Tourism**](#)

97 CORNELL L. REV. 1309 (2012)

[**Transplant Tourism: The Ethics and Regulation of International Markets for Organs**](#)

41 J. L. MED. & ETHICS 269 (2013) (peer-reviewed) (solicited)

[**S.H. and Others v. Austria and Circumvention Tourism**](#)

REPRODUCTIVE BIOMEDICINE ONLINE (2012) (solicited) (peer reviewed)

[**Ethical and Legal Implications of the Risks of Medical Tourism for Patients: A Qualitative Study of Canadian Health and Safety Representatives' Perspectives**](#)

3 BRIT. MED. J. OPEN e002302 (2013) (co-authored with Valorie A. Crooks, Leigh Turner, Janet Bristeir, Jeremy Snyder, Vicky Casey, Rebecca Whitmore)

[**Medical Outlaws or Medical Refugees? An Examination of Circumvention Tourism**](#)

in RISKS AND CHALLENGES IN MEDICAL TOURISM: UNDERSTANDING THE GLOBAL MARKET FOR HEALTH SERVICES CONTROVERSIES IN THE EXPLODING INDUSTRY OF GLOBAL MEDICINE 207 (Jill Hodges et al. eds., Praeger, 2012).

Medical Tourism: Bioethical and Legal Issues

in ROUTLEDGE COMPANION TO BIOETHICS (John D. Arras et al. eds, Routledge, forthcoming 2013)

Medical Tourism for Services Legal in the Home and Destination Country: Legal and Ethical Issues

in BODIES ACROSS BORDERS: THE GLOBAL CIRCULATION OF BODY PARTS, MEDICAL TOURISTS AND PROFESSIONALS (Brownyn Parry et al. eds, Ashgate, forthcoming 2013).

[**Rationing Legal Services**](#)

5 J. L. ANALYSIS 221 (2013)

[Making Residency Work Hour Rules Work](#)

41 J. L. MED. & ETHICS 310 (2013) (co-authored with Charles A. Czeisler and Christopher P. Landrigan) (peer-reviewed)

[The Taxing Power and the Public's Health](#)

367 N. ENG. J. MED. 1777 (2012) (peer-reviewed) (co-authored with Michelle Mello)

[Sherley v. Sebelius and the Future of Stem Cell Research](#)

308 JAMA 2087 (2012) (peer-reviewed) (co-authored with Eli Adashi and Jeremy Feigenbaum)

[Conscientious Objection, Coercion, the Affordable Care Act, and U.S. States](#)

19 ETHICAL PERSPECTIVES 163 (2013) (peer-reviewed) (solicited)

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

(under contract Oxford University Press) (co-editor with Nir Eyal and Norman Daniels and contributing a chapter)

Benjamin Roin

[The Case for Tailoring Patent Awards](#)

61 UCLA L. REV. (forthcoming 2013)

IP vs Prizes: Reframing the Debate

U. CHI. L. REV. (forthcoming 2013)

Einer Elhauge

[RESEARCH HANDBOOK ON THE ECONOMICS OF ANTITRUST LAW](#)

(Edward Elgar Publishing 2012)(editor)

including Ch. 1: **[Introduction and Overview to Current Issues in Antitrust Economics](#)**

[OBAMACARE ON TRIAL](#)

(Smashwords 2012)

[Obamacare and the Theory of the Firm](#)

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

[Anticompetitive Market Division through Loyalty Discounts without Buyer Commitment](#)

Harvard Discussion Paper, no. 723 (2012)(co-authored with Abraham L. Wickelgren)

[Robust Exclusion through Loyalty Discounts with Buyer Commitment](#)

Harvard Discussion Paper, No. 722 (2012)(co-authored with Abraham L. Wickelgren)

Holly Fernandez Lynch

[Protecting Human Research Subjects as Human Research Workers](#)

in THE FUTURE OF HUMAN SUBJECTS RESEARCH REGULATION, I. Glenn Cohen and Holly Fernandez Lynch, eds., MIT Press (forthcoming Spring 2014)

[Human Research Subjects as Human Research Workers](#)

YALE J. HEALTH POL'Y, L., & ETHICS (forthcoming)(peer-reviewed)

[Discrimination at the Doctor's Office](#)

368 NEW ENG. J. MED. 1668 (2013)(peer-reviewed)(solicited)
With corresponding [podcast](#)

[Religious Liberty, Conscience, and the Affordable Care Act](#)

20(1) ETHICAL PERSPECTIVES 118 (2013)(peer reviewed)(solicited)

Michelle N. Meyer

[Regulating the Production of Knowledge: Research Risk-Benefit Analysis and the Heterogeneity Problem](#)

65 ADMIN. L. REV. 237 (2013)

Featured on Larry Solum's *Legal Theory Blog* as "highly recommended" and in David Shaywitz, *Personalized Regulation: More Than Just Personalized Medicine—And Urgently Required*, Forbes.com (Jan. 23 2013)

[Three Challenges for Risk-Proportionate \(Research\) Regulation: Heterogeneity Among Regulated Entities, Regulator Bias, and Stakeholder Heterogeneity](#)

in THE FUTURE OF HUMAN SUBJECTS RESEARCH REGULATION, I. Glenn Cohen and Holly Fernandez Lynch, eds., MIT Press (forthcoming Spring 2014)

[Are You Ready for Some...Research? Uncertain Diagnoses, Research Data Privacy, & Preference Heterogeneity](#)

3 JOURNAL OF LAW (3 The Post) 99 (2013)

[Common Genetic Variants Are Associated With Educational Attainment](#)

Science (epub ahead of print May 30, 2013), with Niels A. Rietveld, et al.

[From Evidence-Based Medicine to Evidence-Based Practice](#)

43 HASTINGS CENTER REP. 11 (March–April 2013) (invited)

Jeffrey M. Skopek

[Anonymity, the Production of Goods, and Institutional Design](#)

82 FORDHAM L. REV. __ (forthcoming 2013)

W. Nicholson Price II

[Legal Implications of an Ethical Duty to Search for Genetic Incidental Findings](#)

13 AM. J. BIOETHICS 48 (2013)

[Making Do in Making Drugs: Innovation Policy and Pharmacy Manufacturing](#)

B.C. L. REV. (forthcoming 2014)

[Problems of Innovation-Deficient Pharmaceutical Manufacturing](#)

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

[Informed Consent for Return of Incidental Findings in Genomic Research](#)

15 GENETICS MED. __ (forthcoming 2013) (peer-reviewed) (co-authored with Paul S. Appelbaum et al.)

[Generic Entry Jujitsu: Innovation and Quality in Drug Manufacturing](#)

3 IP THEORY __ (forthcoming 2013)

2012-13 Affiliate Commentary

Once again, our affiliates were highly sought after for their expert opinions on a number of pressing news items, including the patentability of biological materials, medical tourism, liability for medical malpractice and defective pharmaceutical products, implementation of health care reform and Medicaid expansion, abortion regulation, and reproductive technology. In addition to being heavily quoted in various media outlets, including Nature, NPR, The Wall Street Journal, The Washington Post, The Boston Globe, The Washington Times, The Kansas City Star, The Indiana Star, CNN, Bloomberg News, Global News, Medical Ethics Advisor, Law360, Politifact, CBS Radio, World News Australia, Lawyer2Lawyer, and Reason.com, Center affiliates authored several editorial and commentary pieces,

listed below. Several are also regular bloggers at Petrie-Flom's collaborative blog, [Bill of Health](#), as well as other high-profile blogs, including PrawfsBlawg.com and TheFacultyLounge.org.

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

I. Glenn Cohen & Holly Fernandez Lynch

[Guatemalans Used in Experiments Deserve Compensation](#)

New York Times, July 4, 2012

I. Glenn Cohen

[The Flawed Basis Behind Fetal-pain Abortion Laws](#)

Washington Post, Aug 1, 2012

[It Is Time for the U.S. to Cover IVF \(for Gays and Lesbians too\)](#)

Huffington Post, March 18, 2013

Einer Elhauge

[The Fatal Flaw in John Roberts' Analysis of the Commerce Clause](#)

New Republic, July 20, 2012

[Roberts's Real Long Game?](#)

Atlantic Monthly, July 20, 2012

W. Nicholson Price

[Does Whole-Genome Sequencing Circumvent Gene Patents?](#)

Bio-IT World, Dec. 10, 2012

Fellowship Alumni Update

As indicated above, our Academic Fellowship program aims to promote first-rate scholarship in the areas of health law policy, biotechnology, and bioethics. Several of our past Academic Fellows have gone on to become prolific scholars and

emerging leaders in these fields, allowing the Center's influence to expand far beyond Cambridge, particularly as these alumni train the next generation of health law scholars and practitioners.

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

[Michael Frakes](#)

Academic Fellow, 2009-2011

Currently: Assistant Professor and Jia Jonathan Zhu and Ruyin Ruby Ye
Sesquicentennial Faculty Fellow, Cornell Law School

[The Impact of Medical Liability Standards on Regional Variations in Physician Behavior: Evidence from the Adoption of National-Standard Rules](#)

103 AM. ECON. REV. 1 (2013)

[Does Agency Funding Affect Decisionmaking?: An Empirical Assessment of the PTO's Granting Patterns](#)

66 VAND. L. REV. 67 (2013) (with Melissa Wasserman)

[Defensive Medicine and Obstetric Practices](#)

9 J. EMPIRICAL LEG. STUD. 457 (2012)

[Evaluating the PTO's Proposed Fee Structure](#)

Penn Program on Regulation, RegBlog (September 2012)(with Melissa Wasserman).

[Can New Fees Fix the Patent System?: Don't Rely so Heavily on 'Post-allowance' Fees to Fund USPTO Operations](#)

Wired (September 2012)(with Melissa Wasserman)

[Allison Hoffman](#)

Academic Fellow, 2008-2010

Currently: Assistant Professor of Law, UCLA School of Law

[Retiree Out-of-Pocket Healthcare Spending: A Study of Consumer Expectations and Policy Implications](#)

39 AM. J. L. & MED. 1-72 (2013) (with Howell E. Jackson)

Abby Moncrieff

Academic Fellow, 2007-2009

Currently: Associate Professor of Law and Peter Paul Career Development Professor, Boston University School of Law

Fall 2012: Visiting Associate Professor of Law, University of Pennsylvania Law School

Cost-Benefit Federalism: Reconciling Collective Action Federalism and Libertarian Federalism in the Obamacare Litigation and Beyond

37 AM. J. L. & MED. 288 (2012)

Common Law Constitutionalism, the Constitutional Common Law, and the Validity of the Individual Mandate

92 B.U. L. Rev. 1245 (2012)

Safeguarding the Safeguards: The ACA Litigation and the Extension of Structural Protection to Nonfundamental Liberties

64 FLA. L. REV. 639 (2012)

Christopher Robertson

Academic Fellow, 2008-2010

Currently: Associate Professor, James E. Rogers College of Law, University of Arizona; Visiting Member, Methods Core, Robert Wood Johnson Foundation Public Health Law Research Program; Investigator, Collaborative Research Project, Edmond J. Safra Center for Ethics Institutional Corruption Lab, Harvard Law School

Fall 2013 – Spring 2014: Visiting Professor, Harvard Law School

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

94 B.U. L. REV. __ (2014)(forthcoming)(Professor Robertson presented this paper at our 2013 annual conference, and it was the fifth most downloaded article in the SSRN medical-legal journal articles as of September 2013)

Distributions of Industry Payments to Massachusetts Physicians

30 NEW ENG. J. MED. 2049 (May 1, 2013)(with Aaron S. Kesselheim, Kent Siri, Puneet Batra, and Jessica M. Franklin)

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

98 CORNELL L. REV. 921 (2013)

The Effect of Blinded Experts on Jurors' Verdicts

9 J. EMPIRICAL LEG. STUD. 765 (2012)(with David Yokum)

[A Randomized Study of How Physicians Interpret Research Funding Disclosures](#)

369 NEW ENG. J. MED. 1119 (September 20, 2012)(with Aaron S. Kesselheim, Jessica A. Myers, Susannah L. Rose, Victoria Gillet, Kathryn M. Ross, Robert J. Glynn, Steven Joffe, & Jerry Avorn)

[Effect of Financial Relationships on the Behavior of Healthcare Professionals](#)

40 J. L., MED., & ETHICS 452 (2012)(with Susannah Rose & Aaron Kesselheim)

[Contingent Compensation of Post-Conviction Counsel: A Modest Proposal to Identify Meritorious Claims and Reduce Wasteful Government Spending](#)

64 MAINE L. REV. 513 (symposium, 2012)

[Talha Syed](#)

Academic Fellow, 2006-2009

Currently: Assistant Professor of Law, Berkeley Law

[The Continuum of Excludability and the Limits of Patents](#)

122 YALE L. J. 1900 (2013) (with Amy Kapczynski)

[Patrick Taylor](#)

Academic Fellow, 2010-2012

Currently: Staff Scientist and Director of Ethics Analysis and Applications, Children's Hospital Boston Informatics Program; Assistant Clinical Professor, Harvard Medical School

[The Informed Cohort Oversight Board: From Values to Architecture](#)

13(2) MINN. J. LAW, SCIENCE AND TECH. 669 (2012), with Ingrid A. Holm

Innovation Incentives or Corrupt Conflicts of Interest? Rewarding the Good and Prohibiting the Bad in the Complex World of Biomedical Academic-Industry Partnerships

13(1) YALE J. HEALTH POLICY, LAW & ETHICS 135 (2013)

[Position Statement on the Provision and Procurement of Human Eggs for Stem Cell Research](#)

12(3) CELL STEM CELL 285 (2013), with Haimes et al.

Guidelines for Return of Research Results from Pediatric Genomic Studies: Deliberations of the Boston Children's Hospital Gene Partnership Informed Cohort Oversight Board (ICOB)

Co-authored by Ingrid A. Holm, MD, MPH, Sarah K. Savage, MS, Erin D. Harris, BA, Robert C. Green, MD, MPH, Eric Juengst, PhD, Amy McGuire, PhD, JD, Susan Kornetsky, MPH, Stephanie Brewster, MS, GC, Steve Joffe, MD, MPH, **Patrick Taylor, JD** (under review)

Parents' Preferences for Return of Results in Pediatric Genomic Research

(co-authored, forthcoming)

Networking Safety and Quality into Healthcare IT: Distributed QA Beats Liability Shifts and Weak Regulation

(co-authored with Mandl, forthcoming)

Truth Is Stranger than Fiction: A Responsible Model for Data Donation to Test Technology Against Reality

(co-authored with Mandl, forthcoming)

[Melissa Wasserman](#)

Academic Fellow, 2009-2011

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

[The Changing Guard of Patent Law: Chevron Deference for the PTO](#)

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

[Does Agency Funding Affect Decisionmaking?: An Empirical Assessment of the PTO's Granting Patterns](#)

66 VAND. L. REV. 67 (2013) (with Michael Frakes)

[Evaluating the PTO's Proposed Fee Structure](#)

Penn Program on Regulation, RegBlog (September 2012)(with Michael Frakes).

[Can New Fees Fix the Patent System?: Don't Rely so Heavily on 'Post-allowance' Fees to Fund USPTO Operations](#)

Wired (September 2012)(with Michael Frakes)

Public Events Programming and Conferences

This year, the Petrie-Flom Center hosted a number of fantastic events, from major conferences to smaller panel discussions, some independently and some in collaboration with our colleagues from Harvard and elsewhere.

As has become our tradition, we kicked-off the year with a widely-attended Open House, which allowed interested individuals to meet our affiliates, learn about new initiatives for the year, and hear about possible ways in which they could become involved. We provided information on our upcoming events and programs, as well as information about the vast array of programs and organizations focusing on health policy, biotechnology, and bioethics across the university. The event also served as an opportunity to facilitate new connections and rekindle old ones.

In developing our substantive event agenda, we strive to plan events that are timely, interdisciplinary, and offer exposure to a variety of leading experts, from academics to policymakers to practitioners. This year, we hosted substantial conferences addressing conflicts of interest, major developments in the world of health law (including the implementation of national health care reform), life sciences industry compliance, evidence-based health policy-making, and the future of the Food and Drug Administration. We also hosted a number of smaller panels, addressing topics such as open access to health research, advances in HIV prevention, international human subjects research violations, stem cell therapy and medical tourism, legal careers in the life sciences, developments in food and drug law, challenges to conceptions of personhood raised by new technologies, personalized medicine patenting, and informed consent in an era of managed care.

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

Major Events/Conferences

Institutional Financial Conflicts of Interest in Research Universities

November 2, 2012

This symposium was organized by Dr. David Korn, and co-sponsored by the Petrie-Flom Center and Edmond J. Safra Center for Ethics at Harvard University, with support from the Oswald DeN. Cammann Fund.

While much scholarly attention has been paid to the problems posed by individual conflicts of interest, far less attention is given to institutional conflicts of interest. The symposium aimed to facilitate dialogue about this often overlooked subject, particularly at a time when universities have been increasingly encouraged to become more involved with industry to translate research into concrete public benefits. The symposium convened some of the foremost experts on conflicts of interest, past and present senior management of top research universities, and leadership of federal agencies to discuss the problems facing the contemporary research university. In addition to individual presentations, the symposium featured Q&A sessions, a panel discussion with symposium speakers, and a public reception.

The day's agenda is included below:

Introduction and Overview

- David Korn, M.D., Consultant in Pathology, Massachusetts General Hospital; Professor of Pathology, Harvard Medical School

Evolving Roles, Enduring Values, and Conflicting Public Expectations of American Research Universities

- *A Quest for Utopia: The Great American University Yesterday, Today, and Tomorrow*
Jonathan Cole, Ph.D., John Mitchell Mason Professor of the University and Provost and Dean of Faculties, Emeritus, Columbia University
- *The University's Capacity for Attestation*
William (Terry) Fisher, Ph.D., J.D., WilmerHale Professor of Intellectual Property Law, Faculty Director of the Berkman Center for Internet and Society, Harvard Law School

Institutional Conflicts of Interest in Practice

- *Investing in Faculty Start-Ups and Other Adventures*
Derek Bok, J.D., A.M., University Research Professor and former faculty chair of the Hauser Center for Nonprofit Organizations, and President emeritus, Harvard University
- *The Olivieri Case: Institutional Financial Conflicts Perspectives*
Jonathan H. Marks, B.C.L., M.A., Associate Professor of Bioethics, Humanities and Law, and Director, Bioethics Program, Pennsylvania State University
- *Walking the Tightrope: Protecting Trustworthiness While Engaging with Industry at MIT*
Claude Canizares, Ph.D., M.A., Vice President for Research, Associate Provost, and Bruno Rossi Professor of Physics, Massachusetts Institute of Technology (MIT)
- *The Lion in the Path: Research Universities Confront Society's New Expectations*
Hunter R. Rawlings III, Ph.D., President, Association of American Universities (AAU)

Institutional Conflicts of Interest in Awardee Institutions

- *Managing Financial Conflicts of Interest in an Expanding World of Industry-Academia Collaborations in Science and Medicine*
Sally Rockey, Ph.D., Deputy Director for Extramural Research, National Institutes of Health
- *The Perspective of the DHHS OIG*
Julie Taitsman, M.D., J.D., Chief Medical Officer, DHHS OIG

Conclusion

- Lawrence Bacow, J.D., M.P.P., Ph.D., President emeritus, Tufts University (Rapporteur)

Conference video may be viewed [here](#) and a report of the proceedings is available [here](#).

Health Law Year in P/Review

February 1, 2013

This year, the Petrie-Flom Center co-sponsored the first annual Health Law Year in P/Review event alongside the *New England Journal of Medicine*, with support from the Oswald DeN. Cammann Fund. This inaugural session invited leading experts to review some of the most important changes in the health law landscape over the past year, discuss their implications for the future, and offer a preview of what is to come. Topics and speakers included:

The Affordable Care Act and Health Care Reform

- **Einer Elhauge**, Carroll and Milton Petrie Professor of Law; Founding Faculty Director of the Petrie-Flom Center, Harvard Law School
- Jonathan Gruber, Professor of Economics, MIT

Personhood Amendments and Contraceptives Coverage

- **I. Glenn Cohen**, Professor of Law; Faculty Co-Director, Petrie-Flom Center
- **Holly Fernandez Lynch**, Executive Director, Petrie-Flom Center

Immigrants' Access to Health Care

- Wendy Parmet, George J. and Kathleen Waters Matthews Distinguished University Professor, Northeastern University School of Law

Affirmative Action and Medical School Admissions

- Renee Landers, Professor of Law, Suffolk University Law School

Gene Patenting

- Aaron Kesselheim, Assistant Professor of Medicine, Harvard Medical School

Tobacco and Obesity Policy and the First Amendment

- Kevin Outterson, Professor of Law, Boston University School of Law

Summary and Wrap Up

- Martha Minow, Dean, Harvard Law School
- Kristin Madison, Professor of Law and Health Sciences, Northeastern University School of Law

Video from the event is available [here](#).

Exploratory Meeting – Model Program on Life Sciences Industry Compliance (with open panel, Compliance with and Enforcement of US Healthcare Laws: Evolution of Modern Life Sciences Compliance Programs)

February 18, 2013

With support from the Oswald DeN. Cammann Fund, this invitation-only meeting brought together a variety of stakeholders from industry, government, academia, and various non-profit groups to explore the possibility of developing a model life sciences industry compliance program through the Petrie-Flom Center. It also included an open panel discussion with experts on the evolution of modern life sciences industry compliance programs, problems, and potential solutions.

Welcome, Meeting Overview, Introductions

- **I. Glenn Cohen**, Petrie-Flom Center
- Marc Wilenzick, Core Risks, Ltd.

Remarks from Antitrust Counsel

- Eve Brunts (Ropes & Gray)

Closed Session, Panel 1: The Value Proposition

- Moderator: Marc Wilenzick
- Panelists: Regina Cavaliere (Otsuka), Jean Lance (Boston Scientific), David Ogden (WilmerHale), Lori Queisser (KPMG)

Closed Session, Panel 2: Organization, Funding

- Moderator: Marc Wilenzick
- Panelists: Cindy Cetani (Novartis), Bruce Kuhlik (Merck), **Holly Fernandez Lynch** (Petrie-Flom Center), Tom Schumacher (Medtronic), Chris White (AdvaMed)

Closed Session, Panel 3: Implementation

- Moderator: Marc Wilenzick
- Panelists: Lori Alarimo (Allergan), Dorothy Clarke (J&J), Mark Goodman (Debevoise), Michael Kendall (McDermott, Will & Emery), Keith Korenchuk (Arnold & Porter)

Open Presentation Panel – Compliance with and Enforcement of U.S. Healthcare Laws: Evolution of Modern Life Sciences Compliance Programs

There have been a number of recent prosecutions of life sciences companies under the Food, Drug, and Cosmetic Act and the *qui tam* whistleblower provisions of the False Claims Act. Allegations include things like unlawful promotion, failure to report safety data, and false price reporting practices, resulting in massive settlements, some in the billion dollar range. Understandably, compliance has become a top priority for life sciences companies, which typically have dedicated compliance programs in place with ever more sophisticated internal programs for educating employees, preventing wrongful conduct, detecting and deterring violations, and ensuring prompt remedial action. Accordingly, this panel discussion addressed how life science compliance efforts have evolved in recent years to face a variety of challenges. Video is available [here](#).

- Moderator: Kris Curry (J&J)
- Panelists: Mary Riordan (HHS OIG), James Sheehan (NYC Human Resources Administration), Paul Kalb (Sidley Austin), Kathleen Boozang (Seton Hall)

Wrap-Up & Next Steps

- Marc Wilenzick
- **Holly Fernandez Lynch**, Petrie-Flom Center

Legal Experimentation: Legal and Ethical Challenges to Evidence-Based Practice in Law, Medicine, and Policymaking (with open lecture, Charles Fried, Evidence as a Public Good)

March 1, 2013

This academic workshop was organized by Petrie-Flom Center Academic Fellow **Michelle Meyer**, with support from the Oswald DeN. Cammann Fund. It was prompted by recognition of the fact that both legal scholars and lawmakers have recently called for evidence-based practice (EBP) across a wide variety of areas, including legal services, education, criminal justice, housing, and law- and policy-making in general. Drawing on the most longstanding version of EBP, they

reasonably argue that decisions affecting human welfare should be based on sound evidence about the comparative effects of alternatives. Rigorously studying the effects of an innovative practice on a small scale before implementing it more widely limits the extent of any negative impact it might have. And retrospective testing of already-accepted practices can identify ineffective and inefficient practices. But EBP has faced substantial legal and ethical challenges. Regulations in place since the early 1980s – but, fortuitously, now being questioned by both scholars and regulators – often make it difficult to conduct the research necessary to inform EBP, not only in medicine but in other practice areas. On the other hand, conducting research and integrating research into practice settings that are traditionally understood to involve fiduciary relationships raise legitimate legal and ethical concerns.

Accordingly, this invitation-only workshop sought to unite legal scholars interested in widespread EBP with scholars who work in the area of evidence-based medicine to collectively think through the best approach to these challenges. The day also included a public lecture by Professor Charles Fried.

Welcoming Remarks

- Martha Minow, M.A., J.D., Dean, HLS
- **Michelle Meyer**, J.D., Ph.D., Academic Fellow, Petrie-Flom Center

Opening Presentations: Overview of the Problem and Some Potential Solutions

- Tom Beauchamp, Ph.D., Professor of Philosophy and Senior Research Scholar, Georgetown University Kennedy Institute of Ethics
The Research-Treatment Distinction: A Problematic Approach for Determining Which Activities Should Have Ethical Oversight
- Ruth Faden, Ph.D., M.P.H., Director, John Hopkins Berman Institute of Bioethics
An Ethics Framework for a Learning Health Care System: A Departure from Traditional Research Ethics and Clinical Ethics

Panel 1: Innovation and the Research-Practice Distinction

- Greg Koski, M.D., Ph.D., Associate Professor of Anesthesia, Harvard Medical School
Medical Professionalism as an Alternative to Protectionism: A Practical Approach to Bridging the Great Divide
- John Robertson, J.D., Vinson & Elkins Chair, University of Texas School of Law
Innovative Medical Therapy, Research, and Quality Improvement In Health Care and Public Policy
- Anna Laakmann, M.D., J.D., Assistant Professor of Law, Lewis & Clark Law School
Medical Uncertainty and Physician Innovation

Panel 2: Consent, Duty, Utility, and Paternalism in Research-Integrated-Into-Practice

- Alan Wertheimer, Ph.D., Senior Research Scholar, Department of Bioethics, National Institutes of Health
[Why] Should We Require Consent?
- Jerry Menikoff, M.D., J.D., M.P.P., Director of the Office for Human Research Protections, Department of Health and Human Services
On the Duty to Disclose
- Jeremy Blumenthal, J.D., Ph.D., Professor of Law, Syracuse University School of Law
Anti-Anti-Anti-Anti-Paternalism
- Alex Capron, LL.B., University Professor, University of Southern California
Deontology and Utility: Using a Relationships Lens to Draw Lessons for Public Policy

Public talk by Charles Fried, J.D., M.A., Beneficial Professor of Law, Harvard Law School: “Evidence as a Public Good”

In this talk, Professor Fried moved beyond the discussion of conflict between use of an individual’s information for the public good and that individual’s privacy concerns to focus on the deeper conflict that arises when an individual is used to generate information – public or private – in the first place. His presentation revisited some of the foundational questions that animated his groundbreaking 1974 book, *Medical Experimentation: Personal Integrity and Social Policy*. Video may be viewed [here](#).

Panel 3: Challenges to Generating and Implementing Comparative Effectiveness Data

- Steven Joffe, M.D., M.P.H., Associate Professor of Global Health and Social Medicine, Harvard Medical School
Risk Assessment for Comparative Effectiveness Research: A Modest Proposal
- Richard Saver, J.D., Professor of Law, UNC School of Law
The Uptake Problem For Evidence-Based Practice: Lessons From the Comparative Effectiveness Research Rollout”

Panel 4: Evidence-Based Poverty Policy, Civil Procedure, and Public Health

- Scott Burris, J.D., Professor of Law, Temple University Beasley School of Law
Public Health Law Research
- Shawn Powers, M.Phil., M.P.A., Policy Manager, Abdul Latif Jameel Poverty Action Lab, MIT
Evidence-Based Global Poverty Policy
- Michael Abramowicz, J.D., Professor of Law, George Washington University Law School
Toward Experimentation in Civil Procedure

Panel 5: Evidence-Based Law Practice

- Jim Greiner, J.D., Ph.D., Professor of Law, Harvard Law School; **I. Glenn Cohen**, J.D., Professor of Law, Harvard Law School; and Steve Eppler-Epstein, J.D., Executive Director, Connecticut Legal Services
Ethical Issues in Randomized Research in the Legal Assistance Context
- Bill Simon, J.D., Arthur Levitt Professor of Law and Everett B. Birch Professor in Professional Responsibility, Columbia Law School
Barriers to Evidence-Based Practice in the Legal Profession

Annual Conference: The Food and Drug Administration in the 21st Century

May 3-4, 2013

With support from the Oswald DeN. Cammann Fund, this year’s Petrie-Flom Center Annual Conference boasted record attendance and focused on bringing together a variety of experts from academia, government, and private industry to evaluate FDA in terms of how it is faring in the 21st century. Addressing several of the major products regulated by the agency – drugs, devices, food, and tobacco products – conference panelists identified a number of challenges to FDA’s success, and began to chart a course for how the agency can best meet those challenges going forward.

Video from the conference can be viewed [here](#), and live blogs from each session can be found [here](#). Our edited conference volume is currently under review for publication.

Day One:

Welcome and Introduction

- **I. Glenn Cohen**, Faculty Director, Petrie-Flom Center
- **Holly Fernandez Lynch**, Executive Director, Petrie-Flom Center

Plenary 1

- Peter Barton Hutt, Covington & Burling LLP
Historical Themes and Developments over the Past 50 Years

The FDA in a Changing World

Moderator: **Holly Fernandez Lynch**, Petrie-Flom Center

- Lewis Grossman, American University, Washington College of Law/Covington & Burling LLP
FDA in the Age of the Empowered Consumer
- Theodore Ruger, University of Pennsylvania Law School
After the FDA: A Twentieth Century Agency in a Postmodern World
- Barbara Evans, University of Houston Law Center
The Future of Prospective Medicine under the Food and Drug Administration Amendments Act of 2007

Preserving Public Trust and Demanding Accountability

Moderator: David Korn, Massachusetts General Hospital

- Mark Lange, Eli Lilly
Data Transparency and the Role of the FDA
- Genevieve Pham-Kanter, Edmond J. Safra Center for Ethics, Harvard University
Financial Conflicts of Interest and Voting in FDA Drug Advisory Committees
- **Patrick O'Leary**, Harvard Law School, Petrie-Flom Student Fellow
Credible Deterrence: The Park Doctrine and the FDA in the 21st Century
- Katrice Bridges Copeland, Penn State Dickinson School of Law
The Crime of Being in Charge: Executive Culpability and Collateral Consequences

Keynote Speaker

- Deborah Autor. Deputy Commissioner for Global Regulatory Operations and Policy, U.S. Food and Drug Administration, with an introduction by Jeffrey Senger, Sidley Austin

Protecting the Public Within Constitutional Limits

Moderator: **I. Glenn Cohen**, Petrie-Flom Center

- Aaron Kesselheim/Michelle Mello, Harvard School of Public Health
The Prospect of Continued FDA Regulation of Manufacturer Promotion in an Era of Expanding Commercial Speech
- **Chris Robertson**, University of Arizona James E. Rogers College of Law
When Truth Cannot Be Safely Presumed: A First Amendment Reconstruction of the Regulation of Off-Label Drugs
- Jessica Flanigan, University of Richmond
Patients' Rights, Speech, and Off-Label Marketing

Timing Is Everything: Balancing Access and Uncertainty

Moderator: **Jeffrey Skopek**, Petrie-Flom Center

- Shannon Gibson/Trudo Lemmens, University of Toronto Faculty of Law
Overcoming "Pre-Market Syndrome": Advancing Post-Market Surveillance in an Evolving Drug Development Context
- Efthimios Parasidis, St. Louis University School of Law. moving to The Ohio State University Moritz College of Law
Innovative Regulating as a Public Health Imperative

Major Issues in Drug Regulation

Moderator: R. Alta Charo, University of Wisconsin Law School

- Geoffrey Levitt, Pfizer
Drug Safety Communication: The Evolving Environment
- **W. Nicholson Price II**, Petrie-Flom Center
The Role of Innovation Policy in Pharmaceutical Manufacturing
- Ernst Berndt, MIT Sloan School of Management/Rena Conti, University of Chicago
Anatomy of US Cancer Drug Shortages
- Daniel Carpenter, Harvard University; Jeremy Greene, Johns Hopkins School of Medicine; Susan Moffitt, Brown University; Jonathan Warsh, Oxford University
Therapeutic and Economic Effects of Efficacy-Based Drug Withdrawals: The Drug Efficacy Study Initiative and Its Manifold Legacies

Day Two:

Welcome

- **I. Glenn Cohen**, Petrie-Flom Center

Plenary 2

- R. Alta Charo, University of Wisconsin Law School
Integrating Speed and Safety

Regulatory Exclusivities and the Regulation of Generic Drugs and Biosimilars

Moderator: **Benjamin Roin**, Petrie-Flom Center

- Kate Greenwood, Seton Hall University School of Law
Calibrated Incentives for Orphan Drug Development: Time to Experiment?
- Kevin Outterson, Boston University School of Law
Ending the Game of Shadows in Drug Regulation
- Marie Boyd, University of South Carolina School of Law
Unequal Protection Under the Law: Reforming the Regulation of Generic Drugs
- Henry Grabowski, Duke University
FDA Regulation of Biosimilars

Major Issues in Device Regulation

Moderator: **W. Nicholson Price II**, Petrie-Flom Center

- Jeffrey Shapiro, Hyman, Phelps, McNamara PC
Why the 510(k) Pathway is the Right Approach for Most Medical Devices
- Kayte Spector-Bagdady/Elizabeth Pike, Presidential Commission for the Study of Bioethical Issues
Device-ive Maneuvers: FDA Regulation of the Bifurcation of Direct-to-Consumer Genomic Data and Information
- Thomas R. McLean, American Medical Litigation Support Services)/Alexander McLean, University of Texas at Austin School of Law
Post-Market Surveillance of Medical Devices

Plenary 3

- Susan Winckler, President and CEO, Food & Drug Law Institute

Major Issues in Food, Supplement, and Tobacco Regulation

Moderator: Emily Broad Leib, Harvard Law School

- Robin Craig, Leslie Francis, and Erika George, S.J. Quinney College of Law, University of Utah
The FDA's Authority Over Labeling: Current Ironies and Future Improvements
- Jennifer Pomeranz, Yale Rudd Center for Food Policy & Obesity
Food Labeling and Enforcement
- Diana Winters, Indiana University Robert H. McKinney School of Law
From Industrial to Artisanal: Food Regulation and the Problem of Scale
- Joanna Sax, California Western School of Law
The Tobacco Diaries: Lessons Learned and Applied to Regulation of Dietary Supplements

Addressing the Challenges of and Harnessing New Technologies

Moderator: Frances Miller, Boston University School of Law

- Margaret Riley, University of Virginia School of Law
FDA's Authority to Regulate Regenerative Technology
- Nathan Cortez, Southern Methodist University Dedman School of Law
Is the FDA Equipped to Regulate Mobile Health Devices?
- David Rosenberg, Andrew English, Huaou Yan, Harvard Law School
Enhancing FDA Oversight of Medical Product Usage: A New Regulatory Role for e-Prescriptions

Closing Remarks

- **I. Glenn Cohen**, Petrie-Flom Center

Panel Events

Health Care Reform: A View from Both Sides

September 25, 2012

Alongside the HLS Democrats, HLS Republicans, and HLS American Constitution Society, the Petrie-Flom Center hosted a special off-the-record debate on American health care reform, moderated by the Petrie-Flom Center's Founding Faculty Director, [Einer Elhauge](#). [John McDonough](#), official surrogate of the Obama campaign and director of the Center for Public Health Leadership at the Harvard School of Public Health, and **Oren Cass**, domestic policy director for the Romney campaign, discussed what each candidate would mean for the future of US health policy.

Open Access to Health Research: Future Directions for the NIH Public Access Policy

October 24, 2012

This event was organized by Petrie-Flom Center Student Fellow, **Adriana Benedict** as part of [Open Access Week 2012](#), and was sponsored by the Center, with additional support from HLS Advocates for Human Rights, Harvard University Library Office for Scholarly Communication, Harvard Universities Allied for Essential Medicines, and the Right to Research Coalition. Its focus was the 2008 [NIH Public Access Policy](#), requiring "that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's [PubMed Central](#) an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication." As a way to stimulate progress in health research and clinical practice, as well as relieve financial burden on a public that must otherwise rely exclusively on expensive journal subscriptions to access tax-funded research, the NIH Policy has already been deemed a success. In the past 4 years, compliance rates have improved to roughly 75%, but there is still work to be done. What are the strategies that institutions and researches should be considering to address that remaining 25% "non-compliance"? How can we further expand public access to tax-funded research articles, and support our faculty and students in this endeavor?

Institutional Open Access resolutions such as Harvard's Open Access Policy have helped accommodate the NIH Public Access Policy requirements, but as yet, medical schools have been slow to adopt institutional level open access policies, including Harvard Medical School and Harvard School of Public Health. Furthermore, in May 2012, the Harvard Library Faculty Advisory Council issued a [public letter](#) calling on faculty to promote open access scholarly publishing. How can we work together to help achieve each of these goals and expand Open Access to biomedical and health research?

The event brought together four distinguished panelists to explore these issues:

- [Peter Suber](#), Director of the Harvard Open Access Project
- [Amy Brand](#), Assistant Provost for Faculty Appointments and Information
- [Winston Hide](#), HSPH Professor of Bioinformatics and Computational Biology
- [Patrick Taylor](#), Director of Ethics Analysis and Applications in the Informatics Program and Staff Scientist, Children's Hospital Boston (former Petrie-Flom Center Academic Fellow)

Moderators:

- [Scott Lapinski](#), HMS Digital Resources and Services Librarian and Open Access Liaison
- [June Casey](#), HLS Librarian for Open Access and Scholarly Communication

The panel was followed by two brief "101" sessions on individual-level implementation of both the NIH's Public Access and Harvard's Open Access mandates.

Video is available [here](#).

Advances in HIV Prevention: Legal, Clinical, and Public Health Issues

November 5, 2012

The Petrie-Flom Center, the Center for Health Law and Policy Innovation, and The Fenway Institute co-sponsored this panel discussion on the various legal, clinical, and public health issues related to the 2012 FDA approvals of once-daily Truvada for pre-exposure HIV prophylaxis (PrEP) in uninfected, at-risk adults, and OraQuick, the first at-home HIV test available for sale directly to consumers. Moderated by [Robert Greenwald](#), director of the Center for Health Law and Policy Innovation, the panel illuminated the immense strides towards advocacy consensus in legal and public health arenas undergone since HIV was first identified as the causative agent of AIDS in the 1980s. Though concern still exists regarding whether PrEP will promote risk compensation behaviors or whether deviating from the regimen will create drug resistance, overall opinion seemed encouraging. Both Truvada and OraSure were lauded as positive steps forward in the movement towards HIV eradication.

Panelists included:

- [Douglas A. Michels](#), President and CEO of OraSure Technologies, Inc.
- **David Piontkowsky**, Senior Director for Medical Affairs, HIV and HIV Global Medical Director, Gilead Sciences, Inc.
- [Kenneth H. Mayer](#), Medical Research Director and Co-Chair of The Fenway Institute
- [Kevin Cranston](#), Director of Bureau of Infectious Disease, Massachusetts Department of Public Health
- [Mark Barnes](#), Partner at Ropes Gray and Lecturer in Law at HLS

Video is available [here](#).

The Guatemala STD Inoculation Studies: What Should We Do Now?

November 13, 2012

In conjunction with the Human Rights Program at Harvard Law School, the Petrie-Flom Center sponsored a panel discussion concerning the US Public Health Service [experiments](#) on vulnerable Guatemalan subjects in the late 1940s,

in which prisoners, commercial sex workers, and soldiers were exposed to and infected with a number of STDs without their consent. The experiments were kept hidden for more than half a century, until they were discovered and exposed only recently by historian Susan Reverby. The US government has since apologized for what happened, but a class action suit brought on behalf of the Guatemalan subjects was dismissed in June 2012 and efforts to directly compensate the victims have not been forthcoming. Panelists addressed the study and the possible legal and political responses that may be available now, both domestically and from an international human rights perspective.

Panelists included:

- [Susan Reverby](#), Marion Butler McLean Professor in the History of Ideas, Professor of Women's and Gender Studies, Wellesley College
- [I. Glenn Cohen](#), Professor of Law, Faculty Co-Director, Petrie-Flom Center, Harvard Law School
- [Holly Fernandez Lynch](#), Executive Director, Petrie-Flom Center
- [Wendy Parmet](#), George J. and Kathleen Waters Matthews Distinguished University Professor of Law, Northeastern University School of Law
- [Fernando Ribeiro Delgado](#), Clinical Instructor and Lecturer on Law, Human Rights Program, Harvard Law School

Video is available [here](#).

Stem Cell Therapy and Medical Tourism: Of Promise and Peril?

November 28, 2012

Experimental breakthroughs within the field of regenerative medicine are reported in the media on a daily basis worldwide. Despite this progress, the overwhelming majority of clinical problems for which stem cell-based intervention offers hope remain therapeutically unproven, and a major gap exists between current public understanding and the availability of innovative therapies. This event, co-sponsored by the Petrie-Flom Center and the Harvard Stem Cell Institute, addressed various aspects of medical tourism for stem cell therapy.

Presentations covered the state of stem cell science, historical context and comparisons related to earlier instances of medical utopianism, empirical data on the nature of stem cell tourism, how to address patient hopes in the realm of unproven therapies, and special issues related to stem cell tourism by parents for their children.

Panelists included:

- [M. William Lensch](#), Harvard Stem Cell Institute
- [Brock Reeve](#), Harvard Stem Cell Institute
- [George Q. Daley](#), Harvard Stem Cell Institute
- [Jill Lepore](#), Harvard University
- [Tim Caulfield](#), University of Alberta
- [Insoo Hyun](#), Case Western Reserve University School of Medicine
- [I. Glenn Cohen](#), Petrie-Flom Center, Harvard Law School

Video is available [here](#).

Nourishing a Legal Career in the Life Sciences

November 29, 2012

This event was co-sponsored by the Petrie-Flom Center and the Program on the Legal Profession, with additional support from the HLS Office of Career Services. Aimed at students interested in developing a legal career in the pharmaceuticals and biotechnology industry, the discussion featured [Amy Schulman](#), Lecturer on Law at HLS, Executive Vice President and General Counsel at Pfizer, Inc., President and General Manager of Pfizer Nutrition, and [Mark Nance](#), Senior Vice President and General Counsel at Mylan, Inc. Professor [David Wilkins](#) served as moderator.

Food and Drug Law: Past, Present, and Future

January 17, 2013

Alongside the HLS Dean's Office, the Petrie-Flom Center sponsored an event celebrating [Peter Barton Hutt](#)'s twentieth year of teaching Food and Drug Law during the Winter term at Harvard Law School. Mr. Hutt has worked at the Washington, DC law firm of Covington & Burling, specializing in Food and Drug Law, for more than five decades, representing clients in administrative, legislative, executive, and judicial settings. He began his law practice with the firm in 1960 and is now Senior Counsel; from 1971 to 1975, he was Chief Counsel for the Food and Drug Administration.

Dean [Martha Minow](#)—herself mentored by Mr. Hutt as a summer associate at Covington & Burling—opened the program, and introduced three panelists, all distinguished professors who took FDA law from Mr. Hutt at Harvard Law School:

- [I. Glenn Cohen](#), Professor at Harvard Law School and Faculty Co-Director of the Petrie-Flom Center. Prof. Cohen reflected on the teaching techniques he learned from Mr. Hutt and Mr. Hutt's distinguished and prolific scholarship in food and drug law.
- [Theodore Ruger](#), Professor at the University of Pennsylvania School of Law. Prof. Ruger spoke about the Food and Drug Law casebook he co-edits with Mr. Hutt, his memories of taking the class almost 20 years ago, and Mr. Hutt's role in the ongoing debate over how the Food, Drug, and Cosmetics Act is interpreted.
- [Lewis Grossman](#), Professor at American University Washington College of Law. Prof. Grossman, also a co-editor of the casebook, gave a moving personal description of Mr. Hutt's extraordinary generosity and his love of the law, including its effect on inspiring students both to publish their work in scholarly journals and to become food and drug lawyers themselves.

Mr. Hutt then continued with his own reflections, describing his career as one of the last legal generalists. He discussed his role in moving the FDA from making policy through enforcement choices to making policy through rulemaking, a hallmark of the agency's modern practice. With regard to his teaching career, Mr. Hutt spoke about writing the first Food and Drug Law casebook, his experiences teaching the class for the first time (which he published in the *Journal of Legal Education*), and the pleasure of seeing several of his students become professors themselves teaching FDA law.

Video is available [here](#).

Rethinking Personhood: Fetuses, Animals, and Robots

March 4, 2013

This event was organized by Petrie-Flom Center Academic Fellow, **Jeffrey Skopek**, and co-sponsored by the Petrie-Flom Center and HLS Human Rights Program. It brought together leading academics to discuss the nature of moral and legal personhood by reference to entities whose status is unclear or contested, such as fetuses, animals, and artificial intelligence. The panel explored questions such as: Are there entities that we do not (or would not) recognize as persons but should, or entities that we do (or would) recognize as persons but should not? Should fetuses, animals, or artificial intelligences have rights? On what grounds should we recognize the moral and legal standing of others?

Panelists included:

- [I. Glenn Cohen](#), Harvard Law School
- [Alice Crary](#), Philosophy, New School for Social Research
- [Lawrence B. Solum](#), Georgetown University Law Center

Video is available [here](#).

Personalized Medicine Patenting

March 6, 2013

This lecture by [Professor Shubha Ghosh](#) of the University of Wisconsin Law School was based on his recently published book "[Identity, Invention, and the Culture of Personalized Medicine Patenting](#)" (Cambridge 2012). The discussion addressed medical treatments and diagnostic methods developed to target specific demographic groups and asked whether these innovations are solutions to orphan diseases or whether they foster a culture of niche, designer medicine. Professor Ghosh discussed several specific examples, including BiDil, the first drug FDA approved specifically for the African-American population; Myriad's patented diagnostic method for identifying breast cancer in Ashkenazi Jewish women; Prometheus' patent for treating Crohn's Disease; and other provocative examples at the intersection of patent and health law. [Professor Benjamin Roin](#), Heiken Assistant Professor in Patent Law at Harvard and Petrie-Flom Center Faculty co-Director, served as discussant.

Video is available [here](#).

Revising the Requirement of Informed Consent in an Era of Privatization and Managed Care

April 4, 2013

At this event, [Daniel Sperling](#), Petrie-Flom Center Short-Term Visiting Fellow and Senior Lecturer in Bioethics, Health Law, and Health Policy at the Federmann School of Public Policy & Government and Braun School of Public Health & Community Medicine, The Hebrew University of Jerusalem, presented his current research project, with a response from HLS Professor and Petrie-Flom Faculty Co-Director, [I. Glenn Cohen](#). Dr. Sperling explained that with the increased realization that healthcare is delivered in a complex system changing over time and the prominence of managed care organizations in some places or the rise of private health systems in others, the legal discussion of informed consent has gradually changed, but the bioethical literature has not taken interest in these changes. He then explored this phenomenon, offered potential

explanations, and discussed the implications of these changes for bioethics more generally.

Video is available [here](#).

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:

Michael Sandel, What Money Can't Buy: The Moral Limits of Markets

Organized by the HLS Dean's Office

September 19, 2012

Book Talk and Panel Discussion: Obamacare on Trial, Einer Elhauge

Organized by the HLS Library, with participation by Profs. **Elhauge** and **Cohen**, and former Academic Fellow **Abby Moncrieff**

November 1, 2012

Massachusetts: A Community Approach to Quality, Affordable Health Care

Organized by the Center for Health Law Policy and Innovation

November 13, 2013

Conference: Putting the Label on the Table

Organized by the HLS Food Law Society

March 8-9, 2013

Film Screening and Discussion: deepSouth

Organized by the Center for Health Law Policy and Innovation

April 8, 2013

Conference: Universal Coverage in Developing Country Health Systems

Organized by the Program in Ethics and Health, with support from the Oswald DeN. Cammann Fund

April 18-19, 2013

Issues and Case Studies in Clinical Trial Data Sharing – What Have We Learned?

Organized by the Multi-Regional Clinical Trials Center, with substantial support from the Petrie-Flom Center, and participation by Executive Director Holly Fernandez Lynch and Faculty Co-Director Ben Roin

May 17, 2013

Contributions to HLS Teaching Program

2012-13 Curriculum

The diversity of the HLS curriculum has helped attract outstanding students interested in health law to Harvard, and will help prepare them for a variety of careers, both in academia and practice. For the 2012-2013 academic year, HLS offered a substantial number courses of interest to those looking to study health policy, biotechnology, and bioethics, including several taught by Center affiliates (represented in bold italics). A list of these classes is provided below, along with more detailed information regarding the workshop, reading group, and seminars offered by our leadership and fellows.

- ***Bioethics in the Courts***
 - Disability Law
 - Drug Product Liability Litigation
 - ***Embryos, Animals, and the Environment: Ethically Ambiguous Entities and the Law***
 - Food Law
 - Food Law and Policy Clinic of the Center for Health Law and Policy Innovation
 - Food and Drug Law
 - Food: A Health Law and Policy Seminar
 - Health Law
 - Health Law and Policy Clinic of the Center for Health Law and Policy Innovation
 - ***Health Law and Policy Workshop***
 - Insurance Law
 - Intellectual Property Law
 - Intellectual Property Law: Advanced
 - Law and Policy of Federal Funding Flows
 - Legal and Public Health Perspectives on Food Policy Reading Group
 - ***Patent Law***
 - ***Population-Level Bioethics***
 - Psychiatry and the Law
 - Reproductive Rights and Justice
 - Science, Junk Science, and CSI
 - The Politics of Health: A Center for Health Law and Policy Innovation Seminar
- Holly Fernandez Lynch***
Martha Field
Peter Grossi
Jeffrey Skopek
- Jacob Gersen
Robert Greenwald
- Peter Barton Hutt
Robert Greenwald
Mark Barnes
Robert Greenwald
- I. Glenn Cohen***
Einer Elhauge
Bruce Hay
Jeanne Fromer
William Fisher
Mark Barnes
Emily Broad Leib
- Benjamin Roin***
I. Glenn Cohen
Norman Daniels
Alan Stone
Mindy Roseman
Nancy Gertner
Robert Greenwald

- The Strategic Management of a Mass Tort: Legal & Business Challenges Arising from the COX-2 Inhibitor Litigations Amy Schulman

Health Law Policy and Bioethics Workshop

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 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 2012-2013 line-up is listed below:

- **Alan Wertheimer**, Department of Bioethics, National Institutes of Health Clinical Center: *Why is Consent a Requirement for Ethical Research?*
- **Nick Bagley**, University of Michigan School of Law: *Physician Bureaucrats: Why Medicare Reform Hasn't Worked*
- **Benjamin Roin**, Harvard Law School: *Why Drug Patents Are So Effective*
- **Michele Goodwin**, University of Minnesota School of Law: *Fetal Protection Laws: Moral Panic & The New Constitutional Battlefront*
- **Jon Kolstad**, Wharton School of Business, University of Pennsylvania: *Health Reform, Health Insurance, and Selection: Estimating Selection into Health Insurance Using the Massachusetts Health Reform*
- **Einer Elhauge**, Harvard Law School: *Solving the Patent Settlement Puzzle*
- **William Sage**, University of Texas at Austin Law School: *Antitrust Law, Health Reform, and Emerging Health Care Markets*
- **Terry Fisher**, Harvard Law School: *Developing Drugs for Developing Countries: Some Pieces of the Puzzle*
- **Paul Starr**, Princeton: *Law and the Fog of Health Care: Complexity and Uncertainty in the Struggle Over Health Policy*
- **Allison Hoffman**, UCLA Law School: *Reconceptualizing the Risk of Long-Term Care*

- **Nicholson Price**, Petrie-Flom Center: *Making Due in making Drugs: Innovation Policy and Pharmaceutical Manufacturing*
- **I. Glenn Cohen**, Harvard Law School: *Transplant Tourism: The Ethics and Regulation of International Markets for Organs*

Population-Level Bioethics Reading Group

This reading group, organized by Professors **I. Glenn Cohen** and **Norman Daniels** with support from the Oswald DeN. Cammann Fund, examined issues in ethics and health policy, including a basic account of justice and health; ethical critiques of maximization methodologies, including cost-effectiveness analysis; individual and social responsibility for health; and other topics. The course was taught by multiple instructors rotating between sessions, bringing together philosophical, medical, and legal bioethicists from across the university, some of the leading scholars in the world on these subjects. It was open to all Harvard graduate students; enrolled students came from HLS and FAS, with an auditor from the Advanced Leadership Initiative.

Professors and topics included:

Norman Daniels, HSPH

- Should unauthorized immigrants have insurance benefits under the ACA?
- Role of the courts in determining content of rights to health/health care

Daniel Wikler, HPSH

- Personal responsibility for health: justice and imprudence
- The "standard of care" controversy in "out-sourced" clinical trials
- Paternalism, "libertarian" and otherwise

Robert Truog, HMS

- Bed-side rationing

Holly Fernandez Lynch, HLS

- Is there a duty to participate in clinical research?

Daniel Brock, HMS (*cancelled due to illness*)

- Ethical issues in cost-effectiveness analysis

Nir Eyal, HMS

- Equality, priority, and leveling down
- Coercive approaches to physician maldistribution

Embryos, Animals, and the Environment: Ethically Ambiguous Entities and the Law

Academic Fellow **Jeffrey M. Skopek** taught this seminar in Spring 2013 to 15 JD and LLM students. Cutting across issues in bioethics, animal rights, and environmentalism, the course explored the law's treatment of entities whose ethical status is ambiguous and contested. The first section of the course was devoted to environmental entities, such as the climate, forests, and endangered species. With respect to the climate, for example, the course explored questions such as whether cap and trade regimes create a right to pollute by which they can be ethically differentiated from other regulatory strategies; how a carbon market approach to the problem of global warming conceptualizes the harm of emissions; and what conception of the "good" underlies this conception of harm. The second section of the course was devoted to animal entities, such as farm animals, legally protected animals, and chimeric animals. As to legally protected animals, for example, the course explored questions such as whether animal protection statutes create rights for animals; how the status of animals as property without standing shapes the answer this question; and whether animals should be granted standing or equitable self-ownership. The third section of the course was devoted to human entities, such as embryos, the brain dead, and future persons. Regarding future persons, for example, the course explored whether an activity can be considered harmful to a future person if it significantly alters the genetics of that person's embryo, such that it changes who the resulting person is; whether a law that prevents someone from coming into existence be justified by reference to the best interests of that person; and if it can be justified, in what circumstances and on what grounds. Across these categories, the course explored questions of legal and moral justification, asking whether rights and duties should be created on the basis of general categories, such as species membership; individual capacities, such as sentience or rationality; or another criteria, such as the meaning of an act or the virtue to which it contributes.

Bioethics in the Courts

Executive Director **Holly Fernandez Lynch** taught this seminar in Spring 2013 to 11 JD and LLM students, as well as 2 auditors. The course was sparked by the fact that bioethics is a field of many disciplines, but has been shaped in a number of ways by the law and lawyers. American courts in particular have played an important role, deciding cases in nearly every area of bioethical inquiry. Accordingly, the seminar provided a survey of these key cases, some famous and some less so. By the end of the semester, students developed a strong understanding of the legal background on several bioethics topics, as well as how the law has changed over time and which questions remain outstanding.

Topics covered included:

- Doctor-patient relationship, including informed consent and duty to warn
- Conscience in medicine and health care, from the perspective of institutions, physicians, pharmacists, and healthcare employees/employers
- Pregnancy, including abortion, maternal-fetal conflict, drug abuse and pregnant mothers, wrongful birth, and wrongful life
- Parenthood, including surrogacy, custody over embryos, posthumous parenthood, sperm donation, and paternity
- Sterilization and eugenics, including mental capacity and criminal behavior
- Mental health, including civil commitment and refusal of therapy
- End-of-life issues, including refusal of care/withdrawal of treatment and decision-making standards, futility, and physician-assisted suicide
- Genes, cells, and tissues, including patenting life, biology, and genes, specimen ownership, and stem cell research
- Human subjects research, including regulatory structure, historical background, research litigation, and international trials
- Access to care, including health care reform, experimental therapies, and care afforded to prisoners
- Organ donation, including definitions of death, property interests, insurance coverage, eligibility, and contamination
- Public health, including vaccination, quarantine, tobacco, and obesity
- Current issues at the intersection of bioethics and the First Amendment, including drug marketing, tobacco warnings, and food labeling

Participation of HLS Students in Program Activities

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

Student Fellowship Program

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

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

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.

The Center's 2012-2013 student fellows and projects were as follows:

Adriana Lee Benedict

Harvard Law School, JD 2014

"The Nature of Biotechnology Patents: A Tangled Doctrinal Web of Processes and Products that Can Catch All Genes but Save None"

Adriana is a Harvard Law School student interested in promoting access to medicines and biomedical research. She graduated from Harvard College with a concentration in History and Science, a secondary concentration in government, and a certificate in Mind/Brain/Behavior, and subsequently completed a Master of Science in the Department of Global Health and Population at the Harvard School of Public Health. Adriana has pursued health and human rights work in

Kenya, Tanzania, India, Peru and Colombia, and is currently the co-chair of the Harvard chapter of the [Universities Allied for Essential Medicines](#).

Adriana's research interests lie at the intersection of intellectual property and health law, public interest protections in international trade regimes, pharmaceutical research and licensing, and the international right to health. In the Fall, Adriana organized a panel event, *Open Access to Health Research: Future Directions for the NIH Public Access Policy*, which was financially sponsored by the PFC and is available [here](#). In December, Adriana traveled to Rio de Janeiro, Brazil, for the [2012 Global Congress on Intellectual Property and the Public Interest](#) with the support of a PFC conference travel grant.

For her student fellowship paper, Adriana examined the relevance of the natural phenomenon doctrine to diagnostic biotechnology patents with a view toward the relative weakness of doctrinal distinctions between process and product claims in this realm. The paper will be published in American University's *IP Brief*. In summer 2013, Adriana worked with Public Citizen's Access to Medicines Program as a Ford Foundation Law School Public Interest Fellow.

Jonathan Darrow
Harvard Law School, SJD 2013
"Crowdsourcing Clinical Trials"

Jonathan holds a BS in biological sciences from Cornell University, a JD from Duke University, and an MBA from Boston College. In 2009 he completed the LLM program at Harvard Law School, and became an SJD student. After admission to the bar, Jonathan practiced law in the Silicon Valley offices of Cooley Godward and later worked on patent litigation matters at Wiley Rein & Fielding in Washington, DC. He is admitted to practice before the USPTO. Prior to the LLM program, he served as a lecturer on law at Boston College and as Assistant Professor of Business Law at Plymouth State University. His legal scholarship on technology and intellectual property has appeared in numerous publications including the STANFORD TECHNOLOGY LAW REVIEW, THE JOURNAL OF LAW MEDICINE AND ETHICS, CASE WESTERN'S HEALTH MATRIX: THE JOURNAL OF LAW-MEDICINE, THE INDIANA LAW REVIEW, THE ALBANY LAW REVIEW, and THE HARVARD JOURNAL OF LAW & TECHNOLOGY. His co-authored textbook CYBERLAW: TEXT & CASES was published in 2012, and the next edition is under discussion. His second co-authored textbook, THE LEGAL ENVIRONMENT OF BUSINESS AND ETHICS (Wolters Kluwer) is forthcoming. In 2011, Jonathan examined the global impact of Intellectual Property during a stint at the World Trade Organization in Geneva, Switzerland, returning in 2012 to address global issues at the intersection of trade, intellectual property, and health, at the World Health Organization.

His fellowship project examined the potential for harnessing the distributed power of the Internet to more effectively capture drug use data and

simultaneously avoid the lack of informed consent that currently characterizes the administration of newly approved drugs. The resulting paper, "Crowdsourcing Clinical Trials," is forthcoming in the MINNESOTA LAW REVIEW.

In July, Jonathan began a full-time research position, examining issues of pharmaceutical policy and law, at Harvard Medical School. He has also accepted a 2-year judicial clerkship on the Court of Appeals for the Federal Circuit, the court that hears almost all U.S. patent appeals, to begin in 2014.

Katie Booth

Harvard Law School, JD 2013

"Cyber-Attacks on Medical Devices: Legal Gaps and Regulatory Solutions"

Katie graduated from Harvard Law School in 2013 with a focus on health care law. She attended Yale University, where she majored in English. Prior to law school, Katie worked for two years as a management consultant for pharmaceutical, biotech, and agribusiness companies. This past year, Katie was Editor-in-Chief of the HARVARD JOURNAL OF LAW AND TECHNOLOGY, which focuses on intellectual property law, health law, and technology law. During law school, Katie interned in the Health Care Fraud Unit of the United States Attorney's Office in Boston and in the Health Care Group at Ropes & Gray.

During her fellowship, Katie focused on the issue of cyber-attacks on medical devices, proposing legal and regulatory solutions to a growing problem. Her paper, "Cyber-Attacks on Medical Devices: Legal Gaps and Regulatory Solutions," will be published as an article in the SANTA CLARA COMPUTER AND HIGH TECHNOLOGY LAW JOURNAL. As a student blogger, Katie covered issues such as the New York City soda ban and the Affordable Care Act, and had her posts regularly picked up by other outlets.

Jonathan (Yoni) Schenker

Harvard Law School, JD 2013

"Health Worker Brain Drain: The Classification and Implementation of Financial Support Solutions"

Yoni's primary research interests involve the intersection of population-level bioethics and the law, including issues of health care access, ethical health care policy, and organ donation. He graduated from the University of Maryland, College Park, with degrees in Philosophy and Finance.

Yoni's fellowship project applied both of these areas, as well as his legal training to the problem of healthcare worker migration from developing countries, known as "brain drain." The recently adopted *Global Code of Practice on the International Recruitment of Health Personnel* recommended that

"financial support" solutions be implemented. Yoni attempts to enumerate the various theories under which a financial support solution could be implemented. He also classifies existing financial support proposals within these theories, and proposes a solution of his own. He argues that many of them can actually be framed without attributing moral responsibility to the payer of the support. Finally, he discusses possible avenues of implementation for various existing proposals.

Patrick O'Leary
Harvard Law School, JD 2013
"Policing Research Misconduct"

Patrick graduated from Georgetown University *magna cum laude* with a degree in religious studies. Before law school he worked as an AmeriCorps member at the Capital Area Food Bank in Washington, DC. His research focuses on FDA regulation, U.S. innovation policy, and enforcement in health care and FDA-regulated industries. He is particularly interested in the tension between federal policies promoting innovation in and commercialization of biomedical research and the government's consumer protection and public health missions.

During his fellowship year, Patrick published a Recent Development article focusing on the FDA user-fee system in the *HARVARD JOURNAL ON LEGISLATION*. He also published a law review article about the *Park Doctrine* in the *FOOD AND DRUG LAW JOURNAL* and presented this paper at the Petrie-Flom Center's annual conference.

Patrick's fellowship paper focused on the regulation of basic and clinical research under the Federal Policy on Research Misconduct and the FDA's Application Integrity Policy. Patrick plans to submit this paper as well as an article relating to the regulation of the American dairy industry to law reviews during the next submissions cycle.

Internship Program

This year, we launched the Petrie-Flom Center's first student internship program, open to all undergraduate and graduate students at Harvard, but particularly those studying health policy, philosophy, bioethics, law, medicine, business economics, and the sciences.

The internship involves two primary components: (1) attending the Center's events, including the Health Law Policy and Bioethics Workshops and various other programs; and (2) assisting with various Center projects. These projects included:

- Blog development and regular posting at [Bill of Health](#), including “Weekly Round-ups” of relevant news stories and Twitter feeds, as well as substantive topical posts
- Website updating and content development, including identification of key topical resources for those interested in the field, career-related resources, and relevant programs, centers, courses, etc. around Harvard and beyond
- Research assistance, including literature reviews, assistance with book proposals, support of sponsored projects, etc.
- Reporting on Center events, and assistance with event advertising
- Development of the Petrie-Flom Center’s social media presence
- Development of relevant contact lists for Center communications
- Tracking news related to the Center and its areas of interest

The internship program was created in response to popular demand from students interested in becoming more involved with the Center, and interns were selected after a competitive application process. Our 2012-2013 interns included:

Daniella Adler (Fall)
Harvard Law School, JD 2014

Daniella graduated from Queens College, City University of New York (Phi Beta Kappa) with majors in English and History, and minors in Honors in the Humanities and Psychology, as well as a certificate in Honors in Math and Natural Sciences. While at Queens College, Daniella completed a research internship at North Shore University Hospital and worked as a research assistant in a psychology lab. Her interest in how law affects the delivery of health services was spurred by the recent healthcare debate. She is also interested in technology and biotechnology, and is a line editor for the Journal of Law and Technology.

Thomas Hwang (Spring)
Harvard College, BA 2013

Thomas graduated in 2013 with a self-directed Special Concentration in Biomedical Innovation and Health Policy. He is interested in health economics, administrative law, innovation and ventures in life sciences, and neurological and neglected diseases. Previously, he worked at the White House on US health reform; World Health Organization on tuberculosis drug policy; and Blackstone and Goldman Sachs on healthcare finance.

Hyeongsu Park (Fall and Spring)
Harvard Law School, JD 2014

Hyeongsu is interested in biotechnology and health law. He majored in Biological and Environmental Engineering at Cornell University, where he studied DNA nanospheres for an effective drug delivery system. He is involved in the HARVARD JOURNAL OF LAW AND TECHNOLOGY as a subciter and member of the Submission Committee. He has worked as a summer associate in the Intellectual Property Team of Kim & Chang, a prestigious Korean law firm in Seoul.

Sara Providence (Spring)
Harvard College, BA 2014

Sara is studying Human Evolutionary Biology, and is passionate about issues of education, inequality, and health in urban areas. She serves as Co-Chief Executive Officer of Smart Woman Securities, an organization devoted to educating college women about business and personal finance, and teaches mental health classes to teenagers as a Peer Health Exchange health educator.

Serena Shen (Fall and Spring)
Harvard Graduate School of Arts and Sciences

Serena is a Ph.D. student in the Department of Organismic and Evolutionary Biology, Harvard Graduate School of Arts and Sciences. She earned her B.S. in biology from China's Peking University before she started her graduate research in neuroscience and genetics at Harvard. Serena has been interested in the intersection of law, bioethics and advances in biomedical sciences since her college years, when she conducted an independent undergraduate research project on the ethical issues related to organ transplant and brain death.

Cassandra (Casey) Thomson (Fall and Spring)
Harvard College, BA 2013

Casey recently graduated with a degree in Social Studies (Politics and Art in the Middle East) and a secondary in Global Health and Health Policy. She is particularly focused on issues of bioethics and human rights, especially in relation to women, though she is also greatly interested in global health concerns and health law policy at the national and international levels. She has previously worked to encourage study amongst high schoolers of the situation of AIDS in Latin America through her work with the international conference HACIA Democracy.

Kathy Wang (Summer and Fall)
Harvard College, BA 2014

Kathy is studying Government and pursuing a secondary in Global Health and Health Policy. Her interests primarily lie in considering ethics, especially in terms of medicine and science practices, health policy topics, human rights, and global health issues.

Jennifer Wong (Fall and Spring)
Harvard Law School, JD 2014

Jen is interested in pharmaceutical patent law and the ethical implications of biomedical research. She graduated from the University of British Columbia where she majored in Pharmacology. Prior to coming to law school, Jennifer worked as an intern for Roche researching potential hepatitis C virus treatments. She has also spent time researching the effects of sleep deprivation on rat neurophysiology. Jennifer also serves as Patents and Trade Secrets coordinator for the HARVARD JOURNAL OF LAW AND TECHNOLOGY'S online companion JOLT Digest.

Faculty Participation

As noted throughout this report, faculty participation in the Petrie-Flom Center is both strong and essential. In addition to the clear investment by the Faculty co-Directors **I. Glenn Cohen** and **Benjamin Roin**, and Founding Director **Einer Elhauge**, other faculty members from around the university have traditionally been informally involved through attendance and participation in the Center's Health Law Policy and Bioethics Workshop and other programmed events. As described below, several faculty members are also involved with our blog, [Bill of Health](#).

In order to expand faculty involvement and build connections across campus, this year the Center undertook an initiative to build a substantial cohort of formally affiliated Harvard faculty. Beginning in May 2013, we reached out to a range of faculty members who pursue scholarship in the realm of health law policy, biotechnology, and bioethics, including several with whom we have collaborated strongly in the past and others with whom we hope to work more closely with in the future. We plan to list these individuals as affiliates on our website and invite them to blog at [Bill of Health](#). We will also work with these affiliates to plan and promote Petrie-Flom events, include them in internal workshops used to allow our academic and student fellows to test out new ideas and get feedback on early drafts, and encourage them to develop mentoring relationships with interested students and post-docs. Most importantly, we will rely on affiliated faculty from various disciplines as a sounding board for strategies for expanding the Center and its influence.

Although we will not offer funding or research support, we see this as a first step toward trying to bring together our diverse faculty from around Harvard who share our fields of academic interest. Accordingly, we will facilitate collaboration between faculty affiliates however we can. So far, we have a commitment from the following individuals to join us:

- [David Altshuler](#), Ph.D., M.D., Director, Program in Medical and Population Genetics, The Broad Institute
- [Kate Baicker](#), Ph.D., Professor of Health Economics, Harvard School of Public Health
- [Mark Barnes](#), J.D., Lecturer on Law, Harvard Law School; Partner, Ropes & Gray
- [Barbara Bierer](#), M.D., Professor of Medicine, Harvard Medical School; Senior Vice President, Research and Director, Center for Faculty Development & Diversity, Brigham and Women's Hospital
- [Dan Brock](#), Ph.D., Frances Glessner Lee Professor of Medical Ethics, Department of Global Health and Social Medicine, Harvard Medical School
- [Eric Campbell](#), M.A., Ph.D., Professor of Medicine, Harvard Medical School; Director of Research, Mongan Institute for Health Policy, Massachusetts General Hospital

- [Dan Carpenter](#), A.M., Ph.D., Allie S. Freed Professor of Government, Director of the Center for American Political Studies, Faculty of Arts and Sciences, Harvard University; Director of the Social Sciences Program, Radcliffe Institute for Advanced Study
- [Amitabh Chandra](#), M.A., Ph.D., Professor of Public Policy, Director of Health Policy Research, Harvard Kennedy School of Government
- [Mike Chernew](#), Ph.D., Professor of Health Care Policy, Harvard Medical School
- [Greg Curfman](#), M.D., Assistant Professor of Medicine, Harvard Medical School; Executive Editor, New England Journal of Medicine
- [David Cutler](#), Ph.D., Otto Eckstein Professor of Applied Economics, Harvard University
- [Norman Daniels](#), Ph.D., Mary Saltonstall Professor of Population Ethics and Professor of Ethics and Population Health, Harvard School of Public Health
- [Arnold Epstein](#), M.D., John H. Foster Professor of Health Policy and Management, Harvard School of Public Health
- [Nir Eyal](#), DPhil, Associate Professor of Global Health and Social Medicine, Harvard Medical School
- [William \(Terry\) W. Fisher](#), William Hale Professor of Intellectual Property Law; Faculty Director, Berkman Center for Internet and Society, Harvard Law School
- [Richard Frank](#), Ph.D., Margaret T. Morris Professor of Health Economics, Harvard Medical School
- [Judge \(retired\) Nancy Gertner](#), M.A., J.D., Professor of Practice, Harvard Law School
- [David Grabowski](#), Ph.D., Professor of Health Care Policy, Harvard Medical School
- [Robert Greenwald](#), J.D., Managing Director, Legal Services Center; Director, Center for Health Law and Policy Innovation; Clinical Professor of Law, Harvard Law School
- [Sofia Gruskin](#), J.D., MIA, Adjunct Professor of Global Health, Harvard School of Global Health
- [Robert Huckman](#), Ph.D., Albert J. Weatherhead III Professor of Business Administration, Harvard Business School
- [Haideen Huskamp](#), Ph.D., Professor of Health Care Policy, Harvard Medical School
- [Peter Barton Hutt](#), J.D., Lecturer on Law, Harvard Law School; Senior Counsel, Covington & Burling
- [Steve Hyman](#), M.D., Director, Stanley Center for Psychiatric Research, The Broad Institute
- [Sheila Jasanoff](#), J.D., Ph.D., Pforzheimer Professor of Science and Technology Studies, Harvard Kennedy School
- [Frances Kamm](#), Ph.D., Littauer Professor of Philosophy and Public Policy, Kennedy School of Government, Professor of Philosophy, Faculty of Arts and Sciences, Harvard University
- [Aaron S. Kesselheim](#), M.D., J.D., MPH, Assistant Professor of Medicine, Harvard Medical School; Research Associate, Harvard School of Public Health
- [David Korn](#), M.D., Professor of Pathology, Harvard Medical School

- [Lisa Lehmann](#), M.D., Ph.D., Director, Center for Bioethics, Brigham and Women's Hospital; Associate Professor of Medicine and Medical Ethics, Harvard Medical School
- [Michelle Mello](#), J.D., Ph.D., M.Phil, Professor of Law and Public Health, Harvard School of Public Health
- [Christine Mitchell](#), RN, MS, MTS, Associate Director of Clinical Ethics, Division of Medical Ethics, Harvard Medical School; Director, Office of Ethics, Children's Hospital Boston
- [Joseph Newhouse](#), Ph.D., John D. MacArthur Professor of Health Policy Management, Harvard University
- [Chris Robertson](#), J.D., Ph.D., Visiting Professor, Harvard Law School
- [David Rosenberg](#), J.D., Lee S. Kreindler Professor of Law, Harvard Law School
- [Meredith Rosenthal](#), Ph.D., Professor of Health Economics and Policy, Harvard School of Public Health
- [Sadath Sayeed](#), J.D., M.D., Assistant Professor, Harvard Medical School
- [Eric Schneider](#), M.D., MSc, Associate Professor, Harvard Medical School
- [Michael Stein](#), Visiting Professor, Harvard Law School
- [Mildred Solomon](#), Ed.D., President & CEO, The Hastings Center; Clinical Professor of Anesthesia, Harvard Medical School
- [Alan Stone](#), M.D., Touroff-Glueck Professor of Law and Psychiatry, Harvard Law School
- [Katherine Swartz](#), Ph.D., M.S., Professor of Health Policy and Economics, Harvard School of Public Health
- [Patrick Taylor](#), J.D., Staff Scientist and Director, Ethics Analysis and Applications, Children's Hospital Informatics Program
- [Robert \(Bob\) Truog](#), M.D., Professor of Medical Ethics, Anesthesiology, and Pediatrics, Harvard Medical School; Senior Associate in Critical Care Medicine, Children's Hospital Boston
- [Dan Wikler](#), Ph.D., Mary B. Saltonstall Professor of Population Ethics, Harvard School of Public Health
- [Richard Zeckhauser](#), Ph.D., Frank P. Ramsey Professor of Political Economy, Harvard Kennedy School

We look forward to developing this opportunity of expansive faculty involvement to help offer a centralized location within the university for faculty sharing a collective interest in our fields.

Connections to the Community and Professions

The Center's regular programming focuses on pressing policy issues and is open to the public/posted to our website, thereby reaching the community in a general way. In addition, our affiliates are regularly sought after to provide media commentary on news stories in our fields. However, every year the Center also endeavors to undertake more directed efforts to reach beyond the walls of academia. These efforts create opportunities not only to disseminate scholarship to influence policy, but also to inform Center affiliates' scholarship through perspectives from the real world.

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

New Blog: Bill of Health

Our most important community outreach effort in the past year was without question the September 2012 launch of our new collaborative blog, [Bill of Health](#). The blog is co-edited by **I. Glenn Cohen** and **Holly Fernandez Lynch**, but includes a variety of regular and guest bloggers from the Petrie-Flom Center, Harvard, and beyond; the full list of contributors can be viewed [here](#). Our goal is to provide a one-stop shop for readers interested in news, commentary, and scholarship in the fields of health law policy, biotechnology, and bioethics.

Since our launch a year ago, nearly 85,000 unique visitors have come to the site from the US, UK, Canada, India, Australia, Spain, Germany, Brazil, the Philippines, and elsewhere, and we have an average of about 400 visitors per day. The posts – several per day – cover such topics as abortion, human subjects and animal research, cloning, conflicts of interest, conscience, reproductive health and technology, biotechnology, disability, the doctor-patient relationship, end-of-life issues, enhancement, FDA regulation and pharmaceutical policy, the First Amendment, genetics, global health, GMO food, health care finance, health care reform, health information technology, intellectual property, medical privacy, medical safety and quality, medical tourism, mental health, neuroscience, obesity, organ donation, personal responsibility for health, research misconduct, resource allocation, stem cells, and vaccines, among a variety of others. We host online symposia bringing together a variety of expert commentators to offer their perspective on a given issue, and also regularly post information regarding upcoming events of interest, funding opportunities, and job announcements. We

encourage substantial dialogue through online comments, and we welcome guest posts and cross-posts to related blogs.

Our first year has been quite successful, and we look forward to continuing to develop this online forum in the years to come.

Events with Industry Participation

Life Sciences Industry Compliance Project

In Fall 2012, the Petrie-Flom Center was approached by a colleague from the Multi-Regional Clinical Trials Center at Harvard about the possibility of facilitating a project to advance the development of a model life sciences industry compliance framework. This framework would offer user-friendly, workable, prospective guidance on the key elements of life sciences industry compliance, incorporating materials currently referenced by compliance programs, including the Federal Sentencing Guidelines, OIG Guidance for Pharmaceutical Manufacturers, Voluntary PhRMA Trade Association Code, Voluntary AdvaMed Trade Association Code, and industry standards. Ultimately, the goal of such a framework would be to reduce the complexity, uncertainty, and costs of building or maintaining an effective compliance program that reflects the expectations of both the regulated industry and of government regulators/enforcers.

In order to give due consideration to the possibilities, the Petrie-Flom Center hosted a closed exploratory meeting in February 2013 which brought together a variety of stakeholders from industry, private legal practice, government, academia, and various non-profit groups to discuss whether there was a need for such a model framework; what it might look like; how it might be funded, organized, and implemented; and whether the Petrie-Flom Center might be an appropriate institutional host. The meeting also included an open panel discussion with experts on the evolution of modern life sciences industry compliance programs, problems, and potential solutions. (More detail on this event can be found above.)

Following the exploratory meeting, we spoke to a number of life sciences industry compliance officers, compliance experts, general counsels, and other stakeholders to determine whether there would be adequate interest in pursuing a project that would advance transparent standards by which to assess the claim that a company has an "effective" compliance program, as well as further flesh out the content of a model program. However, as was evident in February, the main outstanding questions regarding this effort had to do with the extent to which the government might participate. We are currently awaiting some additional efforts by industry to pursue various possibilities. Should there be support to pick up this project at some point in the future, we may consider serving a facilitating (or more substantial) role. For now, we plan to consider hosting industry-government-stakeholder

roundtables and other efforts to advance the discussion. We have also developed relationships with industry groups such as PhRMA and AdvaMed, key life sciences industry counsel, former prosecutors, and government officials that we plan to pursue as appropriate in the future.

The FDA in the 21st Century

As noted above, this year's Petrie-Flom Center annual conference addressed a number of current issues facing the Food and Drug Administration and regulated industries. Our plenary speakers were each highly esteemed members of the FDA bar, our keynote address was delivered by FDA's Deputy Commissioner for Global Regulatory Operations and Policy, and several panelists were current or former industry attorneys. In addition, the conference was attended by legal practitioners in government, industry, and private practice; policymakers in the U.S. and abroad; academics in law, medicine, public health, and public policy; the media; and the lay public.

Issues and Case Studies in Clinical Trial Data Sharing: Lessons and Solutions

The Petrie-Flom Center co-sponsored this day-long [conference](#) with the Multi-Regional Clinical Trials Center at Harvard on a topic of particular relevance to the life sciences industry, governing bodies, and research funders: clinical trial data sharing. The conference was heavily attended by industry and government personnel from around the world, who came together to develop practical policy recommendations regarding the best system for data sharing that will balance the needs and interests of patients with the intellectual property and business interests of data generators.

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 actively participate in joint projects wherever appropriate.

This year, our major collaborative efforts included:

- Efforts to initiate the JOURNAL OF LAW AND BIOSCIENCES, with colleagues at Duke and Stanford
- Sponsored research proposals with Harvard Catalyst
- Book projects based on our conferences, with authors from a variety of institutions
- Work with the Multi-Regional Clinical Trials Center at Harvard, including both the conference noted above and **Holly Fernandez Lynch**'s membership on the MRCT Center's ethics working group, which is working to improve the efficiency and effectiveness of ethics committee reviews while maintaining the quality and safety of clinical trials

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

- Edmond J. Safra Center for Ethics
- The Fenway Institute
- Harvard Global Health Institute
- Harvard Program in Ethics and Health
- Harvard Stem Cell Institute
- HLS American Constitution Society
- HLS Center for Health Law Policy and Innovation
- HLS Chapter: Universities Allied for Essential Medicines
- HLS Dean's Office
- HLS Democrats
- HLS Food Law Society
- HLS Human Rights Program
- HLS Program on the Legal Profession
- HLS Republicans
- HMS Division of Medical Ethics
- Multi-Regional Clinical Trials Center at Harvard
- The New England Journal of Medicine

Finally, we have also taken a number of steps to strengthen our existing relationships with the Division of Medical Ethics at Harvard Medical School and the Center for Health Law Policy and Innovation at Harvard Law School as collegial key players in bioethics and health policy. Our specific plans for working together in the future are described in further detail below.

2013-14 Plans for Activities

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

As we pursue these goals, we will continue efforts to prepare our Academic Fellows for the law teaching market and to place them in top teaching jobs. We will also support the scholarly development of several student fellows, and the work of our affiliated faculty. In addition to offering a substantial amount of programming, some of our more specific goals and plans for building the Center – while still tentative – are described below.

Research, Scholarship, and Project Activities

Sponsored Research

As described above, we have two sponsored research projects that we hope to launch in the 2013-2014 academic year: the Harvard Integrated Program to Protect and Improve the Health of Professional Football Players and the Harvard Catalyst Clinical and Translational Science Award. We may also pursue additional sponsored research projects related to defining and measuring the quality and effectiveness of Institutional Review Boards and regulatory barriers to research with controlled substances that may be useful in the treatment/palliation of HIV/AIDS patients.

Academic Fellows

This year, we are pleased to welcome **Matthew J.B. Lawrence** to the Center as an Academic Fellow for the 2013-2015 fellowship term. In 2009, Matt earned a J.D. *magna cum laude* from New York University School of Law, where he was Managing Editor of the N.Y.U. LAW REVIEW and was awarded the Paul D. Kaufman Memorial Prize for writing the most outstanding note. After law school, Matt clerked for the Honorable Douglas H. Ginsburg of the United States Court of Appeals for the District of Columbia Circuit, and then became a Trial Attorney at the Federal Programs Branch of the United States Department of Justice. There he served as attorney of

record for the United States defending federal agency action against statutory and constitutional challenges in district and appellate court, including numerous high-stakes Medicare cases.

Matt's methodological approach is to investigate, by employing a combination of theory and available empirical data, the ways that the design of decision-making processes influences the behavior of participants. His past work has applied this focus to medical malpractice and civil procedure. His current work applies this approach to the federally-mandated procedures that govern disputes about healthcare coverage between patients and their insurers (in the private sector as well as Medicare and Medicaid).

Jeffrey M. Skopek will continue his research on anonymity, privacy, and biotechnologies of surveillance and identification, in addition to starting a new project on biobanking and the control of tissue. He is currently on the entry-level law professor teaching market and will complete his fellowship in Summer 2014.

Finally, **W. Nicholson Price II** is also pursuing placement on the entry-level law professor teaching market. His future scholarship will focus on two areas: further exploring the use of regulatory mechanisms to mediate intellectual property incentives, and examining the legal implications of machine-learning-based personalized medicine.

Faculty

In the summer of 2013, the Center once again provided research support to **Prof. Cohen, Roin, and Elhauge**.

I. Glenn Cohen worked on his book *PATIENTS WITH PASSPORTS: MEDICAL TOURISM, LAW, AND ETHICS* (under contract, Oxford University Press) and two new articles coming out in *LAW AND CONTEMPORARY PROBLEMS* on organ markets. In addition, he submitted the manuscript for *THE FUTURE OF HUMAN SUBJECTS RESEARCH REGULATION* (under contract, MIT Press) (co-editor with Holly Fernandez Lynch). He also continued work on *IDENTIFIED V. STATISTICAL LIVES: ETHICAL, LEGAL, AND MEDICAL PERSPECTIVES* (under contract, Oxford University Press) (co-editor with Nir Eyal and Norman Daniels).

Benjamin Roin worked on a paper about how we can encourage pharmaceutical companies to develop new indications for older drugs and enable more efficient drug pricing by using e-prescribing and e-health records to facilitate differential drug pricing by indication. He also completed another paper entitled *Intellectual Property versus Prizes: Reframing the Debate*. This paper compares the proposals to replace drug patents with prizes against the currently utilized model of government-subsidized

prescription drug insurance, and through this comparison, argues that for the past 200 years, scholars have misunderstood the distinction between intellectual property and prizes. It argues that drug patents serve an important social function even when the government controls drug prices, and that all of the asserted benefits from switching to a prize system could be captured through government-subsidized prescription drug insurance.

Einer Elhauge finished his chapter, "Obamacare and the Theory of the Firm," and presented it both at the HLS faculty workshop and to Medicare officials. He also drafted an article tentatively titled "The Welfare Effects of Metering Ties" and another tentatively titled "Rehabilitating Jefferson Parish: Why Ties without a Substantial Foreclosure Share Should Not Be Per Se Legal," as well as an article on the Supreme Court's Medicaid expansion decision. He also continued work on his book addressing legal regulation of re-engineering human biology.

In addition, the 2013 Tulsa Law Review Symposium, *Health Law Policy: Legal Issues in the Evolving Healthcare Market*, will honor the work of **Einer Elhauge**, and feature contributions from several Petrie-Flom affiliates:

I. Glenn Cohen

What, if Anything, is Wrong with Enhancement? What, if Anything, is Right?

Abigail R. Moncrieff (former Petrie-Flom Academic Fellow)

Elhauge, Originalism, and the ACA: The Trouble with Popular Constitutionalism

Christopher Robertson (former Petrie-Flom Academic and Student Fellow)

A Presumption Against Healthcare Consumption

Talha Syed (former Petrie-Flom Academic Fellow)

Rights Versus Distributive Approaches to Allocating Healthcare

Visitors

We plan to host a variety of visitors at the Petrie-Flom Center this academic year, including Visiting Professor, **Christopher Robertson**, and several Visiting Scholars listed below. 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 present on the topic of their research at a public lecture, and blog about their work at [Bill of Health](#).

Christopher Robertson

HLS Visiting Associate Professor, Academic Year 2013-14

Christopher Robertson will be Visiting Associate Professor at Harvard Law School for the 2013-2014 academic year, during which time he will be co-teaching the Health Law Policy and Bioethics Workshop with Professor Cohen, and teaching courses on Health Law and Torts.

Professor Robertson is currently Associate Professor of Law at the University of Arizona James E. Rogers College of Law. He graduated magna cum laude from Harvard Law School, where he served as a Student Fellow and Academic Fellow at the Petrie-Flom Center, as well as lecturer, and where he has been a Research Associate at the Edmond J. Safra Center for Ethics Institutional Corruption Lab since 2010. He earned a doctorate in Philosophy at Washington University in St. Louis, where he also taught bioethics.

As a practicing attorney, Professor Robertson's legal practice has focused on complex litigation, medical and scientific disputes, and insurance cases, including trials and argument in the federal circuit courts. As an academic, his research falls into three related areas. First, he explores the problems that arise when laypersons (whether jurors, consumers, or patients) must rely upon expert advice in contexts of potential bias, and he develops institutional solutions that may help laypersons make better decisions. Second, he develops empirical data on the impact of unpredictable medical events on home foreclosures and other consumer finances, and explores how the law can be reformed to better protect consumers. Third, he contributes to debates in biomedical ethics, bringing insights from empiricism, law, and political philosophy.

Cansu Canca

Petrie-Flom Center Visiting Scholar, January 2012-December 2013

Cansu Canca will continue her affiliation with the Center (described above) for the remainder of the 2013 calendar year.

Kuei-Jung Ni

Petrie-Flom Center Visiting Scholar, August 2013-July 2014

Kuei-Jung Ni is Professor of Law and Director at the Institute of Technology Law, National Chiao Tung University (NCTU) in Taiwan, where he has been a faculty member since 2000. Professor Ni specializes in international economic law, international environmental law, and biotechnology law. His present research aims at exploring transnational regulations on biotechnology products and developments, including normative works of competent international regimes

such as WTO, WIPO and the Biodiversity Convention, and national implementations as well. He has written dozens of articles appearing in trade, environment, and health law journals, including *Does Science Speak Clearly and Fairly in Trade and Food Safety Disputes? The Search for an Optimal Response of WTO Adjudication to Problematic International Standard-Making*, 68 FOOD & DRUG L.J. 97 (2013).

In 2013, he was awarded a Senior Fulbright Research Grant to support one-year of research in the United States. In addition, to enhance academic exchange between Taiwanese institutions and Harvard University, Professor Ni's visit at the Petrie-Flom Center will be mainly funded by the Taiwan Top University Strategic Alliance (TUSA).

As a Visiting Scholar, Professor Ni plans to pursue a project entitled "Food Safety and Risk Governance: A Comparative Approach." Trade in food and agriculture products has increased significantly in the global market during the past several decades. The modern process of food production using bio-technological methods to promote production has aroused heated debates and disputes regarding the potential risks to human health. Several countries tend to apply a precautionary policy to regulate products involving scientific uncertainties or indefinite risks. However, the restrictions of such food trade may be considered as no-tariff barriers, which may fall short of necessity or constitute discrimination. There is a strong demand to legalize and optimize the national risk governance regime for food safety in order to safeguard national health and to satisfy requirements of international trade rules as well. The European Union (EU) since 2002 has established a sound risk governance system on food safety. In 2010, the US enacted the Food Safety Modernization Act (FSMA) to demonstrate the resolve to prevent the public from food risks. Based on a comparative study of the most responsive risk governance regimes of the US and EU, and international requirements as well, Professor Ni plans to analyze the legal implications and practices of these regulations.

Timo Minssen

Petrie-Flom Center Visiting Scholar, December 2013-February 2014 (tentative)

Timo Minssen is currently Associate Professor in Intellectual Property & Innovation Law at the University of Copenhagen (UCPH), Centre for Information & Innovation Law (CIIR), Denmark. After graduating from law school in Göttingen (Germany) in 2001, he was trained in the German court system. He also passed the Swedish "juris licentiate" and "juris doctor" exams and holds two IP & Biotech-related masters degrees from the Universities of Uppsala & Lund (Sweden). In addition he worked for a life science company and for various law firms in Sweden & Germany. From 2005-2006, Professor Minssen has been a stipendiate at the Max Planck Institute for Intellectual Property and Competition Law in Munich. He was also responsible for a course in comparative patent law

at the Chicago-Kent College of Law (USA) and worked for the European Patent Office. At Lund University he was engaged in interdisciplinary research at the Pufendorf Institute for Advanced Studies. He is co-leading UCPH's Biotech & Pharma Forum and teaches international classes in EU-, Competition-, and Pharmaceutical Law & IPR. Professor Minssen is a frequent speaker on a variety of topics and has published extensively in comparative patent law, EU- and Competition Law. Since joining UCPH in 2009 he organized international conferences (e.g. CPH Stem Cell Symposium) and developed two new courses at UCPH ("CSU 2012 in Pharma Law & Policy for professionals" & "EU Pharma Law, IPR, and the Life Sciences"). In addition he is co-PI and steering committee member in four major interdisciplinary projects focusing on legal issues in biobanking, synthetic biology, user generated law & new EU research infrastructure (e.g. ESS and Max IV to be build in Lund).

While visiting the Petrie-Flom Center, Professor Minssen will work on an international publication of his 2012 PhD thesis "Assessing the Inventiveness of Bio-Pharmaceuticals under European & US Patent Law: A comparative study with special emphasis on DNA & protein-related technology" with an international US or UK publisher. This book provides a detailed examination of the relevant legal framework and case-law developments relating to the European and U.S. assessment of the inventive step/non-obviousness requirement. More specifically, this study aims to scrutinize aspects that are particularly crucial to the (bio-) pharmaceutical industry. Special emphasis is laid on DNA-related technology and the "obvious to try" issue. The final chapters discuss the findings stemming from the analysis from a broader innovation policy-perspective and provide recommendations on how to address future challenges.

Professor Minssen also plans to pursue collaborative article writing and other projects with Harvard affiliates during his stay, and to organize a public workshop.

Aziza Ahmed

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

Aziza Ahmed is Assistant Professor of Law at Northeastern University 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.

Professor Ahmed has served as an expert member of the Technical Advisory Group on HIV and the Law convened by the United Nations Development Programme (UNDP) and as an expert for the American Bar Association (ABA).

She is on the board of the Center for Health and Gender Equity (CHANGE) and the Sexuality Information and Education Council of the United States (SIECUS). Professor Ahmed has served as a peer referee for numerous publications including THE LANCET, THE BULLETIN OF THE WORLD HEALTH ORGANIZATION, GLOBAL PUBLIC HEALTH, THE JOURNAL OF THE INTERNATIONAL AIDS SOCIETY, AMERICAN JOURNAL OF PUBLIC HEALTH, and THE SIGNS JOURNAL OF WOMEN IN CULTURE AND SOCIETY. She has also served as a grants referee for several funding institutions. Professor Ahmed has received grants from the Ford Foundation and the Northeastern University School of Law Health Law and Policy Seed Grant Initiative.

Prior to joining the Northeastern faculty, Professor Ahmed was a research associate at the Harvard School of Public Health Program on International Health and Human Rights. She came to that position after a Women's Law and Public Policy Fellowship with the International Community of Women Living with HIV/AIDS (ICW). She has worked on issues related to HIV and the law in a variety of settings including South Africa, Namibia, India, the United States and the Caribbean, and has consulted with various United Nations agencies and international and domestic non-governmental organizations.

Professor Ahmed holds a J.D. from the University of California Berkeley, an MS in Population and International Health from the Harvard School of Public Health, and a BA from Emory University.

As a visitor at the Petrie-Flom Center, Professor Ahmed plans to pursue work on the following projects: Public Health, Medical, and Scientific Expertise in Abortion Jurisprudence; Criminal Laws on Sex Work and HIV Transmission; and Science and Law of the HIV Epidemic: Implications for Race and Health.

Book Projects

As has become common practice, Faculty Co-Director **I. Glenn Cohen** and Executive Director **Holly Fernandez Lynch** will 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 Spring 2014, we anticipate release of our volume **The Future of Human Subjects Research Regulation** from MIT Press, which is based on our 2012 annual conference and described below:

Although there have been many books written on the ethics of human subjects research and several that address the inadequacies of the current regulatory approach, THE FUTURE OF HUMAN SUBJECTS RESEARCH REGULATION is the first to bring together authors from various disciplines all responding to the single question:

how should human subjects research be regulated today and in the future? The result is a collection of novel and diverse ideas for how to make the system better, some revolutionary and others incremental, but each directed at real-world policy change. Readers will be exposed to some of the major debates in the field of human subjects research oversight, and take away not only an understanding of the nuance involved in regulating this burgeoning enterprise, but also an understanding of the multitude of options for doing so.

Now is the perfect time to launch a reexamination of the existing regulatory system because attention is high and change is plausible. In July 2011, the U.S. Department of Health and Human Services released a much-touted Advanced Notice of Proposed Rulemaking (ANPRM) titled "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators." This ANPRM proposed to substantially amend the main federal regulations governing human subjects research (known as the "Common Rule") for the first time in twenty years. When the public comment period ended, the Department had received more than 1100 submissions over the course of only three months, signaling the high level of interest in this issue. In addition, in September 2011, President Obama's Commission for the Study of Bioethical Issues made a number of recommendations to improve the regulatory protection of subjects in federally-funded research. Moreover, as our book details, the increasing globalization of human subjects research and the need to harmonize divergent approaches suggests we are at a moment when the regulatory scheme is ripe for re-thinking. So much has changed in the recent past, from multi-regional clinical trials, to the expansion of Institutional Review Board review, to the increasing use of biospecimens for research purposes that this is the perfect time for a book on the future of research regulation. Indeed, the fact that the regulators themselves are considering change indicates that this book will arrive at a moment when it is likely to have the most impact in shaping that future.

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We are also in the midst of seeking a publisher for our volume **The Food and Drug Administration in the 21st Century**, based on our 2013 annual conference:

The Food and Drug Administration bears the monumental task of safeguarding the public health through regulation of food, drugs and biologics, devices, cosmetics, animal products, radiation-emitting products, and now, tobacco; nearly twenty-five cents of every dollar spent in the U.S. is spent on a product regulated by FDA. The agency faces perennial issues related to funding, relationships with industry, and striking the proper balance between consumer choice and consumer protection. It also confronts distinctly modern challenges related to globalization, novel technologies, newly added responsibilities, and changing threats to the public health.

THE FOOD AND DRUG ADMINISTRATION IN THE 21ST CENTURY is the first book to bring together authors from a diversity of disciplines and professions to offer insight into how the United States government's oldest comprehensive consumer protection agency is faring today and how it ought to change moving forward. What are the greatest challenges to the FDA's success, and what does success look like? What lessons has it learned and how can it best meet modern challenges? Should we keep the agency we have, pull it apart, or rebuild from scratch? To answer these critical and timely questions and more, this book calls on leading experts from academia, government, and private industry to begin charting a course for FDA's future. Topics range from the broad – addressing FDA as an institution – to the specific – addressing each of the major product areas the agency regulates.

Given the tremendous public attention currently paid to FDA in the face of food recalls, drug safety debates, tobacco control, and the like, this book is poised to be highly influential. Indeed, in recent years, FDA has been called before Congress the equivalent of every other week, demonstrating not only the very high stakes, but also the demand for input in this field. Throughout the conference on which the book will be based, we heard that we had successfully brought together *the* leading experts in the field to discuss the most pressing topics, a discussion that was sorely needed but had never previously been achieved. We plan to capitalize on that success by memorializing and extending the discussions initiated at that conference in this book.

Events Programming and Conferences

In the 2013-14 academic year, the Center is planning to host and co-sponsor a number of exciting public events, in addition to our annual Open House, including the following:

- “Patient Discrimination Against Medical Personnel,” with **I. Glenn Cohen**, Kimani Paul-Emile, Renee Landers, and Fidencio Saldana
- “Gene Patenting, the Supreme Court’s Myriad Decision, and the Future of Biotechnology,” with Dean Martha Minow, Eric Lander, **I. Glenn Cohen**, **Benjamin Roin**, Claire LaPorte, and Tania Simoncelli (with The Broad Institute)
- Book launch and panel discussion of Professor Cohen’s edited volume, *THE GLOBALIZATION OF HEALTH CARE: LEGAL AND ETHICAL ISSUES*, with **I. Glenn Cohen**, Sue Golde, Neel Shah, and **Einer Elhauge** (with the HLS Library and the Harvard Global Health Institute)
- A reception at the Public Responsibility in Medicine & Research Annual Conference (with the Division of Medical Ethics)
- “Reproductive Rights Around the Globe,” with **I. Glenn Cohen**, **Aziza Ahmed**, and Alicia Yamin (in collaboration with the HLS Human Rights Program and the Harvard Global Health Institute)
- “Ethics and Animals: Where Are We Now?,” featuring Peter Singer (with Harvard High-Impact Philanthropy)
- A celebratory event for our colleague Dan Brock, Frances Glessner Lee Professor of Medical Ethics, Department of Global Health and Social Medicine, Harvard Medical School (with the Division of Medical Ethics)
- A conference on rating corporations for their global health impact (with the Division of Medical Ethics and the Safra Center)
- Our second annual “Health Law Year in P/Review Event” (with the New England Journal of Medicine)
- An event on intellectual property and pharmaceuticals, with **Timo Minssen**, **Benjamin Roin**, and **Nicholson Price**
- An event discussing the Presidential Commission for the Study of Bioethical Issues and careers in law and bioethics, with Michelle Groman and **Holly Fernandez Lynch**
- An event related to the new Diagnostic and Statistical Manual of Mental Disorders, with Steve Hyman
- An event on HIV law and policy (with Gay Men’s Health Crisis)
- Workshops addressing the intersection and conflicts between legal and ethical analyses of abortion and reproductive technology (in collaboration with Yale and Rutgers law schools)
- A conference on regulatory biostatistics (with the Food and Drug Law Institute)

- Panel discussions, lectures, and/or workshops including and organized by each of our academic fellows and visiting scholars
- A book launch event for our volume on the future of human subjects research regulation
- Our annual conference, topic TBD
- Additional events, for example related to biospecimen ownership, comparative effectiveness research, etc.

Contributions to HLS Teaching Program

In 2013-2014, Harvard Law School will offer a number of courses related to health policy, biotechnology, and bioethics, including several taught by Center leadership and fellows:

- Anatomy of a Mass Tort Amy Schulman
- Constitutional and Health Law: Reproductive Rights Martha Field
- Drug Product Liability Litigation Peter Grossi
- Food Law and Policy Robert Greenwald
- Food Law and Policy Clinic of the Center for Health Law and Policy Innovation Robert Greenwald
- Food and Drug Law Peter Barton Hutt
- **Genetics and the Law** **Nicholson Price**
- **Health Law** **Christopher Robertson**
- Health Law and Policy Clinic of the Center for Health Law and Policy Innovation Robert Greenwald
- **Health Law and Policy Workshop** **I. Glenn Cohen**
Christopher Robertson
- Intellectual Property Law: Advanced William Fisher
- Law of Research with Humans and Animals Mark Barnes
- **Lawyers, Doctors, Ethics, and Professionalism** **I. Glenn Cohen**
- **Patent Law** Rebecca Brendel
- Public Health Law **Benjamin Roin**
- Public Health Law and Policy Mark Barnes
- Reproductive Rights and Justice Robert Greenwald
- **Rethinking the Legal and Ethical Status of Humans, Animals, and the Environment** Mindy Roseman
Jeffrey Skopek
- Risk and Insurance Bruce Hay

Health Law Policy and Bioethics Workshop

The workshop will continue this year as a curricular requirement for Petrie-Flom Center Student and Academic Fellows; Academic Fellows are also required to present at the workshop at least once during their appointment.

The 2013-2014 workshop is co-taught by Professors **Cohen** and **Robertson**, and will feature the following presenters:

- **Dov Fox**, University of San Diego Law School
“Interest Creep and the Puzzle of Potential Life”
- **Kimani Paul-Emile**, Fordham University School of Law
“Beyond Title VII: Rethinking Race, Ex-offender Status And Employment Discrimination In The Information Age”
- **Bernard Black**, Northwestern University School of Law
“*The Effect of Health Insurance on Near-Elderly Mortality*”
- **Kimberly D. Krawiec**, Duke University School of Law
- **Jennifer Prah Ruger**, University of Pennsylvania Perelman School of Medicine
- **Aaron Kesselheim**, Harvard Medical School
- **Christopher Robertson**, The University of Arizona James E. Rogers College of Law; Visiting Associate Professor, Harvard Law School
- **Kevin Outterson**, Boston University School of Law
- **I. Glenn Cohen**, Harvard Law School
- **Abbe Gluck**, Yale Law School
- **Matthew Lawrence**, Petrie-Flom Center

Genetics and the Law

Academic Fellow **Nicholson Price** will offer this course in Spring 2014, which will consider the law and policy implications of advances in genetics and the spread of genetic technology. Personal genome sequencing is getting cheaper and easier, and genetic analyses are increasingly used by public and private actors. These advances raise important issues for law and policy, for areas as diverse as family law, criminal law, torts, intellectual property, and of course health law. Likely topics include:

- Basics of genetics
- Genetic screening of fetuses, newborns, children and adults
- The patentability of genes and genetic tests
- Liability for failure to detect or warn about genetic disorders
- Links between genetics, criminal responsibility, and punishment
- Discrimination on the basis of genetic traits
- Implications of genetics for family law
- Public health implications of whole-genome sequencing
- Limits on genetic research and genetic manipulation of humans

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

Academic Fellow **Jeffrey Skopek** will offer this course again in Spring 2014, which will cut across issues in bioethics, animal rights, and environmentalism to explore the law's treatment of entities whose legal and ethical status is ambiguous or contested. The first section of the course will be devoted to human entities, such as embryos, the brain dead, and future persons. With respect to future persons, for example, the course will ask whether an activity can be considered harmful to a future person if it alters the person's genetics so much that it changes the person's identity; whether a law that prevents someone from coming into existence can be justified by reference to the best interests of that person; and if it can be justified, in what circumstances and on what grounds. The second section of the course will be devoted to animal entities, such as primates, farm animals, and chimeras. With respect to primates, for example, the course will ask whether animal protection statutes should be understood as granting rights to primates; how their status as property without legal standing to enforce these statutes shapes the answer to that question; and whether they should be granted standing or a functional alternative, such as equitable self-ownership. The third section of the course will be devoted to environmental entities, such as the climate, forests, and endangered plant species. With respect to the climate, for example, the course will ask whether cap and trade regimes create objectionable rights to impose harm by which they can be meaningfully distinguished from other regulatory regimes; how a cap and trade solution to the problem of global warming conceptualizes the harm of emissions; and what conception of the "good" of the environment underlies this conception of harm.

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

Lawyers, Doctors, Ethics, and Professionalism

This reading group, offered for the first time this Spring by Professors **Cohen** and **Brendel**, will cross-enroll Harvard Law and Harvard Medical School students to explore the ways in which professional responsibility and ethical issues common to law and medicine are handled by the two professions. Potential topics to be covered include: 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.

Participation of HLS Students in Program Activities

This year we endeavor to provide students with a variety of resources on our new website, including compilations of key resources on important health law policy, biotechnology, and bioethics topics, guides to related groups and programs around Harvard, and career resources. We will also continue to offer several opportunities for selected students to become directly engaged with the Petrie-Flom Center.

Student Fellows

We are pleased to welcome the following individuals to the Petrie-Flom Center as Student Fellows for the 2013-2014 academic year. They will pursue independent research under the supervision of Center faculty and fellows, regularly contribute to our blog, and enroll in the Health Law Policy and Bioethics Workshop.

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

Matthew Baum

Paper: "Philosophical and Ethical Issues in the Development of Predictive Biomarkers in Psychiatry and Neurology"

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

Nathaniel Counts**Paper: "Reworking Incentives for Mental Health Treatment of Defendants at the Pre-Trial Stage "**

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

Jeremy Kreisberg**Paper: Health Policy and Finance, Topic TBD**

Jeremy is a third-year J.D. student at Harvard Law School. He received his undergraduate degree from the University of Michigan, where he majored in Political Science. Prior to law school, Jeremy spent one year as a paralegal at Proskauer Rose LLP. Jeremy is currently a Notes Editor on the *HARVARD LAW REVIEW*, and has previously served as the President of the HLS Democrats and the Secretary of the HLS Chapter of the American Constitution Society. He was also a semi-finalist in the Upper Level Ames Moot Court Competition. During his law-school summers, Jeremy has worked as an intern in the Medicare Branch of the Office of Management and Budget and as a summer associate at Williams & Connolly LLP. Jeremy has been published in the *HARVARD LAW REVIEW*, and he was the co-author of a policy brief that appeared in [IS U.S. GOVERNMENT DEBT DIFFERENT?](#), a book published by the Wharton Financial Institutions Center. After school, Jeremy will clerk for Judge Stephen R. Reinhardt of the United States Court of Appeals for the Ninth Circuit.

Ching-Fu Lin**Paper: "Scientification of Politics and Politicization of Science in International Food Safety Lawmaking"**

Ching-Fu, the 2013-2014 Peter Barton Hutt Student Fellow, received his LLM in 2010 from Harvard Law School, where he is currently a candidate for the SJD. He holds a double degree in law (LLB) and chemical engineering (BS) from National Taiwan University. He is currently Researcher and Associate Journal Editor at the Asian Center for WTO & International Health Law and Policy. His areas of research include food safety regulation, WTO law, international health law, and international relations theory. His legal scholarship has appeared in

numerous journals and edited collections including *Global Food Safety: Exploring Key Elements for an International Regulatory Strategy* (VIRGINIA JOURNAL OF INTERNATIONAL LAW, 2011), *SPS-Plus and Bilateral Treaty Network: A "Global" Solution to the Global Food Safety Problem?* (WISCONSIN INTERNATIONAL LAW JOURNAL, 2012), and *Reassessing the Limits of the Codex Alimentarius Commission* (COLUMBIA SCIENCE AND TECHNOLOGY LAW REVIEW, forthcoming).

Julián Urrutia

Paper: "Health and Human Rights in Prisons: Special Rights and Special Duties Around Special Populations"

Julián is a PhD candidate in Health Policy, Ethics Concentration, at Harvard University. He holds a BA in Philosophy, Politics, and Economics from the University of Pennsylvania. In 2009, Julián enrolled in the Medical School of the University of Los Andes in Bogotá, Colombia. Julian's interests lie in the intersection between ethics, constitutional law, and health policy, with a particular focus on disparities in health outcomes and health resource prioritization. Over the summer of 2013, Julian worked at the Colombian Ministry of Health and Social Protection as part of a team in charge of creating a regulatory framework for new medical procedures. He also served as Ad Hoc Secretary to the Bioethics Committee at the Colombian National Medical Academy, which was commissioned by the Ministry of Health to draft a law bill to update the Medical Code of Ethics. Additionally, Julian is coordinating a project to undertake a health needs assessment in Colombian national prisons, which is being funded by the Administrative Unit for Penitentiary Affairs of the Colombian Ministry of Justice and Law, and which will be implemented beginning in the summer of 2014.

Michael J. Young

"Medical Repatriation and the Ends of Healthcare"

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

Student Interns

With the success of last year's inaugural internship program and the strong interest of students in getting involved with the Center, we have decided to continue the program for the 2013-2014 academic year. Through their work, attendance at Petrie-Flom events, and interaction with Center affiliates, student interns are exposed to scholarship, news, and various resources related to health law policy, biotechnology, and bioethics. They are involved in reporting on our events, developing topical and curricular resources for our website, contributing news round-ups for our blog, and various other items.

This year's interns are:

- Parker Davis, College, 2015
- Aleeza Hashmi, College, 2015
- Fatima Mirza, College, 2015
- Sara Providence, College, 2014
- Chloe Reichel, College, 2015
- Elizabeth Zhang, HLS, 2014

Journal of Law and Biosciences Student Editors

As described above, this academic year, the Petrie-Flom Center will be launching a new peer-reviewed journal. We have already accepted several student editors who will be responsible for drafting the "new development" section, comprised of book reviews, reviews of recent cases, and comment on new legislation. Student editors will also have the opportunity to blog on law and biosciences topics at [Bill of Health](#), and to help with organization and planning of any events and workshops associated with the Journal.

This year's student editors are:

- Adriana Benedict, HLS, 2014
- Komal Karnik, HLS/HSPH, 2014
- Nicholas Meyers, HLS, 2014
- Deborah Cho, HLS, 2015
- Ashish Bakshi, HLS/HBS, 2016

New Initiatives and Collaborations

As the Petrie-Flom Center embarks on the second year of its expansion, we look forward to pursuing a number of new opportunities. In addition to the projects we have planned ourselves, the Center has become widely known nationally and internationally as a leading academic research program, leading to frequent “pitches” for interesting collaborations. For example, we have been approached for possible collaboration on projects related to the regulation of research with controlled substances that might be useful for HIV/AIDS patients, the regulation of pharmacy compounding, and analysis of laws and regulations related to intravenous drug use in Malaysia. These all remain in their nascent stages, but some of our planned projects and tentative initiatives are described below:

- **Website redesign:** The Petrie-Flom Center’s website is currently in the process of being completely overhauled in an effort to become the go-to place for news, scholarship, commentary, and other information on health law policy, biotechnology, and bioethics. Our new site will continue to provide information about the Center, our fellows and affiliates, events and conferences, our blog, and the like, but will now highlight key national and international news stories in our focus areas, offer a resource page with primers on various issues under our umbrella; provide information about related resources throughout Harvard; link to career resources and job postings; and more. We expect the revamped site to go live by the end of September 2013.
- **State Bioethics Task Force:** In collaboration with the Division of Medical Ethics at Harvard Medical School and as part of an effort for the Petrie-Flom Center to become more involved in the policy realm, we are in the very early stages of exploring the possibility of organizing a state-level bioethics task force in Massachusetts. To start, we will bring together several individuals who have played an integral role in the New York State Task Force on Life and the Law, a relevant model for Massachusetts, in order to review its history and current structure, as well as hear more about its successes, challenges, and lessons learned. We will then evaluate various possibilities for Massachusetts, including assessment of government interest, appropriate structure, and possible topics for deliberation. Should we choose to pursue this further, we will work to develop a public-private partnership in which Harvard can offer its expertise in health policy and bioethics to state policymakers.
- **Additional collaboration with DME:** In addition to the Task Force initiative described above, we have begun efforts to strengthen our partnership with the Division of Medical Ethics through co-hosted events, the reading group on legal and medical professionalism being offered in Spring 2014, and

possible collaboration on research ethics consultations and a scholarly working group.

- **Executive Education:** In the coming years, the Petrie-Flom Center may consider offering some type of training course or programs for professionals and policymakers looking to learn more about our areas of specialization. There are a few existing models to consider (*e.g.*, at [Georgetown](#), [Yale](#), and [Harvard Medical School](#), as well as programs directed at Congressional staffers) but we would focus on legal aspects and other gaps in the current market. We may also pursue the possibility of offering Continuing Medical/Legal Education credits for our existing programming as a way to engage the professional community in our work.
- **Collaboration with the Food and Drug Law Institute:** As a result of connections made through our 2013 Annual Conference focused on the future of the Food and Drug Administration, we are currently exploring various collaborations with the Food and Drug Law Institute, the premier professional membership organization for food and drug lawyers. We will be co-sponsoring a conference in the Spring related to regulatory uses of biostatistics, and have begun discussions to work together on journal publication with student involvement.
- **American Health Lawyers' Association School Alliance:** This year, we plan to join the [American Health Lawyers' Association School Alliance Program](#), which will unlock a host of benefits for students, including:
 - Electronic access to 16 AHLA Practice Group websites
 - Resources and information on a content-rich website to aid in writing and research efforts
 - Ability to browse hundreds of publications at the AHLA Bookstore
 - Involvement in Practice Groups, discussion lists, and educational programs
 - Access to AHLA's Health Law Archive

In addition, we will be able to:

- Register for AHLA's webinars for a reduced rate
- Receive the AHLA's annual [Year in Review](#)—a summary of the leading developments in case law, legislation, and administrative actions affecting healthcare
- Receive a discount when ordering the *Fundamentals of Healthcare Law*—which covers the basic issues of health law practice
- Receive assistance in identifying health law experts to speak to students and student groups about healthcare legal issues

- Access [AHLA's Career Center](#), where students will find resources to begin a career in health law and search available positions in the legal community

To launch the program, the Petrie-Flom Center will purchase 10 memberships for interested students.

- **Additional Collaborations within HLS:** In addition to pursuing collaborative possibilities with the Center for Health Law and Policy Innovation, we have begun discussion of a project related to law and neuroscience and a project related to food law with our HLS colleagues.