



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

*2011-2012
Annual Report*

Executive Summary

This has been another fantastic year for the Petrie-Flom Center and for health law, health policy, bioethics, and biotechnology at Harvard Law School.

The Affordable Care Act was a major focal point for the Center, and is likely to be next year as well, as we contemplate the impact of the Supreme Court's ruling on the constitutionality of the law. Our affiliated faculty led public discussion of this issue, publishing commentary in a variety of news outlets from *The New Republic* and *The New York Times* to *The New England Journal of Medicine*. We also hosted a number of events discussing aspects of the Act, its legal status, and its current and future implementation.

The Center's Annual Conference also took on a topic of substantial relevance and urgency, although one that has received far less media attention than health care reform: the regulation of human subjects research. In response to a number of signals that this issue was ripe for reconsideration, we brought together more than 80 leading thinkers on the subject to provide reflections and advice to the Department of Health and Human Services as it undertakes a revision of the main federal rules governing such research.

Other events addressed such wide-ranging issues as the ethics of embryo-destructive research, resource allocation to identified versus "statistical" persons, non-gendered parenting, and the constitutional foundations of bioethics. In addition, we were fortunate to work again with the Federal Judicial Center to provide training to federal judges, this time by focusing on health policy aspects of offender re-entry and reducing recidivism. We also partnered with the Autism Self-Advocacy Network on ethical, legal, and social implications of autism research. And our Health Law Policy Workshop continued to provide the premiere forum to develop new scholarship in this field, while exposing students to cutting-edge ideas and leading academics from around the country.

Once again this year, Center faculty and fellows have successfully placed their scholarship with a number of prestigious law reviews (at Cornell, Minnesota, Georgetown, Virginia, and Yale); top medical, bioethics, public health, and science journals (*The American Journal of Transplantation*, *Developing World Bioethics*, *The American Journal of Public Health*, *The Hastings Center Report*, *The Journal of Medical Ethics*, *Genome Research*,

Genetics in Medicine, and *Nature Reviews Genetics*); and leading academic presses (Oxford University Press). Their published work covered everything from regulating reproduction and medical tourism, to organ sale and unethical research with human subjects, to ethical issues in genetic research and conflicts of interest in biomedical academic-industry relationships.

Ongoing faculty projects include work on medical tourism, patent settlements between innovators and generics, human enhancement, patent law, and pharmaceutical innovation. Meanwhile, the Center's Academic Fellows are currently working on projects focused on anonymity in various legal domains, reproductive ethics, and several issues related to human subjects research. We look forward to supporting these fellows on the academic job market this fall, and to welcoming a new fellow this summer.

Finally, our student fellows continue to produce top-notch scholarship, with papers on diverse subjects including the commercialization of health technology, the organization and regulation of surrogacy brokerages, conflicts of interest in pharmaceutical marketing, distracted driving laws, and genetically modified crops.

We are expecting another outstanding year in 2012-2013. On November 2, 2012, we will host a major event on Institutional Financial Conflicts of Interest in Research Universities, featuring among others NIH Director Francis Collins and former Harvard President Derek Bok. With the help of our new Executive Director, Holly Fernandez Lynch, we plan to launch several new initiatives that we hope will further extend the great work done by our students, faculty, and university.

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

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2011-2012 Report of Activities

Areas of Inquiry

The Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics was founded in 2005 as an interdisciplinary program intended to respond to the need for leading legal scholarship in these fields. Today, we advance this mission through our faculty and fellows' academic publications and commentary, course offerings intended to train the next generation of practitioners and scholars, and conferences, panel discussions, and lectures on current issues at the intersection of law and medicine.

Research and Scholarship

Academic Fellows

The tightening of the law school teaching market over the past several years, alongside the Center's previous success placing our Academic Fellows in health law, biotechnology, and bioethics openings at the nation's most prestigious law schools, has increasingly resulted in a level of market saturation. As a result, we anticipate that the Petrie-Flom Center Academic Fellowship program will shrink in the coming years, likely to one outstanding new fellow per cohort. This will allow us to continue strong placement of our Fellows, thereby meeting their expectations and preserving our reputation for excellence.

That said, our current fellows continue to produce top-notch scholarship, and look forward to a number of promising opportunities in legal academia and elsewhere. In addition to their own independent research and writing, the 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. Their work, successes, and reflections are individually summarized below.

2010-2012 Academic Fellows

Michelle Meyer will be submitting four full-length law review articles (all tentatively titled) in the Fall 2012 submission cycle. Two of those — *Rights To and Not To Procreate* and *Towards a Jurisprudence of Procreation* — reflect Michelle's longstanding interest in reproductive ethics. The other two articles — *Research Risk-Benefit Analysis and the Problem of Participant Heterogeneity* and *The Market in Research Risks and Benefits* — pertain to the regulation of human subjects research, which has been Michelle's primary research and teaching focus during the fellowship.

In the past year, Michelle developed and taught a seminar on research regulation at Harvard Law School, and has presented her work on research regulation at HLS, Union Graduate College, and Saint Louis University School of Law, the latter as a 2011 ASLME Health Law Scholar. She was also appointed to the Advisory Board of the Social Science Genetic Association Consortium, an international consortium of

researchers who aggregate genetic data to research complex economic and other behavioral traits (e.g., risk preferences). In that capacity, she consults with the consortium's Directors and members of its Phenotype Working Group. She also works with actual and prospective cohorts on ethical and regulatory issues involved in social science research on aggregated genetic data, and recently gave a talk on "Ethical Issues in the Genetics of Social Science."

For the 2012-2013 academic year, Michelle will continue her affiliation with the Center as Academic Fellow, during which time she will pursue several ongoing projects involving the regulation of knowledge production. One of these — rethinking the so-called research/practice distinction — inspired a workshop she will host through the Petrie-Flom Center next spring. The workshop will bring together scholars from diverse disciplinary backgrounds to collectively think through the challenges of integrating research into various practice settings in order to enable evidence-based practice in such areas as medicine, legal services, and lawmaking.

Patrick Taylor entered his Academic Fellowship with the goal of producing two published papers and deepening his experience with empirical research. Thanks "entirely to the Center's leadership and community approach, the support of [his] colleagues, the intellectual richness of the Center, its financial support, and the original vision behind the Center," he ends the Fellowship this summer with eight published peer reviewed papers on issues of genomics, ethics, and science policy in preeminent scientific journals; another peer reviewed paper accepted for the Winter issue of the *Yale Journal of Health Policy, Law and Ethics*; another paper in peer review in *Science*; two published law and policy commentaries solicited by the prestigious journal *Nature*; fifteen major talks in venues as diverse as Oxford University, Harvard Law School, the International Society for Stem Cell Research, The National Center for Informational Genomics, The National Academy of Sciences, the Columbia University IRB Conference, and the Harvard Clinical Ethics Consortium; involvement in two collaborative projects (one with Oxford University, and one with the Hinxtion Group); three solicited interviews for *The Scientist* and *Wired*; and participation as a co-investigator in four federally-funded grants, two with the National Institutes of Health, one with the National Library of Medicine, and one with the federal Office of Research Integrity.

After completing the fellowship, Patrick will continue his career as an Assistant Clinical Professor at Harvard Medical School, and a grant-funded researcher and Director of Ethics Analysis and Applications at Boston Children's Hospital, with some associated legal practice at Boston Children's Hospital where he was formerly Deputy General Counsel and Chief Counsel for Research Affairs.

2011-2013 Academic Fellows

Holly Fernandez Lynch was named Executive Director of the Petrie-Flom Center in June 2012, and is thrilled to help the Center advance into its next phase of development. Holly was previously an Academic Fellow for the 2011-2012 and 2006-2007 academic years. She is nearing completion of a law review article titled *Human Research Subjects as Human Research Workers*, in which she argues that subjects in biomedical research ought to be granted a number of the same protections extended to workers by labor and employment law, such as unrestricted payment, a modified minimum wage,

no-fault compensation for injury, and various labor rights. This year, Holly has also published two essays on the recently uncovered STD inoculation studies conducted by the US government in Guatemala in the mid-twentieth century. The first, *Ethical Evasion or Happenstance and Hubris: The US Public Health Service STD Inoculation Study*, published in the Hastings Center Report, argues that American researchers went to Guatemala with benign motives but ended up taking terrible advantage of their circumstances once there. The second, *The Rights and Wrongs of Intentional Exposure Research: Contextualizing the Guatemala STD Inoculation Study*, published in the Journal of Medical Ethics, aimed to clarify that intentional exposure research can be done ethically, under circumstances that were clearly not followed in Guatemala.

Jeffrey Skopek's research has focused on the unexplored territory that anonymity occupies in the law's production of public goods. The first component of his project is taxonomic, identifying the diverse legal domains in which the production of goods is facilitated and controlled by rules that make anonymity and non-anonymity into rights, conditions of exercising rights, and conditions that extinguish rights. The second component is theoretical, developing an account of the rationales that might fit and justify these rules across three facets of production: creation, evaluation, and allocation. The third component is applied, demonstrating how this framework can be used to rethink our current uses of anonymity rules and find new solutions to difficult questions of law and policy. Jeff's future research will build on this project by exploring other contexts, including the Fourth Amendment, where the rights and capacities of the subjects of our liberal democracy are potentially being defined in terms of the subjects' absence. Jeff will be pursuing placement on the entry-level law professors market in 2012-13.

2011 Faculty Summer Research Support

In the summer of 2011, the Center underwrote research projects conducted by both Faculty co-Directors, **I. Glenn Cohen** and **Benjamin Roin**, as well as Founding Director, **Einer Elhauge**. 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.

I. Glenn Cohen continued work last summer on two major research projects, which focus on reproduction/reproductive technology and medical tourism/globalization of health care.

On the reproduction/reproductive technology front, he published *Rethinking Sperm Donor Anonymity: Of Changed Selves, Non-Identity, and One Night Stands*, 100 GEO. L. J. 431 (2012), which focuses on recent proposals for the U.S. to adopt a prohibition on sperm donor anonymity like that in place in the UK, Australia, and many other countries that require sperm donors to put their names and identifying information into a registry available to donor conceived children at age 18. It shows that most of the arguments conventionally offered in favor of such registries run into philosophical and policy problems, such that these registries are not justified. He also published *Prohibiting Anonymous Sperm Donation and the Child Welfare Error*, 41 HASTINGS CTR. REP., Sept.-Oct. 13 (2011), examining similar issues for a bioethics audience.

On the medical tourism and globalization of health care front, Prof. Cohen wrote *Circumvention Tourism*, 97 CORNELL L. REV. _ (forthcoming, 2012), which examines medical tourism for services illegal in the patients' home country but legal in the patient's destination country. Focusing on travel abroad to obtain abortions, female genital cutting, assisted suicide, and reproductive technologies, it examines the power of home countries to extend their criminal prohibitions extraterritorially, and also the normative and political theoretical case for doing so. In *How to Regulate Medical Tourism (and Why It Matters for Bioethics)*, 11 DEVELOPING WORLD BIOETHICS 9 (2012), the focus was on the regulatory tools available to and challenges faced by home countries, destination countries, and international bodies in regulating all forms of medical tourism. Prof. Cohen also edited THE GLOBALIZATION OF HEALTH CARE: LEGAL AND ETHICAL CHALLENGES (Oxford University Press, forthcoming 2013), a volume made up of papers from last year's Petrie-Flom Center annual conference focused on medical tourism, medical migration, telemedicine, research and development of pharmaceuticals abroad, and global health equity and governance issues. Besides editing the volume, he also authored an introduction and a chapter on the effects of medical tourism on access to health care by the destination country poor.

Finally, along with former Dean of Brown University, **Eli Adashi**, Prof. Cohen wrote *In the Wake of Guatemala: The Case for Voluntary Compensation and Remediation*, 102 AM. J. PUB. HEALTH e4 (2011), arguing for the Obama Administration to voluntarily create a remediation program for recently uncovered intentional infection studies done on non-consenting members of the Guatemalan population decades ago.

Benjamin Roin has been pursuing two lines of research related to pharmaceutical innovation. The first concerns the impact of government-supported or -run health insurance on drug prices. This work focuses on the political pressures that can lead governments to direct more money toward labor (i.e., physicians and nurses) at the expense of new innovations (i.e., drugs, medical devices, diagnostics, etc.). The findings are relevant to the design of national health insurance systems that might use either government price controls or private markets to negotiate prices for health care.

The second line of research concerns the effects of FDA regulations on the incentives for drug development. While most scholarship views FDA regulations as a barrier to the development of new drugs, this project demonstrates that those same barriers are also provide protection against competition that help support investments in R&D.

Einer Elhauge has also focused on two issues in his recent research. First, he has been working on the problem of reverse payment patent settlements, which couple payments to generics with settlements that preclude generic entry until a date specified by the settlement. Patents are often sufficiently weak that the expected entry date from patent litigation might be much earlier than the settlement entry date, making such settlements anticompetitive. But the problem that has bedeviled the courts in antitrust cases is how to determine when this is so without re-litigating the patent issue that was supposed to have been resolved in the settlement. Prof. Elhauge is working on a model that proves how courts can, in certain cases, determine that a patent settlement is anticompetitive without inquiring directly into the patent merits.

Second, he has been working on a book, tentatively entitled “A Little Lower Than God,” about efforts to re-engineer human biology. The treatment-enhancement distinction that is currently used to limit these efforts is a major organizing principle of modern health care. The book argues that this distinction is unsustainable and will inevitably break down in the face of developing technology. It argues that we thus need new sustainable limits on these efforts that the book articulates, justifies, and grounds in social practices. The book also argues that, properly regulated, such efforts not only will not exacerbate inequality, but can lead to far more equality than otherwise would have been possible.

2011-2012 Affiliate Scholarship

Once again, Center faculty and fellows produced a wide-ranging portfolio of scholarship this year, the importance and quality of which is demonstrated by its successful placement with leading journals and publishers. This strong and prolific scholarly output in the areas of assisted reproduction, medical tourism, research ethics, stem cell policy, biorepository research, and conflicts of interest in health care has generated academic conversation, invitations to events, inquiries from the press, and a great deal of positive attention to our Center.

I. Glenn Cohen

Regulating Reproduction: The Problem with Best Interests

96 MINN. L. REV. 423 (2011)

Beyond Best Interests

96 MINN. L. REV. 1187 (2012)

Rethinking Sperm Donor Anonymity: Of Changed Selves, Non-Identity, and One Night Stands

100 GEO. L. J. 431 (2012)

Prohibiting Anonymous Sperm Donation and the Child Welfare Error

41 HASTINGS CTR. REP., Sept-Oct. 13 (2011)

The Globalization of Health Care: Legal and Ethical Challenges

(Oxford University Press, forthcoming 2013) (editor, and contributing introduction and chapter)

Circumvention Tourism

97 CORNELL L. REV. _ (forthcoming 2012)

Medical Outlaws, Medical Refugees

in MEDICAL TOURISM: RISKS AND CONTROVERSIES IN THE EXPLODING INDUSTRY OF GLOBAL MEDICINE (Jill Hodges et al. eds., ABC CLIO, forthcoming 2012)

How to Regulate Medical Tourism (and Why It Matters for Bioethics)

12 DEVELOPING WORLD BIOETHICS 9 (2012)

Medical Tourism, Access to Health Care, and Global Justice

52 VA J. INT'L L. 1 (2011)

In the Wake of Guatemala: The Case for Voluntary Compensation and Remediation

102 AM. J. PUB. HEALTH e4 (2011) (with Eli Adashi)

Can the Government Ban Organ Sale? Recent Court Challenges and Future of U.S. Law on Selling Human Organs and Other Tissue

12 AM. J. TRANSPLANTATION _ (forthcoming 2012)

Holly Fernandez Lynch

The Rights and Wrongs of Intentional Exposure Research: Contextualising the Guatemala STD Inoculation Study

J. MED. ETHICS, Online First (Mar. 2012)

Ethical Evasion or Happenstance and Hubris? The US Public Health Service STD Inoculation Study

42 HASTINGS CTR. REP. 30 (2012)

Patrick Taylor

Disclosing Pathogenic Genetic Variants to Research Participants: Quantifying an Emerging Ethical Responsibility

22 GENOME RES. 421 (2012)(with Christopher A. Cassa et al.)

The Beliefs, Motivations and Expectations of Parents Who Have Enrolled Their Children in a Genetic Biorepository

14 GENET. MED. 330 (2012)(with Erin D. Harris et al.)

From Patients to Partners: Participant-Centric Initiatives in Biomedical Research

13 NAT. REV. GENET. 371 (2012)(with Jane Kaye et al.)

The Informed Cohort Oversight Board: From Values to Architecture

MINN. J. L., SCI. & TECH. (with I. Holm) (forthcoming 2012)

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

YALE J. HEALTH POL'Y, L. & ETHICS (forthcoming 2012)

2011-2012 Affiliate Commentary

This year, our affiliates were highly sought after for their expert opinions on a number of pressing news items, ranging from health care reform to Mississippi's proposed constitutional amendment to define personhood as beginning at the moment of fertilization. In addition to being heavily quoted in various media outlets, they also authored several editorial and commentary pieces, listed below. These contributions 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

The Constitutionality of the ACA's Medicaid-Expansion Mandate
366 NEW ENG. J. MED. 103 (2012) (with Jim Blumstein)

Interview on the Constitutional Challenge – Podcast
NEW ENG. J. MED. (2012)

Selling Bone Marrow – Flynn v. Holder
366 NEW ENG. J. MED. 296 (2012)

Mississippi's Ambiguous 'Personhood' Amendment
THE NEW YORK TIMES, October 31, 2011 (with Jonathan F. Will)

Einer Elhauge

Even the Most Conservative Supreme Court Justices Have Already Declared Mandates Constitutional
THE NEW REPUBLIC, June 21, 2012

What a Nobel Prize-Winning Economist Can Teach Us About Obamacare
THE ATLANTIC, May 23, 2012

A Further Response to Critics on the Founding Fathers and Insurance Mandates
THE NEW REPUBLIC, April 21, 2012

A Response to Critics on the Founding Fathers and Health Insurance Mandates
THE NEW REPUBLIC, April 19, 2012

It's Not About the Broccoli: The False Case Against Health Care
THE ATLANTIC, April 16, 2012

If Health Insurance Mandates Are Unconstitutional, Why Did the Founding Fathers Back Them?
THE NEW REPUBLIC, April 13, 2012

The Roberts-Kagan Compromise on Obamacare?
THE NATIONAL LAW JOURNAL, March 28, 2012

Don't Blame Verrilli for Supreme Court Health-Care Stumble
THE DAILY BEAST, March 28, 2012

Economists Argue Over the Cost of Caring for the Uninsured
THE DAILY BEAST, March 25, 2012

The Irrelevance of the Broccoli Argument Against the Insurance Mandate
366 NEW ENG. J. MED. e1 (2012)

The Broccoli Test

THE NEW YORK TIMES, November 15, 2011

Profs. Cohen and Elhauge

7 Experts Try to Read Supreme Court Health-Care Tea Leaves

THE DAILY BEAST, March 29, 2012

Holly Fernandez Lynch

A Lesson from the Contraception Coverage Uproar? Rethink Employer-Based Insurance

HASTINGS CENTER BIOETHICS FORUM, February 17, 2012

Michelle Meyer

Stem Cell Policy as Bar Room Brawl: A Round in the Courts

OBSERVATIONS, The Nelson A. Rockefeller Institute of Government, August 2011
(with James W. Fossett)

Public Events Programming and Conferences

The Petrie-Flom Center prides itself in hosting and co-sponsoring an impressive array of events each academic year, and this year was no exception. Our 2011-2012 events brought together academics, policymakers, practitioners, students, and the public to discuss various features of health care reform, reproductive ethics and family law, and the first major attempt to revise the regulations governing human subjects research in over two decades. 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. 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.

Health Care Reform Events for 2011-2012

October 27, 2011

Recent and Forthcoming Rulings Regarding the Expanded Medicaid Component of the Affordable Care Act

At this event, **James F. Blumstein**, University Professor of Constitutional Law and Health Law and Policy, and Director of the Vanderbilt Health Policy Center, delivered a talk addressing constitutional issues related to the expanded Medicaid component of the Affordable Care Act, in which he specifically discussed relevant state challenges. **Prof. Cohen** moderated the event, and subsequently co-authored a piece in *The New England Journal of Medicine* with Prof. Blumstein on this topic. The talk was simulcast via live streaming video at Vanderbilt Law School.

November 1, 2011

Health Insurance Exchanges and the Affordable Care Act

Until his recent departure in Fall 2011, **Joel Ario** was the Director, Office of Insurance Exchanges, U.S. Department of Health and Human Services, and the Obama Administration's point person for standing up health insurance exchanges – the competitive Web-based marketplaces intended to modernize the way Americans purchase health insurance and move the country toward universal coverage by making health care more accessible and affordable for millions of uninsured citizens. Prior to his role at HHS, Ario devoted his professional career to shaping and implementing public policy, primarily in the areas of health reform, consumer rights, and environmental protection. After more than a decade in the non-profit sector, he served as Insurance Commissioner in both Oregon and Pennsylvania.

During his presentation, Ario spoke about his experiences at HHS, as well as the highlights of his career in the non-profit and public service sectors. The talk was followed by a robust question and answer session, moderated by **Prof. Cohen**, including candid views on the Administration's position on health care reform, the feasibility of the Affordable Care Act, and career advice for students considering jobs in the government sector.

March 29, 2012

Implementing the Affordable Care Act: Getting from 2010 to 2014

In this talk, moderated by **Prof. Cohen**, **Timothy Jost**, Robert L. Willett Family Professor of Law at Washington and Lee University School of Law, discussed the plethora of implementation issues facing the Affordable Care Act, as statutory timeframes for action by various federal agencies and the states draw near. The implementation issues were particularly interesting – and challenging – given continued uncertainty as to the fate of the Act.

Additional Events for 2011-2012

February 1, 2012

Embryo Ethics and the Law

Along with the HLS Federalist Society, the Petrie-Flom Center co-sponsored this debate on the philosophical and legal issues surrounding embryonic research. **Chris Tollefsen**, Professor of Philosophy, University of South Carolina, argued against embryo destructive research on the grounds that it is morally wrong to kill an innocent human being. **Prof. Cohen**, on the other hand, suggested that embryonic research could be accepted by conservatives, libertarians, pro-life, and pro-choice alike, so long as religious perspectives on personhood were not permitted to dictate public policy.

February 13, 2012

Unsex Mothering

The Petrie-Flom Center co-sponsored a panel discussion of “Unsex Mothering: Toward a New Culture of Parenting,” by **Darren Rosenblum**, Professor of Law, Pace Law

School, which was published in the *Harvard Journal of Law and Gender*'s Fall 2011 volume. Rosenblum's piece challenges the ways in which "mothering" and "fathering" have been "inappropriately tethered to biosex," and proposes that with the elimination of biosex tethers to specific parental roles "a parent could define herself as 'parent,' 'mother,' or 'father' with some fluidity." Along with Prof. Rosenblum, panelists included **Katherine Kraschel**, Petrie-Flom Center Student Fellow; **Mary Ann Case**, Arnold I. Shure Professor of Law, University of Chicago Law School; **Elizabeth Emens**, Professor of Law, Columbia Law School; and **Suzanne Kim**, Associate Professor of Law, Rutgers School of Law – Newark. In addition, **Prof. Cohen** wrote a contribution for the online colloquium accompanying the panel discussion.

Conferences

November 10-11, 2011

The Constitutional Foundations of Bioethics: A Cross-National Comparison

The Petrie-Flom Center co-hosted this interdisciplinary, international workshop in collaboration with the Program on Science, Technology, and Society at the Harvard Kennedy School. It was the closing event in a research project generously supported by the Greenwall Foundation. Led by **Sheila Jasanoff**, Pforzheimer Professor of Science and Technology Studies, Harvard Kennedy School, the project also involved **Benjamin Hurlbut**, Assistant Professor at the Arizona State University School of Life Sciences, and **Krishanu Saha**, Postdoctoral Fellow at the Whitehead Institute for Biomedical Research at MIT, and a Science, Technology and Society Fellow at the Harvard Kennedy School of Government, as collaborators. Advisers included **I. Glenn Cohen** and **Patrick Taylor**, both of the Petrie-Flom Center, as well as **Rudolf Jaenisch**, Member of the Whitehead Institute and Professor of Biology at MIT, and **Robert Martensen**, Director of the Office of History at the National Institutes of Health.

The project was designed to explore the changing landscape of the biosciences and bioethics in Western nations, with particular emphasis on research areas and objects that challenge pre-existing legal classifications. Focusing on cross-national differences in the governance of genomics, stem cell biology, regenerative medicine, and synthetic biology, the project team sought to understand why divergence occurs and what can be learned about the deeper legal, political, and cultural foundations of the observed variations. Four comparative case studies examined how national differences in constitutional thinking—including the web of tacit rules governing state-society relations—has affected ethical norms and policy responses with respect to: (1) direct-to-consumer genetic testing, (2) animal-human chimeras, (3) synthetic biology, and (4) discourses of over- and under-regulation in reproductive medicine and human embryo research. The workshop brought together key experts and decision-makers in science, industry, government, law, ethics, and science and technology studies to comment on the cases. Participants also discussed the implications of the project for future teaching and training in the biosciences, bioethics, law, and science and technology policy.

April 19-20, 2012

Identified Lives Versus Statistical Lives: Ethics and Public Policy

In collaboration with the Harvard Global Health Institute and other partner organizations, the Center was a co-sponsor to a University-wide program focusing on how decision-makers and the public tend to feel more strongly obligated to assist “identified” people at risk than to assist “statistical” ones, and the implications of this distinction for public policy and resource allocation. This two-day conference was the first to take an in-depth look at this issue from across disciplinary boundaries. Conference questions included discussion of what factors trigger or explain this difference in attitude and behavior; how it is manifested when we think about global health problems, such as treatment and prevention (and “treatment as prevention”) for HIV/AIDS; whether the law expresses a bias in favor of “identified” people; and whether there is any ethical justification for this bias.

The conference was organized by **Norman Daniels**, Mary B. Saltonstall Professor of Population Ethics and Professor of Ethics and Population Health, Harvard School of Public Health; **I. Glenn Cohen**, Assistant Professor of Law, and Faculty co-Director Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Harvard Law School; **Nir Eyal**, Assistant Professor of Global Health and Social Medicine, Harvard Medical School; and **Stephen Resch**, Deputy Director, Center for Health Decision Science, and Lecturer, Department of Health Policy and Management, Harvard School of Public Health.

May 18-19, 2012

The Future of Human Subjects Research Regulation

The Petrie-Flom Center’s Annual Conference

Last summer, the U.S. Department of Health and Human Services released an Advanced Notice of Proposed Rulemaking (ANPRM) titled “Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators,” which proposed to substantially amend the Common Rule governing federally funded human subjects research for the first time in twenty years. This development, as well as attention by the Presidential Commission for the Study of Bioethical Issues, suggests that the regulation of human subjects research is ripe for re-thinking. This year's annual conference was meant to gather leading experts from the U.S. and across the globe to assist in that endeavor.

Over the course of a day and a half of panels, plenaries, and extensive Q&A, conference attendees heard from a wide range of presenters, from the former director of the Office for Human Research Protections, **Greg Koski**, to social science researchers, lawyers, clinicians, and federal employees. Although the ANPRM served as a jumping off point, presentations and discussions were not so limited, and covered research risks, vulnerable populations, privacy of tissue specimens and data, the researcher-participant relationship, governance issues, and the parameters of regulatory authority. A driving theme was the tension between whether to accept the ANPRM’s approach of tweaking the current system but keeping its primary elements intact, or simply starting from scratch.

Petrie-Flom Center Executive Director **Holly Fernandez Lynch** and Academic Fellow **Michelle Meyer** presented their work, Academic Fellows **Patrick Taylor** and **Jeffrey Skopek** moderated panel discussions, as did Faculty co-Director **I. Glenn Cohen**, who masterminded the entire event. Federal regulators have expressed interest in output from the conference, and plans are in the works to disseminate the conference papers to a wider audience.

Events with Petrie-Flom Center Affiliate Participation

October 19, 2011

Building a Career in a Health Related Field

A discussion sponsored by the HLS Association Recent Graduates Council Health Careers Network, featuring **Prof. Cohen** and **Daniel Vorhaus**, former Petrie-Flom Center Student Fellow, among others

March 29, 2012

What Happens If the ACA Is Struck Down?

Sponsored by the HBS Health Industry Alumni Association and featuring discussion by **Einer Elhauge**, Founding Director of the Petrie-Flom Center

April 17, 2012

Parenthood for Sale: Should the U.S. Regulate Reproductive Technology?

Hosted by the American Constitution Society at HLS, moderated by **Katherine Kraschel**, Petrie-Flom Center Student Fellow, and with discussion by **Prof. Cohen**

Contributions to HLS Teaching Program

2011-2012 Curriculum

For the 2011-2012 academic year, Harvard Law School offered 17 courses related to health policy, biotechnology, and bioethics, including several taught by Center affiliates. The diversity of the 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. A list of these classes is provided below, along with more detailed information regarding the workshop, reading group, and seminar offered by our affiliates.

- | | |
|--|----------------------------------|
| • Disability Law | Prof. Stein |
| • Drug Product Liability Litigation | Prof. Grossi |
| • Evolution of Gender Crimes: Seminar | Prof. McKinnon |
| • Food and Drug Law | Prof. Hutt |
| • Food: A Health Law and Policy Seminar | Prof. Greenwald |
| • Health Law | Prof. Barnes |
| • <i>Health Law Policy Workshop (17 enrolled)</i> | <i>Prof. Cohen & Elhauge</i> |
| • Health, Disability and Estate Planning:
Law and Policy Clinical Seminar | Prof. Greenwald |

- International Reproductive/Sexual Health Rights: Reading Group Prof. Roseman
- Law and Cognition: Seminar Prof. Kahan
- Law and Psychology-The Emotions: Seminar Prof. Cope
- Law, Psychology, and Morality: An Exploration through Film: Seminar Prof. Stone
- *Patent Law (60 enrolled)* Prof. Roin
- *Population Level Bioethics Reading Group (9 enrolled)* Prof. Cohen & Daniels
- Real Science, Junk Science and CSI: Reading Group Prof. Gertner
- *Regulating the Production of Knowledge: The Law and Ethics of Research (14 enrolled)* Prof. Meyer
- Sex Equality Prof. McKinnon

Health Law Policy Workshop

The Health Law Policy Workshop is offered annually at HLS to students from across the university, and is a required course for Petrie-Flom Center student fellows. This year, there were seventeen students enrolled, but 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.

For full text of the presentation drafts and previous years' presentations, refer to the [PFC website Workshop page](#). This year's line-up is listed below:

Mark Hall

Fred D. & Elizabeth L. Turnage Prof. of Law, Wake Forest University School of Law
Commerce Clause Challenges to Health Care Reform

Arti K. Rai

Elvin R. Latty Professor of Law, Duke Law School

Patentability Policy Across the Executive Branch: What the DNA Patent Controversies Teach About Institutional Choice

Al Roth

George Gund Prof. of Economics and Business Administration at Harvard University
& Judd Kessler

Assistant Professor of Business and Public Policy, The Wharton School

Organ Allocation Policy and the Decision to Donate

Tom Baker

*Deputy Dean and William Maul Measey Professor of Law and Health Sciences,
University of Pennsylvania Law School*

Incorporating Insights of Judgment & Decision Making and Behavioral Economics into the Design of the Health Exchanges

Katherine Baiker

Professor of Health Economics, Harvard School of Public Health

The Oregon Health Insurance Experiment: Evidence from the First Year

Max Mehlman

Professor of Bioethics and Professor of Law, Case Western Reserve University

Enhanced Warfighters: A Policy Framework

Nita Farahany

Associate Professor of Law and Professor of Philosophy, Vanderbilt Law School

Searching Secrets (Neuroscience and Criminal Law)

Russell Korobkin

Professor of Law, UCLA School of Law

Bounded Rationality, Moral Hazard, and the Case for Relative Value Health Insurance

Richard Epstein

Laurence A. Tisch Professor of Law, New York University School of Law

The Constitutional Protection of Trade Secrets and Patents under the Biologics Price Competition and Innovation Act of 2009

Frank Pasquale

Schering-Plough Prof. in Health Care Regulation and Enforcement, Seton Hall Law

From Transparency to Intelligibility: Rethinking Disclosure in Health and Finance Reform

Holly Fernandez Lynch

Executive Director, Petrie-Flom Center

Human Research Subjects as Human Research Workers

Jeffrey Skopek

Academic Fellow, Petrie-Flom Center

Anonymity Rules: Biological Identity and the Control of Human Tissue

Christopher Robertson

Associate Professor of Law, The University of Arizona James E. Rogers College of Law

The Split Benefit (Adding Skin in the Game for Insurance)

Population-Level Bioethics Reading Group

Once again this year we offered a popular reading group on population-level bioethics, coordinated by **Prof. Cohen** and **Norman Daniels**, Mary B. Saltonstall Professor of

Population Ethics and Professor of Ethics and Population Health, Harvard School of Public Health. The group was open to all Harvard graduate students but enrollment was limited to facilitate discussion. The nine enrolled students were led by multiple instructors – leaders in their respective fields – rotating between sessions:

Dan Brock

Frances Glessner Lee Professor of Medical Ethics, Department of Global Health and Social Medicine, Harvard Medical School; Director of the Division of Medical Ethics

- Ethical Issues in Cost Effectiveness Analysis

I. Glenn Cohen

Assistant Professor of Law, and Faculty co-Director Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Harvard Law School

- Medical Tourism
- Reproduction, Population, and Ethics
- Allocating Legal Services Compared to Allocating Medical Goods

Nir Eyal

Assistant Professor of Global Health and Social Medicine, Harvard Medical School

- Equality, Priority, and Leveling Down
- Coercive Approaches to Physician Maldistribution

Frances Kamm

Littauer Professor of Philosophy & Public Policy, Harvard Kennedy School; Professor of Philosophy, Harvard Faculty of Arts and Sciences

- Wrongful Life

Daniel Wikler

Mary B. Saltonstall Professor of Population Ethics and Professor of Ethics and Population Health, Harvard School of Public Health

- Personal Responsibility for Health: Justice and Imprudence
- Paternalism, Libertarian and Otherwise
- The "Standard of Care" Controversy in Out-Sourced Clinical Trials

Regulating the Production of Knowledge: The Law & Ethics of Research

This seminar was offered in Spring 2012 by **Michelle Meyer**, Petrie-Flom Center Academic Fellow, and had fourteen enrolled students. It focused on how the law does – and should – regulate research. In particular, the course addressed Institutional Review Boards and proposals for reform, informed consent, conflicts of interest, compensation for research-related injury, vulnerable research populations, and special issues in genetics and imaging research. It also discussed the normative issues associated with setting research agendas, and considered topics beyond research with human subjects, such as research fraud and misconduct, commercialization and ownership of research results, and First Amendment concerns.

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. We look forward to expanding our student outreach further in the coming academic year, potentially through facilitation of internship opportunities, contributions to a Center blog, development of a resource page for those interested in learning more about our fields of study, and collaboration with the career planning office.

Student Fellowship Program

In 2011-2012 the Center sponsored six student fellows who were selected through a competitive application process. Representing three Harvard University graduate schools, and mentored by the Center's faculty and Academic Fellows, the student fellows conducted research and writing on a diverse range of topics, from conflicts of interest in medicine to regulation of GMO foods to empirical research on distracted driving laws. They also had the opportunity to present their works in progress, and to learn from established scholars through participation in the Health Law Policy Workshop. This year's student fellows and their research projects are listed below:

Devin Cohen

Harvard Law School, JD 2012

Pills, Quills, & Dollar Bills: Reconceptualizing Conflicts of Interest in Medicine in the Contemporary Era of Pharmaceutical Marketing

Before enrolling in Harvard Law School, Devin attended Brown University, where he concentrated in history and religious studies. He began his work in health care fundraising for 26 pediatric oncology centers nationwide, and later acted as a health intern for then-Senator Hillary Clinton. His primary research interests include payment reform, the financial implications of pharmaceutical marketing practices, anti-kickback litigation, and PPACA implementation. Devin's fellowship research project focused on conflicts of interests arising out of pharmaceutical marketing and research practices, and considered the costs and benefits of regulatory reforms aimed at providing greater federal oversight over the industry. As a fellow, Devin also assisted in planning a symposium on institutional financial conflicts of interests in research universities that the Center will co-sponsor in Fall 2012.

Sachin Desai

Harvard Law School, JD 2013

"Upgrading" Government Support of Technology Innovation by Introducing New Types of Funding Contracts: Current Efforts, Future Challenges

Sachin's scholarly interests focus on improving technology commercialization and the introduction of new business models into heavily regulated industries such as health care. His fellowship project focused on how complex legal, regulatory, and administrative structures surrounding health care impact the effectiveness of traditional

technology commercialization methods. Sachin entered law school after working as a strategy consultant at Deloitte, assisting numerous clients in regulated industries and health care. He graduated with a Masters in Aerospace Engineering and a Bachelors in Mechanical Engineering from Cornell University.

Dorothy Du

Harvard Law School, JD 2013

Rethinking Risk Factors in the Regulation of Genetically Modified Crops

Dorothy's interests in genetic engineering, biomedical devices, and pharmaceutical regulation were the focus of her research while a Student Fellow. She graduated from Cornell University where she majored in Biology and Society, with a focus on genetics and society. Her research has focused on the globalization of clinical trials, the changing role of Traditional Chinese Medicine in modern China, and patent disputes between traditional societies and pharmaceutical companies. Her writing project for the fellowship focused on the shortcomings of the U.S. regulatory framework for genetically modified crops, and evaluated various proposals for resolving regulatory deficiencies, seeking a solution that effectively balances the goals of fostering biotechnology and protecting human and environmental health and safety. A modified version of Dorothy's paper was recently accepted for publication by Harvard Law's Journal of Law and Technology (JOLT).

Rebecca Haffajee

Harvard Graduate School of Arts and Sciences, PhD 2013

Harvard Law School, JD 2006

Harvard School of Public Health, MPH 2006

Are the Roads Safe for Driving? Regulating Texting While Driving to Avoid Car Crashes

Rebecca is a PhD candidate in Health Policy at Harvard's Graduate School of Arts and Sciences, where she is concentrating on evaluative science and statistics. She holds a JD from Harvard Law School, an MPH from Harvard School of Public Health, and a BA in the Women's Studies Program with a Certificate in Health Policy from Duke University. She has practiced as a health law attorney at Ropes & Gray LLP, advising domestic health care providers on regulatory compliance and reimbursement issues. She was previously a Law Fellow at the O'Neill Institute for National and Global Health Law at Georgetown University where she pursued projects relating to U.S. health care reform as well as international health. Rebecca's current research focuses on the empirical effects of laws and policies on health care outcomes, in particular public health laws and patient safety/quality initiatives. Her fellowship project was an empirical examination of the impact of distracted driving laws on fatal car accident rates.

Katherine Kraschel

Harvard Law School, JD 2012

Brokering the Deal of a Lifetime: Aligning the Surrogacy Debate with the Realities of the Deal

Katherine's primary research interests include assisted reproductive technologies, biomedicalization through the regulation of health care and insurance, and gender

equity in health care. She graduated from Mount Holyoke College in Biochemistry, where she served as Student Body President and played on the varsity soccer team. Prior to law school, Katherine worked as a senior associate scientist at Pfizer Global Research & Development. Her fellowship project examined the ways in which existing regulatory frameworks, such as those governing clinical trials and prostitution, may be used as models for surrogacy regulation. She also considered the appropriate point of regulatory intervention within the surrogacy transaction.

Rachel Sachs

Harvard Law School, JD 2013

Harvard School of Public Health, MPH 2013

Patently Misguided: Harms to Follow-On Innovation from Broad Diagnostic Method Patents

Rachel is a joint-degree student at Harvard Law School and the Harvard School of Public Health. She graduated from Princeton University with a degree in Bioethics, an independent concentration. Her research interests lie at the intersection of public health and the law, and specifically include vaccine ethics and policy, access to medicines in developing countries, and the ownership of human biological materials. During her fellowship, Rachel examined the role of public health in patent law injunctions. Her project focused on both descriptive and normative accounts as to what factors courts consider when evaluating whether public health concerns are relevant to the “public interest” prong of the patent law injunction standard.

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 attend and participate in the Center’s Health Law Policy Workshop. They also collaborate on and attend the Center’s programmed events.

Connections to the Community and Professions

In addition to Center programming that is open to the public and reaches the community in a general way, every year, the Center also endeavors to undertake more directed efforts to reach legal and medical practitioners in particular. These “on-the-ground” events create opportunities not only to disseminate scholarship to influence policy, but also to inform Center affiliates’ scholarship through perspectives from the real world.

September 7-9, 2011

Facilitating Offender Re-Entry to Reduce Recidivism

At the start of the academic year, the Center hosted a Federal Judicial Center (FJC) workshop on facilitating offender re-entry to reduce recidivism, a priority for the

multitude of jurisdictions facing unsustainable prison populations alongside dwindling corrections budgets. The Center saw this as an important issue within its purview given the need to translate the most recent advances in the social sciences, neuroscience, and criminology into practical applications and resources to support all stages of the judicial system. Moreover, given how many individuals returning to the community from prison suffer from significant cognitive deficiencies, substance abuse and dependency issues, and mental health challenges, their recidivism is in many ways an issue of health policy.

The workshop brought together teams of federal judges, prosecutors, defense attorneys, probation officers, and treatment providers to learn about evidence-based and innovative approaches to facilitating federal prisoners' transition from prison to community and reducing recidivism. A major theme was the need for collaboration among a number of diverse – and sometimes traditionally adversarial – stakeholders in order to facilitate successful re-entry and avoid imposing unnecessary obstacles to the transition back to community. Deputy Attorney General **James M. Cole** gave the keynote address, which emphasized the need to allocate scarce financial resources appropriately toward the most effective programs to reduce the prison population while preserving public safety.

December 9-10, 2011

Ethics in Autism Research

Along with the Autism Self-Advocacy Network and the Harvard Law Project on Disability, the Petrie-Flom Center co-sponsored a symposium on the Ethical, Legal, and Social Implications (ELSI) of Autism Research. Supported by a grant from the Department of Health and Human Services' Administration on Developmental Disabilities, the event served as the launching point for a robust conversation about changing the way our society approaches autism research. In particular, the symposium sought to generate meaningful dialogue between those conducting research and the community of autistic adults, youth, and their families. Among the topics discussed were prenatal testing, community involvement in research, and inappropriate goals for intervention. Key participants included Administration on Developmental Disabilities Commissioner **Sharon Lewis** and National Institute of Child Health and Human Development Director **Alan Guttmacher**.

Collaborations

As described throughout this report, the Petrie-Flom Center engages in numerous collaborations with other research programs at Harvard Law School and the University, as well as with student groups and outside organizations. This academic year, we worked with the following:

- The Autism Self-Advocacy Network
- The Federal Judicial Center
- The Greenwall Foundation
- Harvard Global Health Institute

- Harvard Journal of Law and Gender
- Harvard Kennedy School Program on Science, Technology, and Society
- Harvard Law School Federalist Society
- Harvard Law School Project on Disability
- Harvard University Program in Ethics & Health
- Vanderbilt Health Policy Center

2012-2013 Plans for Activities

During the next year, we plan to expand the Center's reach and influence with the help of our new Executive Director (and previous Academic Fellow), **Holly Fernandez Lynch**. As in the past, 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 and Scholarship

Academic Fellows

We're pleased to welcome **W. Nicholson Price II** to the Center as Academic Fellow for the 2012-2014 fellowship term. Nicholson earned a J.D. from Columbia Law School, where he served for three years as Submissions Editor of the Columbia Science and Technology Law Review, and a Ph.D. in Biological Sciences, also from Columbia University. He holds an A.B. in Biological Sciences from Harvard College. After law school, he clerked for Judge Carlos T. Bea of the U.S. Court of Appeals for the Ninth Circuit, and was a Visiting Consortium Scholar at the UCSF/UC Hastings Consortium on Law, Science and Health Policy. Nicholson's past scholarship has involved genetic testing patents and the implications of human cloning for family law. His current scholarship has two broad foci: the legal regulation of the scientific research process, including aspects of informed consent and conflicts of interest; and the interaction of patents and the pharmaceutical development process.

Michelle Meyer will continue her affiliation as a non-residential Academic Fellow for the next academic year, while she completes several law review articles and organizes a workshop on the research/practice distinction, described below.

Jeffrey Skopek will complete his Academic Fellowship in Summer 2013. He plans to enter the law professor teaching market this fall.

Finally, as noted above, the Center will likely accept only one new Academic Fellow each year going forward, in order to avoid poor placement as a result of an oversaturated teaching market.

2012 Faculty Summer Research Support

Awards to Harvard Law School faculty pursuing or continuing research projects in health law remain a strong component of our mission to foster the development of new research in the field. In the summer of 2012, the Center will once again provide research support to Profs. Cohen, Elhauge, and Roin.

I. Glenn Cohen will continue work on a new book, “Patients with Passports: Medical Tourism, Ethics, and Law.”

Einer Elhauge will expand upon his research on issues related to reverse payment patent settlements, and continue work on his book manuscript, tentatively entitled “A Little Lower Than God,” about efforts to re-engineer human biology.

Benjamin Roin will continue research projects on patent law and issues related to pharmaceutical innovation.

Events Programming and Conferences

In the next academic year, the Center is planning to host and co-sponsor a number of exciting events, drawing distinguished speakers to HLS from various academic disciplines, as well as government service. Two major events are already substantially developed:

November 2, 2012

Institutional Financial Conflicts of Interest in Research Universities

Welcome

I. Glenn Cohen, Petrie-Flom Center

Lawrence Lessig, Edmond J. Safra Center for Ethics

(with an Afternoon Welcome from **Martha L. Minow**, Harvard Law School)

Introduction and Overview

David Korn, Massachusetts General Hospital; Harvard Medical School

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

Jonathan Cole, Columbia University – *A Quest for Utopia: The Great American University Yesterday, Today, and Tomorrow*

William (Terry) Fisher, Harvard Law School – *The University’s Capacity for Attestation*

Ezekiel Emanuel, University of Pennsylvania – *An Ethical Perspective on Institutional Financial Conflicts of Interest*

Institutional Conflicts of Interest in Practice

Derek Bok, Harvard University – *Investing in Faculty Start-Ups and Other Adventures*

Jonathan Marks, Penn State – *The Olivieri Case: Institutional Financial Conflicts Perspectives*

Claude Canizares, Massachusetts Institute of Technology – *Walking the Tightrope: Protecting Trustworthiness While Engaging with Industry at MIT*

Hunter Rawlings, Association of American Universities – *The Lion in the Path: Research Universities Confront Society’s New Expectations*

Institutional Financial Conflicts of Interest in Awardee Institutions

Francis Collins & Sally Rockey, National Institutes of Health – *Managing Financial Conflicts of Interest in an Expanding World of Industry-Academia Collaborations in Science and Medicine*

Julie Taitsman, US Department of Health and Human Services (DHHS), Office of the Inspector General (OIG) – *The Perspective of the DHHS OIG*

Concluding Session

Charles Vest, National Academy of Engineering – *Rapporteur's Remarks, Facilitated Conversation with Symposium Speakers (full panel), and Audience Discussion*

Spring 2013

Legal Experimentation: Legal and Ethical Challenges to Evidence-Based Practice in Law, Medicine, and Policymaking

In Spring 2013, the Center will host a closed workshop organized by Academic Fellow **Michelle Meyer** on the legal and ethical challenges of evidence-based practice (EBP). Recently, both legal scholars and lawmakers have called for 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 — evidence-based medicine (EBM) — 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 EBM 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. The workshop will unite legal scholars interested in widespread EBP with scholars who work in the area of EBM to collectively think through the best approach to these challenges to EBP. Confirmed participants include some of the architects of the relevant regulations.

The Petrie-Flom Center is also working to plan the following tentative events for the upcoming academic year:

Fall Events

- An event analyzing the outcome of the health care reform litigation
- An event discussing the Supreme Court's decision in the *Prometheus* case, in collaboration with the Broad Institute of Harvard and MIT
- A discussion of potential legal and political responses to the STD inoculation studies conducted in Guatemala in the late 1940s, with Susan Reverby of Wellesley College
- An event on international humanitarian law, human rights, and the changing nature of the human, in collaboration with the Human Rights Program

- A panel discussion on stem cell therapy tourism, in collaboration with the Harvard Stem Cell Institute

Spring Events

- An event on private equity and health care, in collaboration with McDermott, Will & Emery
- An event in collaboration with Center for Health Law and Policy Innovation
- An event in collaboration with the Berkman Center
- A panel coordinated by Jeffrey Skopek, Center Academic Fellow
- An event in collaboration with the Harvard Catalyst Clinical and Translational Science Center and/or Research Ethics Working Group
- The Petrie-Flom Center Annual Conference

Contributions to HLS Teaching Program

In 2012-13, Harvard Law School will offer 17 courses related to health policy, biotechnology, and bioethics, including several taught by Center Affiliates:

- | | |
|--|----------------------------------|
| • <i>Bioethics in the Courts</i> | <i>Prof. Lynch</i> |
| • Drug Product Liability Litigation | Prof. Grossi |
| • Ethics, Economics and the Law | Prof. Sandel |
| • <i>Embryos, Animals, and the Environment: Ethically Ambiguous Entities and the Law</i> | <i>Prof. Skopek</i> |
| • Food: A Health Law and Policy Seminar | Prof. Greenwald |
| • Food and Drug Law | Prof. Hutt |
| • Food Law and Policy Clinic | Prof. Greenwald |
| • Gender and Human Rights: Clinical Seminar | Prof. Popowski |
| • <i>Health Law Policy Workshop</i> | <i>Prof. Cohen & Elhauge</i> |
| • Health Law | Prof. Barnes |
| • Health and Policy Clinic | Prof. Greenwald |
| • Intellectual Property Law: Advanced | Prof. Fisher |
| • International Reproductive Health Rights | Prof. Roseman |
| • Insurance Law | Prof. Hay |
| • <i>Patent Law</i> | <i>Prof. Roin</i> |
| • Sexual Orientation & Gender Identity Law and Policy | Prof. Sears |
| • The Politics of Health: Seminar | Prof. Greenwald |

Health Law Policy Workshop

The workshop will continue as a core initiative of the Center. Jointly run by **Profs. Cohen and Elhauge**, who regularly present their works in progress, the workshop is 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 two-year appointment. The following is a tentative list of the 2012-2013 workshop presenters and their affiliations:

Alan Wertheimer

Senior Research Scholar, Department of Bioethics, NIH Clinical Center

I. Glenn Cohen

*Assistant Professor and Faculty co-Director, Petrie-Flom Center, Harvard Law School
2012-2013 Radcliffe Institute Fellow*

Michelle Goodwin

Everett Fraser Professor of Law, University of Minnesota Law School

Paul Starr

*Professor of Sociology and Public Affairs, and Stuart Professor of Communications
and Public Affairs, Princeton University*

Allison Hoffman

Acting Professor of Law, University of California Los Angeles School of Law

Nicholas Bagley

Assistant Professor of Law, University of Michigan Law School

Jonathan Kolstad

*Assistant Professor of Health Care Management, The Wharton School, University of
Pennsylvania*

William Sage

*Vice Provost for Health Affairs, James R. Dougherty Chair for Faculty Excellence,
University of Texas at Austin School of Law*

Einer Elhauge

*Petrie Professor of Law and Founding Faculty Director, Petrie-Flom Center, Harvard
Law School*

William Fisher

*Hale and Dorr Professor of Intellectual Property Law and Director, Berkman Center
for Internet and Society, Harvard Law School*

Benjamin Roin

*Hieken Assistant Professor in Patent Law and Faculty co-Director, Petrie-Flom
Center, Harvard Law School*

W. Nicholson Price

Academic Fellow, Petrie-Flom Center

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

Academic Fellow **Jeffrey Skopek** will offer this seminar in Spring 2013, which will cut
across issues in bioethics, animal rights, and environmentalism to explore the law's

treatment of entities whose ethical status is ambiguous and contested. The course will address questions such as:

- What does it mean for something to “harm the environment”? Do different regulatory schemes answer this question differently? What if anything is wrong with paying to pollute?
- Should animals be patentable? How does standing doctrine impact animal rights? Should the creation of human-animal hybrids be regulated, and if so, using what criteria?
- Can an activity that significantly alters the genetics of an embryo—that changes who the resulting person is—be considered beneficial or harmful to that person? Why did embryonic stem cell research cause so much more controversy in the United States than it did in the United Kingdom? Should prenatal sex selection be prohibited, and if so, on what basis?

In exploring these questions, the course will touch areas of law including property, tort, constitutional law, and environmental law, focusing on the interconnected resolution of legal and ethical uncertainty.

Bioethics in the Courts

This seminar will be offered by **Holly Fernandez Lynch**, the Center’s Executive Director, and will focus on the ways in which bioethics has been shaped by the law and lawyers. American courts in particular have played an important role in shaping this field, deciding cases in nearly every area of bioethical inquiry. This seminar will provide a survey of these key cases, some famous and some less so. Likely topics include:

- Pregnancy and parenthood (abortion, maternal-fetal conflict, surrogacy, parental discretion over medical care)
- Doctor-patient relationship (informed consent, confidentiality, duty to warn, conflicts of conscience)
- Palliative care and end-of-life issues (withdrawal of treatment, assisted suicide, medical marijuana, refusal of care)
- Research (ownership of bodily materials, stem cells, experimental drug access)
- Disability and eugenics
- Public health (quarantine, mandatory vaccination)

Participation of HLS Students in Program Activities

This year, we are excited to offer student fellowships to the following individuals, who – if they accept – will pursue independent research and writing projects under the mentorship of Petrie-Flom Center faculty and Academic Fellows:

Adriana Lee Benedict
Harvard Law School, JD 2014

Harvard School of Public Health, SM 2011
Assessing Implementation of the NIH Public Access Policy and Legal Alternatives

Katie Booth

Harvard Law School, JD 2013

Wireless Medical Devices and the Threat of Cyber-Attacks: Regulation and Reform

Jonathan Darrow

Harvard Law School, SJD candidate

Cap and Crowdsourcing: A New Approach to Clinical Trials

Yu-Chi Lyra Kuo

Harvard Law School, JD 2014

Princeton University, PhD 2016

Philosophical Puzzles and Life Extension

Patrick O’Leary

Harvard Law School, JD 2013

Research Integrity Regimes

Jonathan (Yoni) Schenker

Harvard Law School, JD 2013

Ethical and Practical Solutions to Medical “Brain Drain”

New Initiatives and Collaborations

In June 2012, we welcomed **Holly Fernandez Lynch** as Executive Director of the Petrie-Flom Center. Holly’s biosketch can be found [here](#).

In addition to her own scholarship, Holly will work with the Faculty co-Directors **I. Glenn Cohen** and **Benjamin Roim** on a number of new initiatives over the short and long term. Plans are still being developed and remain tentative, but potential areas of expansion include the following:

- **Web Development:** One of our primary goals is to expand the Center’s website in order to make it the go-to place for news, scholarship, commentary, and other information on health law policy, biotechnology, and bioethics. One way we plan to do this is to develop a blog, with cross-posting from the existing Health Law Professors blog and substantive content from our Center faculty, Academic and Student Fellows, and potentially student interns posting on a regular basis. We also plan to add new content to our site, including links to current news items of relevance to those interested in our fields; a resource page with primers on various issues under our umbrella; career resources and job postings; and event announcements, at Harvard and elsewhere.

- **Fellows and Center Projects:** Although we have decided to consolidate our academic fellowship program, we hope to welcome different types of fellows to the Center going forward, such as the Senior and Visiting Fellows we have hosted on various occasions in the past, who are generally established academics seeking to pursue their scholarship in relevant areas at Harvard. We are also considering the possibility of taking on Policy Fellows who would come to the Center not to work on their own independent scholarship per se, but rather to work on Center projects, such as white papers and briefs on topics related to the Center's mission.
- **Student Outreach:** In addition to our student fellowship program, we hope to provide a number of new services and opportunities to students in the coming years, given consistent requests from students seeking to become more involved with the Center and its affiliates. Possibilities include development of a Petrie-Flom Center internship program, in which students might work on Center events and projects; facilitation of topical internship and clinical opportunities in the Boston/Cambridge area; initiation of a student writing contest for outstanding scholarly work in health law policy, biotechnology, and bioethics; and the launching of a journal club to discuss new scholarly developments with interested individuals from around the University.
- **Publishing:** Finally, we are considering collaborative development of a peer-reviewed journal featuring articles in law and the biosciences.