



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

Annual Report of Activities 2009-2010

Executive Summary

2009-2010 has been another successful year for the Center, as we further consolidated our position as the preeminent academic institution examining how law intersects with health care, bioethics, and biotechnology.

Our academic fellowship program, offering two years of support and mentorship for post-graduates, continues its remarkable record as a pipeline to top academic positions. Our outgoing fellows published highly-lauded work on the interplay between health insurance mandates and health care fragmentation and how to avoid biased experts as part of medical malpractice trials. These papers were published respectively in the *American Journal of Law and Medicine* and the *New York University Law Review*. After turning down several other offers, they ultimately accepted professor positions at the law schools at UCLA and the University of Arizona, adding to the Center's prior placements at Harvard, UC Berkeley, and Boston University. Our current academic fellows are working on papers in topics such as reforming the Patent and Trademark Office, and the effects on medical malpractice rules on obstetrics and other medical practices.

Our student fellows continue to produce impressive work on a broad range of issues in health law, bioethics, and biotechnology. The intensive mentorship from Petrie-Flom affiliated faculty and from our academic fellows continues to pay dividends in improving the quality of these students' work, and we are pleased to have played a part in the placement of two of our former student fellows in positions at Duke Law School and the MIT economics department.

Our founding director, Einer Elhauge, published an edited volume with Oxford University Press this year entitled *The Fragmentation of U.S. Health Care: Causes and Solutions*, with papers stemming from a conference the Center convened two years ago, and which is both relevant and important in plotting the course forward.

Speaking of health reform, in our programming for the public, the Center capitalized on this exciting moment in health care history. Our program included events on the relationship between being under- and uninsured and going bankrupt or experiencing home foreclosure; an address from one member of Obama's Domestic Policy Council and Director of the Office of National AIDS Policy on the then-evolving health reform plans on HIV/AIDS and disability rights issues; and an examination of comparative models for health reform. In the pharmaceutical and biotechnology sphere we convened leading thinkers to discuss the use of medical prize funds as alternative rewards for medical innovation; and the then-pending legislation on intellectual property protection for follow-on biologics. Our bioethics oriented programming included events on the new politics surrounding regulation of stem cell research, and how developments in neuroscience and evolutionary biology should impact our thinking about law and morality.

We also held four important closed-door events. The first brought together economists, philosophers, lawyers, and policy-makers to develop consensus on an appropriate set of metrics and tools for evaluating the impact of innovation on global health. The second focused on best practices and emerging legal and ethical issues in conducting multi-regional clinical trials and gathered high-level executives from the major pharmaceutical and biotech firms, academics from schools including Harvard, Duke, Toronto, Tufts, Penn, Johns Hopkins, foreign experts from Brazil, India, Malawi, the U.K., and the Czech Republic, and representatives of many government and private-public partnerships, including the National Institutes of Health and the Gates Foundation. The third event was a training program for approximately 40 federal judges to learn about the most recent research in neuroscience and what impacts they may or may not have on the legal cases they see in their courtrooms. Finally, our annual conference, this year entitled *Moral Biology?? What (if anything) Can Advances in the Mind Sciences and Evolutionary Biology Tell Us about the Law and Morality*, brought together a prestigious group of leading scholars in law, psychology, neurology, evolutionary biology, economics, and philosophy to discuss what implications developments in the mind sciences and evolutionary biology should have on moral and legal analysis of responsibility, punishment, addiction, cooperation, and racism

This report describes these accomplishments in greater detail, and briefly outlines plans for next year's programming.

2009-2010 Report of Activities

Research and Scholarship

Academic Fellows

The continued successes of the Academic Fellowship program, which is at the core of the Center's intellectual life, underscore the prominent place the Petrie-Flom Center holds as the nation's leading program for the study and promotion of academic research in areas at the intersection of health and the law. This year's fellows have once again earned highly coveted teaching jobs at prestigious law schools, as well as produced first-rate scholarship of national recognition. Their participation in the various forums associated with the Center's activities consistently enriches the experience of students and faculty who also participate, encouraging more robust discussions and exchange of ideas and some of the most innovative scholarship being done in the field.

In addition to developing their own intellectual and career goals, the Academic Fellows have played an important role in the Center's activities through mentoring students, teaching seminars and planning public events on important topics in health law. They have also contributed to the intellectual life within the Harvard Law School community as well as other local and national venues where they have presented their research. Their work and successes are individually summarized below:

2008-2010 Academic Fellows

After interviewing for entry-level teaching positions at several top ranking law schools, **Allison K. Hoffman** accepted an appointment as Acting Professor of Law at the UCLA School of Law where she will specialize in health law. While a fellow at the Center, Allison's scholarship explored how different models of health care regulation can create both intended and unintended consequences with respect to individual health, financial security, and equity concerns. She wrote a policy analysis of the possible advantages and potential risks of a health reform measure that imposes an individual mandate to require citizens to carry health insurance. This article, *Oil and Water: Mixing Individual Mandates, Fragmented Markets, and Health Reform*, was the focus of her research presentations while she was on the job market, and it was published in the American Journal of Law and Medicine in May, 2010. Since accepting her position at UCLA, Allison has been working on several projects including: an analysis of how several different theories of health insurance are each separately represented in the new health reform law (the Patient Protection and Affordable Care Act of 2010), that create incoherence in the bill that will pose challenges for implementation; and an article on how current shifts in U.S. long-term care policy and financing (including the CLASS Act, which creates the beginnings of social insurance for long term care as part of the health reform law) will have negative and inequitable impact on informal caregivers, who assume the role of care giving for friends or family and who shoulder a significant burden in the process.

During her two-year fellowship tenure, Allison was frequently called upon to participate as an expert on panels focusing on various issues related to health care reform. Most recently, she participated on a panel at the University of Massachusetts Medical School. In her first month as a fellow, she planned an important event that included advisors to the Obama and McCain 2008 Presidential Campaigns which was a debate concerning the feasibility of the

respective candidates' proposals for health reform. Additionally, Allison made substantial contributions to the intellectual life of the Center through hands-on mentoring of students interested in health law, and in the 2010 Spring Semester, she taught the seminar *Health Reform: Normative Empirical and Policy Perspectives* with co-fellow Christopher Robertson. The course provided a very timely way for law students to study health reform and its implications.

Christopher Robertson is the first Petrie-Flom Academic Fellow who also participated in the Student Fellowship Program while a Harvard Law School student in 2006. The capstone of Christopher's affiliations with the Center was his appointment to Associate Professor of Law at the James E. Rogers College of Law at the University of Arizona in the Fall of 2010. While an Academic Fellow at the Petrie-Flom Center, Christopher completed an article on expert witness bias in technical cases. The article, *Blind Expertise*, proposes a litigant-driven solution, and was published in the New York University Law Review spring 2010 issue. He also received an offer to publish this piece as a monograph.

During his time with the Center, Christopher worked on numerous other articles and projects, including an article called *Regulation of Epistemic Asymmetry and Conflicting Interests*, which provides new empirical findings and expands on some of the themes in *Blind Expertise* beyond the litigation setting. He presented early versions of this paper at the Conference on Empirical Legal Studies at the University of Southern California, and at the Bioethics Works in Progress series at the Harvard Medical School. This paper has been accepted for publication in the *Emory Law Journal*, forthcoming in 2011.

During the fall of 2009, Christopher organized a panel of leading experts and policy makers to discuss the financial impact on families who confront financial ruin as a result of health care crises. The substance of this panel drew from research Christopher conducted as a Student Fellow with the Center in 2006, when he co-authored an article entitled *Get Sick, Get Out: the Medical Causes of Home Foreclosures*. This paper was an empirical project demonstrating that medical causes put 1.5 million people at risk of losing their homes every year. The article gained national attention in the contexts of health reform debates and the financial crisis of 2008. Christopher taught two classes during his Academic Fellowship: in the Spring of 2009, he taught the class *Health Care Reform and Financial Insecurity* and in Spring 2010 he co-taught the seminar *Health Reform: Normative Empirical, and Policy Perspectives* with his co-fellow Allison Hoffman.

2009-2011 Academic Fellows

Michael Frakes began his fellowship in the summer of 2009 and has spent his first year working on a number of empirical research projects concerning health policy, law and economics. Prior to beginning his tenure, Michael produced drafts of several papers that explore the relationship between medical malpractice law and physician behavior. During his first fellowship year, he has made revisions to these projects and has presented them at a number of workshops and seminars in numerous venues. He presented a paper titled *The Impact of Medical Liability Standards on Regional Variations in Cesarean Utilization: Evidence from the Adoption of National-Standard Rules* (along with a related working paper titled *Malpractice Standards of Care and Regional Variations in Physician Practice Styles*) at the Health Law Policy Workshop at Harvard Law School, the O'Neill Institute Empirical Health Law Conference, and the Health Law Society Seminar at Boston College Law School. This paper was submitted for publication with empirical journals in the spring

of 2010. Michael also presented a paper titled *Defensive Medicine and Obstetric Practices* at the Conference on Empirical Legal Studies, the Law and Economics Seminar at Harvard Law School and the American Law and Economics Association Annual Meeting. Michael is also working on a number of additional empirical projects exploring such topics as defensive medicine and cancer screening, defensive medicine and inpatient admission decisions, the relationship between malpractice pressures and physician location decisions, and the impact of statutory rape laws on teenage pregnancy and STD rates. In the spring of 2011, Michael will teach a seminar at Harvard Law School entitled *Economic Analysis of Health Care Law*.

Since arriving at the Center, **Melissa Wasserman** has worked on a research paper entitled *Asymmetric Incentives: Expansion of Substantive Patent Law*. The article outlines the underappreciated discretion the Patent and Trademark Office (PTO) has with respect to substantive patent law and argues that the PTO's discretion might be biased in a particular direction by two types of asymmetric incentives: unidirectional review of PTO determinations and the PTO's fee-structure. These incentives may introduce a bias that encourages the PTO to develop the law in favor of expansion on close legal issues, resulting in PTO examiners applying legal standards that are too lenient. The article also explores how an expansive bias at the PTO level may also affect, over time, the evolution of legal standards enunciated by the courts, even if the judiciary is itself not biased. Melissa will present her article in the Intellectual Property Scholars Conference at the University of California, Berkeley in August 2010.

During this past school year, Melissa delivered a guest lecture on gene patents in I. Glenn Cohen's course *Reproductive Technology and Genetics: Legal and Ethical Issues: Seminar*. In addition to mentoring two student fellows, Melissa planned and moderated a panel on patent policy and innovation which featured participation by The Hon. Sharon Prost of the United States Court of Appeals for the Federal Circuit, Michael Meurer of Boston University School of Law, and Dan Burk of the University of California Irvine School of Law as panelists. In the spring of 2011, Melissa will teach a course at Harvard Law School on Innovation Policy and the Biopharmaceutical Industry.

Faculty Research Support

An important goal of the Center has been to encourage existing Harvard faculty to use their expertise in diverse areas of the law to focus on long-neglected issues falling within the Center's mandate. In the summer of 2009, the Center continued the Faculty Summer Research Grant program to support full time Harvard Law School faculty members' research projects in health-related legal matters. These grants were made to:

- **I. Glenn Cohen** who researched and wrote an article titled *Protecting Patients with Passports: Medical Tourism and the Patient Protective Argument*. This article, which will appear in the June 2010 issue of the Iowa Law Review examines the phenomenon of "medical tourism," patients who are U.S. residents who travel to another country to pursue medical treatment, often for cost savings; this practice is quickly becoming a multi-billion dollar industry. The article focuses on concerns about health care quality and medical malpractice recovery for patients paying out of pocket or prompted by their insurer to use medical tourism and appropriate regulatory interventions. Glenn also published two offshoots of this project for medical audiences, *Medical Tourism:*

The View from 10,000 Feet, in the March-April 2010 issue of the Hastings Center Report, and *Medical Tourism, Consumer-Driven Healthcare, and Patient Protection*, forthcoming in the Spring 2010 issue of the Lahey Clinic Medical Ethics Journal. These papers consider additional ethical and legal questions stemming from medical tourism, including its effects on health care access of the poor in the destination country and concerns about circumventing prohibitions on the provision of certain services in the patient's home country (such as reproductive technology usage, euthanasia, experimental drugs, etc)

- **Einer Elhauge** who completed the manuscript for the volume of edited essays concerning the challenges of integrating the national health care delivery system entitled *The Fragmentation of U.S. Health Care: Causes and Solutions*. The book was published in February 2010 by Oxford University Press and has received widespread attention and praise. Professor Elhauge also used his summer research to continue work on a book that explores how best to regulate the re-engineering of human biology.

Contributions to HLS Teaching Program

For the 2009-2010 academic year, Harvard Law School offered thirteen courses in health law, policy and bioethics, including several reading groups and seminars taught by our Academic Fellows. Such a diverse curriculum has proved to be instrumental in attracting the most competitive students interested in health law to Harvard. This year, enrollments continued to be strong, averaging about 20 students per course. Following is a list of these classes:

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| • Ethics, Economics & Law: Seminar | Prof. Sandel |
| • Health Care Reform, Past, Present and Future | Prof. Ruger |
| • Health Law and Regulation | Prof. Ruger |
| • Health Law Policy Workshop (fall and spring) | Profs. Cohen & Elhauge |
| • Health, Disability and Planning: Clinical | Prof. Greenwald |
| • Realizing the Right to Health through Litigation | Profs. Roseman & Yamin |
| • Food & Drug Law | Prof. Hutt |
| • Psychiatry & the Law | Prof. Stone |
| • Health Reform, Normative, Empirical and Policy | Profs. Hoffman & Robertson |
| • Genetics & Reproductive Technology: Seminar | Prof. Cohen |
| • Intellectual Property Law: Advanced | Prof. Fisher |
| • Patent Law | Prof. Roin |
| • Public Health Law | Prof. Barnes |

Health Law Policy Workshop

The Petrie-Flom Center's Health Law Policy Workshop has continued to grow its national recognition as a leading venue for launching and vetting new research in health law, bioethics, biotechnology, and associated fields. Responding to demand from local attendees, the Workshop meetings took place on regularly scheduled Mondays across the entire school year. The more flexible scheduling of the workshop facilitated attendance and participation from a wider audience of professors and researchers from across Harvard University. Best known for its cross-disciplinary nature, workshop presentations this year

demonstrated the many different approaches scholars employ to grapple with the complex problems of our health care system. The following is a list of the participants and the titles of their presentations:

Michael Frakes & Melissa Wasserman, Petrie-Flom Center Academic Fellows, Harvard Law School; Frakes: *Malpractice Standards of Care and Regional Variations in Physician Practice Styles*; Wasserman: *Innovation at the PTO?*

Theodore Ruger, Professor of Law, University of Pennsylvania Law School and Visiting Professor Harvard Law School, *The Thomsonian Movement and the Structures of American Health Law*

Elizabeth Warren, Leo Gottlieb Professor of Law, Harvard Law School, *What is a Medical Bankruptcy?*

Barak Richman, Professor of Law, Duke University School of Law, *Mental Health Care Consumption and Outcomes: Considering Preventative Strategies Across Race and Class*

Michelle Mello, Professor of Law and Public Health, Harvard School of Public Health, *The Politics of HPV Vaccination Policy Formation in the States, and Pharmaceutical Companies' Role in State Vaccination Policy Making: The Case of HPV Vaccination*

Colleen Flood, Canada Research Chair in Health Law and Policy, University of Toronto Law, *Is Canada Odd? A comparison of European and Canadian Approaches to Choice and Regulation of the Public/Private Divide in Health Care*

Kathy Swartz, Professor of Health Policy and Economics, Harvard School of Public Health, *Health Care for the Poor: For Whom, What Care, and Whose Responsibility?*

Hank Greely, Professor of Law, Stanford Law School, *Human/Non-Human Chimeras: Assessing the Issues*

Sadath Sayeed, Instructor in Global Health and Social Medicine, Harvard Medical School, (1) *Impact of Ethics and Economics on End-of-Life Decisions in an Indian Neonatal Unit*; (2) *The Problem of Non-identity in valuing Newborn Human life*

I. **Glenn Cohen**, Assistant Professor of Law and Co-Director Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics, Harvard Law School, *Well, What About the Children?: Best Interests Reasoning, The New Eugenics, and the Regulation of Reproduction*

Benjamin Roin, Hieken Assistant Professor of Patent Law and Co-Director Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics, Harvard Law School, *Intellectual Property versus Prizes: A Policy-Lever Analysis*

Kristin Madison, Professor of Law, University of Pennsylvania Law School, *The Diffusion of Health Care Quality Reporting*

Participation of HLS Students in Program Activities

Student engagement with the Center continued to increase in the 2009-2010 academic year. Health law and policy continues to generate high interest among the law school student body and the national focus on health reform in 2009-2010 further galvanized their interest and activities related to our program.

Student Fellowship Program

In 2009-10 the Center sponsored six student fellows who conducted research in a diverse range of topics related to health law. The fellows hailed from programs representing four of the Harvard University graduate schools, and were mentored on their writing projects by the Center's post-graduate fellows, affiliates, and faculty, and through participation in the Center's Health Law Policy Workshop. The following is information on this year's student fellows and their research projects:

Maya Babu

Harvard Medical School, Harvard Business School

Maya is a fifth-year MD/MBA candidate at Harvard Medical School/Harvard Business School. She has worked at the Department of Health and Human Services, and served in leadership roles with the Committee on Legislation and Advocacy of the American Medical Association, Association of Women Surgeons, and Massachusetts Medical Society's Committee on Legislation. As an undergraduate at the University of Minnesota, she studied the developmental effects of iron deficiency on learning and memory. More recently at the Department of Health Care Policy at Harvard Medical School, she has been examining the impact of welfare reform on access to treatment for women with serious mental illness. During her fellowship, Maya completed a paper studying the socioeconomic factors that underlie patient transfers to a Level I trauma center. The findings from this research were selected for oral presentation as part of the Trauma and Critical Care Panel at the 2010 American Association of Neurological Surgeons Annual Meeting held in Philadelphia, and was awarded first place in the Socioeconomic Division of the AANS Poster Symposium.

Charlotte Harrison

Graduate School of Arts and Sciences, Department of Religion

Charlotte is a graduate of Harvard Law School and also holds degrees in public health and religion from Harvard. She is currently a candidate for a PhD in Religion at the Harvard Graduate School of Arts and Sciences, where she is writing a doctoral dissertation that explores questions of collective responsibility and governance in organ transplantation. Her research interests include the law and ethics of organ transplantation; the ethics of professional collaboration when collaborators abide by differing moral standards; the respective roles of individual doctors, the public and intermediate institutions such as hospitals and professional organizations in determining the ethics of medical practice. Charlotte is also interested in the intersections of bioethics with intellectual property law, which was her main area of practice before returning to graduate school to study ethics. Her Student Fellowship research project was titled *Collective Responsibility and Governance in Organ Donation after Cardiac Death: The Ethics of Professional Collaboration in a Regime of Varying Norms*. This paper will eventually be published as a chapter of her doctoral dissertation.

Blaine Saito

Harvard Law School and Harvard Kennedy School of Government

Blaine is a joint degree candidate in law and public policy at Harvard Law School and the Kennedy School of Government. His research interest centers on the intersection of taxation and health policy. In particular, his writing examines how the tax code effectively or ineffectively manages our health care financing system. Blaine also has more general interests in tax and health care financing. The research paper Blaine completed during his student fellowship is titled *Exercising Complete Dominion: Taxing Employer Sponsored Insurance Benefits*. He is currently finalizing the manuscript for submission to professional law and policy journals.

Faina Shalts

Harvard Law School

Faina is a student at Harvard Law School interested in bioethics, international health, and access to health care. She graduated from the University of California, San Diego in 2006 as a double major in Ethnic Studies and Political Science and completed an Ethnic Studies honors thesis on Russian Jewish immigrants' experience with health care in America as compared to other immigrant groups. During her fellowship, Faina researched the structural, legal, and ethical position of the World Health Organization (WHO) in preventing and containing pandemics, as well as its ability to effectively deal with global health crises. Her paper, which was entitled *Sovereignty and Solidarity in International Vaccine Access*, assessed the structural, legal, and ethical questions raised by her inquiry through the lens of the recent spread of H1N1, or "Swine Flu."

Ariane Tschumi

Harvard Law School, Harvard School of Public Health

Ariane is a joint JD/MPH student at Harvard Law School and Harvard School of Public Health focusing on issues of global health. Her research interests lie in health care delivery, early childhood and preventable diseases, maternal mortality, and the use of litigation as a strategy for realizing the right to health. Her fellowship research assessed the notion of a right to health care for the poor in the United States through judicial analogy. By comparing arguments that the U.S. Supreme Court has made to incrementalize a limited right to health care for certain populations with the particular burdens placed on the poor through the structural determinants of poverty, Ariane's research sought to demonstrate that a right to health care for the poor may not be as "radical" as it first appears. Her fellowship paper was titled *Conceptualizing a Right to Health Care for the Poor in the United States through Judicial Analogy*

Yuanheng (Sally) Wang

Harvard Law School, Harvard School of Public Health

Sally is a joint JD/MPH student at Harvard Law School and Harvard School of Public Health. Her areas of research interest focus primarily on matters of regulation but span a range of questions including how health policy and regulation affect the delivery of essential medicines, the elimination of systematic inefficiencies, the reduction of health care costs, and creation of incentives for more research in the biotechnology, pharmaceutical, and medical device industries. During her fellowship, Sally worked on a paper on the property and economic incentives involved in pharmaceutical marketing, and the effects that an improved regulatory regime would have in this area. Her research project

was titled *Elements of a New Procedural Regime with Respect to Marketing Approved Drugs: Why Look at Approved Drug Marketing?*

Student Fellowship Alumni

While most alumni of the Petrie-Flom Student fellowship program have taken their education in health law to careers in law firm practice, in government, or in the not-for-profit sectors, a few have gone on to pursue careers in academia. We're pleased to share news of these alumni's accomplishments, which further demonstrate the success of the Center's goal to foster the development of first-class scholarship by the most promising young scholars in the field.

Daniel Chen

JD, Harvard Law School; PhD Economics, MIT

Petrie-Flom Student Fellow, 2009

Since completing his fellowship in 2009, Daniel Chen has earned a reputation as a promising scholar in the areas of law and economics and the development of legal institutions. In the spring of 2010, Daniel accepted an entry-level law teaching position at Duke University School of Law. From 2009 to 2010 Daniel was a Kauffman Fellow at the University of Chicago Law School. Most of Daniel's scholarship is in the fields of law and economics and his teaching interests span the areas of tax, contracts, and procedure. While a student fellow, Daniel completed a research project on fertility and reproductive technology titled *Trading Off Reproductive Technology and Adoption: Do IVF Subsidies Decrease Adoption Rates and Should it Matter?* This article, which was co-authored with Petrie-Flom Faculty co-Director I. Glenn Cohen, will be published in the Minnesota Law Review in December 2010. Daniel will begin teaching at Duke this fall.

Heidi Williams

PhD Economics, Harvard

Petrie-Flom Student Fellow 2007 and 2009

Heidi was a Petrie-Flom Student Fellow while she pursued a PhD in the Economics Department at Harvard. She graduated from Harvard in June 2010. She has accepted a position as Assistant Professor in the Massachusetts Institute of Technology Economics Department, which she will begin in the Fall of 2011, after taking one year of leave to be a Visiting Fellow in Aging Research at the National Bureau of Economic Research (NBER) in Cambridge. Her research focuses on studying the causes and consequences of technological change, particularly in health care markets. Heidi's primary dissertation chapter studied how intellectual property rights on an existing technology can affect subsequent innovation, focusing on the empirical question of how intellectual property rights on human genes have affected subsequent scientific research investments into learning about genes' functions within the human body, and the likelihood that genes are used in medical diagnostic tests.

Connections to the Community and Professions

Every year, a component of the Center's events programming is developed to foster mutually beneficial exchanges between academics and legal and/or medical practitioners. The aim of these interactions is to create opportunities to disseminate the most up-to-date

scholarship in the fields at the intersection of health and the law in order to best inform the rapidly changing issues in these fields of practice. Our professional community driven events programming also affords our affiliates opportunities to learn first hand about the challenges practitioners face due to rapidly evolving changes in technology and legal and medical practice, in order to better inform their research with real-world relevance.

January 19, 2010

Multi-Regional Clinical Trials Industry Summit

The Center hosted a two-day summit of industry and academic leaders concerned with conducting clinical trials of pharmaceuticals. The Summit, held in cooperation with the Harvard Medical School Division of Medical Ethics, the Harvard University Program on Ethics and Health, the Harvard Office of Sponsored Research, Education Development, Inc., and Pfizer, Inc., was the second in a series of meetings aimed at enhancing standards and practices for ethically conducting biomedical multi-regional clinical trials, especially those that involve the developing world. On hand were high-level executives from pharmaceutical and biotech firms including Amgen, Genzyme, GlaxoSmithKline, Johnson and Johnson, Merck, Novartis, Pfizer, and Vertex; academics from schools including Harvard, Duke, Toronto, Tufts, Penn, Johns Hopkins; foreign experts from Brazil, India, Malawi, the U.K., and the Czech Republic; and representatives of many government and private-public partnerships, including the National Institutes of Health and the Gates Foundation. The main purpose of the meeting was to review proposals from five working groups and chart the path forward. The five working groups presented recommendations relating to: Quality and Efficiency of Ethics Review, Data and Safety Monitoring, Site Selection & Investigator Team and Expertise, Professionalism of Monitors, and Model Contract Provisions.

February 20, 2010

Conference on Article 12 of the United Nations Convention of the Rights of Persons with Disabilities (CRPD)

The Center co-sponsored with the Harvard Program on Disabilities a major international one-day conference on questions surrounding the United Nations Convention of the Rights of Persons with Disabilities (CRPD) Article 12. The goal of this conference was to present a variety of perspectives on the scope and operation of legal capacity from self-advocates/advocates, academics, and members of civil society from diverse regions of the globe. Following the conference, a report is being compiled to provide comparative examples to draw on when working through both the theory and reality of domestic level implementation of the CRPD.

March 11-12

Federal Judiciary Training Session on Developments in Neuroscience and the Law

Designed to be an interactive workshop for federal judges to learn about the most recent research in neuroscience and what impacts they may or may not have on the law, this event was hosted by the Center in conjunction with the Federal Judiciary Center (FJC) and the Gruter Institute for Law and Behavioral Research. The event was the last of a series of training sessions on recent advances in neuroscience designed for members of the Federal Judiciary organized by the FJC and the Gruter Institute as part of the MacArthur Foundation Law and Neuroscience Project. Approximately forty federal judges attended and participated in the discussions on the leading edge research in the mind sciences and their implications for the law. Over thirty prominent academics and researchers comprised

the panelists who presented their research and discussed with the judges the implications of their findings. Panelists included Harvard University Provost, **Steven Hyman**, and **Nita Farahany** Associate Professor of Law and Associate Professor of Philosophy, Vanderbilt University and a newly appointed member of the Presidential Commission for the Study of Bioethical Issues, among other leading academic researchers in the fields of psychology, neurology, ethics and the law.

Public Events Programming and Conferences

The events programming for the 2009-10 academic year promoted the Center as an agenda-setter and intellectual meeting place for matters related to health law, bioethics, and biotechnology, both for the Harvard community and nationally. In addition to providing opportunities to continue collaborations with internal colleagues throughout Harvard, many of this year's events also featured collaborations with major players in industry, and prominent national not-for-profit organizations focused on health care reform and delivery. Our events continued to draw large audiences and participation from groups around Harvard and the Boston area, and all parts of the country. The following are descriptions of this year's events:

Public Events

September 22, 2009

When Medical Care Compromises Financial Health

With debates over various forms of universal health insurance on the horizon, this panel examined and discussed a growing body of empirical research that has shown, even for those who enjoy health insurance, medical crises can push families to the financial brink, causing them to load up credit cards, miss work, forgo additional care, lose their homes to foreclosures, and even declare bankruptcy. Panelists explored these problems and debated potential solutions, including insurance regulation, paid family leave, and reforms to the tax code, the bankruptcy code and debtor-creditor laws. Panelists included **Christopher Robertson**, Academic Fellow at the Petrie-Flom Center, **Melissa Jacoby**, Professor of Law and University of North Carolina School of Law, **Cathy Schoen** of The Commonwealth Fund, and **Matt Selig**, of Health Law Advocates.

October 7, 2009

Health Law, HIV/AIDS & Disability Rights: A View from the White House

Jeff Crowley, a member of the Domestic Policy Council in the Obama administration and Director of the Office of National AIDS Policy (ONAP), came to Harvard Law School to discuss leading issues in the Obama Administration's policies for health reform and HIV/AIDS and disability rights. In his talk, he discussed his role in the Administration to coordinate the U.S. government's efforts regarding HIV/AIDS prevention, treatment and care, and to develop a national AIDS strategy. Previously, Mr. Crowley was a senior scholar and researcher at the Institute for Health Policy at Georgetown University where he focused on Medicare and Medicaid policy from 2000 to 2009. At this event, Mr. Crowley spoke broadly about the Obama Administration's health care reform agenda, and other health, HIV and disability-related initiatives.

October 27, 2009

Electronic Health Records and Medical Liability

The American Recovery and Reinvestment Act of 2009 promises to trigger an explosion in the use of electronic health records through direct payments to health providers. While the privacy concerns related to electronic health records (EHR) have been discussed at length, little attention has been given to the impact EHR might have on a provider's medical malpractice liability risk. Former Petrie-Flom Student Fellow **Lindsey Murtaugh** came to Harvard Law School to present new research she is conducting on the potential risks and benefits to malpractice liability posed by EHR in four areas: (1) risks arising during EHR implementation; (2) changes in practice patterns as the systems mature; (3) an evolving standard of care; and (4) the malpractice litigation process. Currently, Lindsey holds a position as Research Associate at Harvard School of Public Health's Department of Health Policy and Management.

November 3, 2009

Comparative Models of Health Care Reform

This colloquium brought together specialists on a group of model states and countries to discuss relevant health care systems, their successes and limitations, and their potential application to the reform of health care in the United States. The event aimed to interpret the U.S. reform effort in the context of the global system and to gauge the likely gains and possible challenges that the U.S. may face with the adoption of health care proposals that were debated during the year. Issues covered included employer and individual mandates, financing mechanisms, cost containment, consumer choice, and rationing. The national health care systems of Canada, Switzerland, the Netherlands, Germany, and Britain, were discussed, as well as the early reports of successes and limitations surrounding the implementation of universal health care in Massachusetts. Panelists included **Jon Kingsdale**, Executive Director of the Massachusetts Commonwealth Health Insurance Connector, **Ted Marmor**, Professor Emeritus at the Yale School of Management, **Kieke Okma**, independent consultant and expert on the Dutch national health care system, and **Mary Ruggie**, Professor in the Department of Sociology at Harvard University who is an expert in the German health care system. The event was moderated by **Ted Ruger**, Visiting Professor at Harvard Law School

November 5, 2009

Medical Prize Funds: An Alternative Reward Mechanism for Medical Innovation

Patenting and other rewards that rely on protected markets to encourage research investment in medical technology do not always provide the right incentives needed to optimize public health. In recent years, a number of proposals have focused on replacing or supplementing the patent system and related incentives with a mechanism that rewards medical research based on its value to human health -- as opposed to its value in the marketplace. This panel examined the potential and suitability of prize funds as a mechanism that would offer pharmaceutical innovators a supplementary reward based on the health impact of their products. Panelists discussed various prize proposals and debated the potential interactions between prize funds and patenting and other market-based reward mechanisms in the context of health innovation. Panelists included HLS Professors **Yochai Benkler** and **William Fisher**, **Aidan Hollis** of the University of Toronto, and **Kevin Outterson** of Boston University School of Law

January 6, 2010

Developments and Implications of New Legislation on Follow-on Biologics

This panel examined current legislative debates concerning the development of regulatory approval processes for follow-on biologics, or large molecule drugs that are created by biological processes, as opposed to medicines created by chemical formulas. The panelists were **Peter Hutt**, Senior Counsel at Covington & Burling LLP and Lecturer on Law at Harvard Law School, and **Bruce Leicher**, Senior Vice President and General Counsel at Momenta Pharmaceuticals. The panel was moderated by Professor **Benjamin Roin**.

February 5, 2010

“Through Deaf Eyes”: a Film Screening and Discussion

The Petrie-Flom Center partnered with the Harvard Law School Project on Disability to screen selected portions of the PBS documentary film *Through Deaf Eyes* which explores the nearly 200 year history and culture of deaf communities in America. The film presents the shared experiences of American history - family life, education, work, and community connections - from the perspective of deaf citizens, and also articulates stories of conflicts, prejudice and affirmation within deaf culture in America. After the screening an open discussion was led by **Susan Burch**, Associate Professor of American Studies and Director of the Center for the Comparative Study of Race and Ethnicity at Middlebury College.

April 1, 2010

Current and Future Regulation of Stem Cell Research

In previous years, the regulation of stem cell research has been a politically controversial topic. However the change from the Bush to the Obama administration presents potentially substantial changes in the regulatory environment for stem cell research, with far reaching implications for the important though controversial technology. A group of leading scholars and practitioners was convened to discuss the challenges and potential opportunities a new regulatory outlook could imply. **Brock Reeve**, the Executive Director of the Harvard Stem Cell Institute (HSCI), **M. William Lensch**, a researcher and faculty member of HSCI, **Patrick Taylor**, General Counsel of Children's Hospital Boston and **Pearl O'Rourke**, Director of Human Research Affairs at Partners HealthCare System were the panelists at this event. The event was moderated by Petrie-Flom Faculty co-Director **I. Glenn Cohen**.

April 15-16, 2010

Moral Biology?? What (if anything) Can Advances in the Mind Sciences and Evolutionary Biology Tell Us about the Law and Morality

Serving as the public component of the Center's annual conference, this panel discussed the scientific advances in psychology, neurology, and evolutionary biology as they pertain to improving (or potentially occluding) our understandings of whether morality is an innate human trait, or one fostered through social interaction. This panel featured presentations by, and debates between four prominent scholars who also participated in the two-day conference; **Joshua Greene**, of Harvard University Department of Psychology, **William FitzPatrick**, from the Department of Philosophy at Virginia Tech, **Adina Roskies**, of Dartmouth College Department of Philosophy, and **Walter Sinnott-Armstrong**, of the Kenan Institute for Ethics at Duke University. **Thomas Scanlon** of the Harvard University Department of Philosophy participated as a respondent to the other panelists' arguments, and helped to further inform the central debates in this fascinating topic. Petrie-Flom Faculty co-Director **I. Glenn Cohen** served as moderator for this event.

April 23, 2010

Patent Policy and Innovation

This panel focused on how patent law affects various industries differently. The pharmaceutical and high-tech industries offer perhaps the most vivid examples of this divergence. Panelists discussed whether patent law currently is or should be technology specific, and also explored questions concerning which institutional actor would be in the best position to craft substantive patent law to promote innovation policy. Participants included the Honorable Judge **Sharon Prost** of the U.S. Court of Appeals for the Federal Circuit, and **Dan Burk** of the University of California Irvine School of Law, and **Michael Meuer** of the Boston University School of Law. The event was moderated by **Melissa Wasserman**, Academic Fellow at the Petrie-Flom Center.

Conferences

November 5-6, 2009

Health Metrics Workshop

Over two days in November, the Center convened leading thinkers in the area of health metrics evaluation to develop consensus on an appropriate set of metrics and tools for evaluating the impact of innovation on global health. The workshop brought together 30 distinguished scholars, medical researchers, and practitioners with experience in law, economics, philosophy, business, medicine, and public health. The sessions focused on calibrating a fair and effective metric for evaluation of health impact, identifying methods of data collection, and making evaluations in a real-world setting. The workshop was co-sponsored with colleagues at Yale University working on an initiative to establish a Health Impact Fund that would pool contributions from international governments in order to allow pharmaceutical companies to register new medicines and treatments in order to receive direct payment proportional to their impact on global health. This innovative way of conceiving reward mechanisms is still in its early stages of development but is being internationally considered as an alternative to current reward and incentive schemes which leave the costs of essential medicines beyond the means of people living in poorer regions of the globe. Presenters and participants in the conference included highly distinguished scholars and practitioners such as **Frances Kamm**, the Littauer Professor of Philosophy and Public Policy at Harvard Kennedy School, **Christopher Murray**, Director of the Institute for Health Metrics and Evaluation, **Erik Nord**, Senior Researcher at the Norwegian Institute of Public Health in Oslo, **Aiden Hollis**, Professor and Fellow at the Institute for Advanced Policy Research of the University of Calgary, and **Thomas Pogge**, the Leitner Professor of Philosophy and International Affairs at Yale University, and Research Director at the Centre for the Study of Mind in Nature, University of Oslo. Harvard Law School faculty participants included **Yochai Benkler**, **I. Glenn Cohen**, **William Fisher** and **Benjamin Roin**.

April 15-16, 2010

Moral Biology?? What (if anything) Can Advances in the Mind Sciences and Evolutionary Biology Tell Us about the Law and Morality

The Center's banner conference for the 2009-2010 academic year gathered a prestigious group of leading scholars in law, psychology, neurology, evolutionary biology, economics, and philosophy to debate the nature of morality and whether scientific advances in these fields had implications for our conceptions of Responsibility, Punishment, Addiction,

Cooperation, and Racism. A series of six panels over the course of two days extensively explored implications of recent scientific advances in evolutionary biology and the mind sciences as they pertain to improving (or potentially occluding) our understandings of whether morality is an innate human trait, or one fostered through social interaction. With these rapidly emerging scientific discoveries, the fundamental “nature versus nurture” debate that has been at the core of scholarly inquiry for generations has taken on dramatic new dimensions, with some of the most basic assumptions about human nature being called into question by this new research. The implications for how these discoveries affect our understandings of human nature could have radical implications for legal and ethical questions relating to personal responsibility, judgment, prejudice, and how law should be conceived or altered accordingly. Over 30 of the most prominent academics and researchers in the respective fields participated in the two-day program that included **Steven Hyman**, Provost of Harvard University, **Nita Farahany**, Associate Professor of Law and Philosophy at Vanderbilt, and a newly appointed member of the Presidential Commission for the Study of Bioethical Issues, **Rita Goldstein**, Scientist at Brookhaven National Laboratory, **Stephen Morse**, Professor of Psychology and Law, University of Pennsylvania Law School and many others. The conference also included a public panel described in further detail elsewhere in this report. The program was a collaborative effort undertaken with colleagues from the Project on Law and Mind Sciences at Harvard Law School, the Gruter Institute for Law and Behavioral Research, the Law and Neuroscience Project of the John D. and Catherine T. MacArthur Foundation, and the Program in Ethics and Health at Harvard University.

2010-11 Plans for Activities

During our fifth year of full operations in 2010-2011, we hope to consolidate and continue the good work the Center has done. Now that health reform legislation has been passed, we hope to mount events around its implementation, including the complicated regulatory substructure that will surround it. We will continue our work on educating judges about developments in neurosciences by hosting a training session for state judges in collaboration with the American Association for the Advancement of Science in the fall. We will partner with the program on Science and Technology Studies at the Kennedy School to convene a series of colloquia on science governance on issues such as the creation of human/non-human chimeras.

In the fall we will be joined by Kathy Zeiler as our senior fellow, a prominent law and economics scholar who will share her empirical work on medical malpractice and how to reform it. We will be working to place two of our current fellows, Michael Frakes and Melissa Wasserman, into top teaching jobs, and welcoming two new fellows (Michelle Meyer and Patrick Taylor) who will add to the intellectual diversity of the Center. We also have an outstanding new crop of student fellows, and are in the midst of planning the programming for the coming year's Health Law Policy Workshop. Below are the details concerning our programs that have been fully planned thus far. Plans for many other events are still in the works, and we look forward to updating you on the Center's full agenda as it evolves over the summer

Research and Scholarship

Incoming Academic Fellows

We are pleased to announce the appointment of **Kathryn Zeiler** as Senior Academic Fellow for the fall semester of 2010. Professor Zeiler will join the Center while on sabbatical from Georgetown Law School, where she is a permanent member of the faculty. During her fellowship, she will be working on a co-authored book to be published by Yale University Press titled *To Sue is Human: A Profile of Medical Malpractice Litigation*. The book will provide the most detailed empirical study of the performance of the medical malpractice system available to date. The project utilizes data on approximately 16,000 medical malpractice claims closed from 1988 to 2005 to study the liability system and insurance markets in Texas. She is also authoring a book chapter that will appear in the *Tort Law Handbook*, (edited by Jennifer Arlen). The chapter will report results from a meta-analysis of empirical research investigating the impacts of medical malpractice tort reform on payouts, claims rates and insurance premiums.

Michelle Meyer will join the Center as an Academic Fellow in the summer of 2010. Michelle earned a Ph.D. in religious studies from the University of Virginia and a J.D. from Harvard Law School, where she was an editor of the Harvard Law Review, and a founding co-editor of the Harvard Law Review Forum. Following law school, she clerked for Judge Stanley Marcus of the U.S. Court of Appeals for the Eleventh Circuit. Michelle's past scholarship includes work on stem cell research, regulation of assisted reproductive technologies, property approaches to protecting genetic privacy, post-conviction DNA

testing and offender databases, federalism and bioethics, and comparative professional ethics. During the fellowship, she plans to consider what human subjects research (construed broadly to include not only biomedical research but also "research" by, e.g., sociologists and historians) would look like if the investigator-subject relationship were defined by principles of contract law (in which there is room, within certain bounds, for all parties to negotiate the terms of the relationship) rather than by preexisting duties imposed uniformly on a diverse range of investigative activity.

Patrick Taylor comes to the Petrie-Flom Center Academic Fellowship Program with lengthy, intertwined experience in policy-making, health care and biotechnology legal practice, bioethics and academics, most recently as Deputy General Counsel at Children's Hospital in Boston. He is the first Academic Fellow to be a concurrent faculty member at Harvard Medical School. His longstanding, multidisciplinary research interest is the mutual translation and evolution of law and policy imperatives in health care, science policy and biotechnology. He often explores how traditionally legal interests (like intellectual property), traditionally ethical ones (like public benefit and social justice), and traditionally biomedical ones (like data and materials sharing) enrich each other or clash in theory and application. He has been actively involved as a lawyer on policy-making bodies where the ideas are reflected, stating new norms. During his fellowship, he will explore governments' increasing use of bioethics to influence or validate policy-making, within legal systems that also must address public participation and democratic values.

Faculty Summer Research Grants

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 2010, summer research grant recipients will be

- **I. Glenn Cohen** who is finishing a forthcoming paper (co-authored with Daniel Chen) for publication in the December issue of the *Minnesota Law Review* on the effect that subsidizing reproductive technologies through insurance mandates has on the rate of adoption of children in America and abroad. He is also working on a new article on the problems with arguments for the regulation of reproduction focused on harm to children that result.
- **Einer Elhauge** will continue his book-length research project dealing with ethical and legal issues surrounding issues of technological human enhancement.

Contributions to HLS Teaching Program

Building on our successes to help grow the curriculum of health related classes at Harvard Law School, we will continue to offer an impressive array of courses in 2010-2011. Following is the list of course offerings to date:

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|--|------------------------|
| • Economic Analysis of Health Care Law | Prof. Frakes |
| • Ethics Economics and the Law | Prof. Sandel |
| • Health Law Policy Workshop | Profs. Cohen & Elhauge |
| • Health Law | Prof. Barnes |

- Health Disability and Estate Planning Clinical Workshop Prof. Greenwald
- Intellectual Property Law: Advanced Prof. Fisher
- Patent Law Prof. Roin
- Innovation Policy and the Biopharmaceutical Industry Prof. Wasserman
- Food & Drug Law Prof. Hutt
- Psychiatry & the Law Prof. Stone
- International Reproductive Health Rights Prof. Roseman
- Genetics & Reproductive Technology: Seminar Prof. Cohen

Participation of Students in Program Activities

Student Fellowship Program

We're pleased to report that interest in the Student Fellowship Program remained strong again this year. Proposals for Fellowship were submitted by students from across many of Harvard's graduate schools and the specific proposal topics drew from a broad distribution of areas of focus on health law, bioethics, and biotechnology. The roster of student fellowship awardees for the 2010-2011 academic year is:

Kourtney Baltzer

Harvard Law School, JD 2012

Patent Policy Relating to Improvement of Patient Access to Genetic Testing

Matthew Frank

Harvard Divinity School, MDiv 2009,

Harvard Graduate School of Arts and Sciences, Health Policy Program PhD 2013

Ethical Issues in Health Care Decision Making

Maggie Francis

Harvard Law School, JD 2011

Pilot Programs in the Patient Protection and Affordable Care Act

Lindsay Heck

Harvard Law School, JD 2011

FDA Rejection of Declaration of Helsinki for International Clinical Trials

Arta Lahiji

Harvard School of Public Health, MS 2011

Patient Centered Medical Homes Financing and Recent Health Care Reform

Abigail Lauer

Harvard Law School, JD 2012

Effects of Biotech Patents on the U.S. Health Care System

Rajan Sonik

Harvard Law School, JD 2012

Understanding the Legal Needs of Low Income Youth with Sickle Cell Disease