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

Annual Report of Activities 2010-2011

Executive Summary

2010-2011 has been another successful year for the Center, as we further advanced our position as the preeminent academic institution examining how law intersects with health care, bioethics, and biotechnology. That success was, however, tinged with sadness by the news of Joe Flom's passing. The Center is the realization of the vision that Joe and the Petrie Foundation set out for the Law School, and we remain grateful for his foresight and generosity. We are proud to carry forward the mantle of his name.

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 in health law. After turning down several other offers, our outgoing fellows ultimately accepted professor appointments at the law schools at Cornell and the University of Illinois, adding to the Center's prior placements at Harvard, UC Berkeley, UCLA, Boston University, and the University of Arizona. Our current academic fellows are working on papers in topics such as rethinking conflicts of interest policies in academic medicine and reforming human subjects protection, and we are excited to welcome in two additional fellows beginning this summer.

Our fellows and faculty published or have forthcoming award-winning work not only in the leading law reviews, but also in medicine (*The New England Journal of Medicine*), science (*Nature*, *Cell*), economics (*The American Economic Review*), and bioethics (*The American Journal of Bioethics*, *The Hastings Center Report*).

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 enabling them to publish while still enrolled students.

We held three important closed-door meetings this year. A one-day conference on the repeal of the McCarran-Ferguson Act, which exempts insurance companies (including health insurance companies) from several elements of federal antitrust regulation. The conference brought together academics working in business schools, law schools, and economics departments from around the country in discussions with practicing antitrust and health care lawyers and advocacy groups.

We also collaborated with the Federal Judicial Center, the American Association for the Advancement of Science, the Federal Judicial Center, the National Center for State Courts, the American Bar Association Judicial Division, and the Dana Foundation to host a two-day training session for approximately 40 federal and state judges on the most recent research in neuroscience and what impact it may or may not have for the law.

Our annual conference continued the tradition of bringing together leading thinkers from a across the globe, this time to wrestle with one of the most challenging issues in health law, bioethics, and biotechnology: its globalization. *The Globalization of Health Care: Legal and Ethical Challenges* brought together experts from practice and academia, working in fields that included law, philosophy, medicine, public health, government, anthropology, and geography, which produced an event that crossed borders and paradigms to gain insight on the vexing questions emerging from this rapidly changing field. The conference tied together the manifestation of this globalization in four related subject areas – medical tourism, medical migration (the physician "brain drain"), telemedicine, pharmaceutical research and development – and integrated them with a philosophical discussion of issues of justice and equity relating to the globalization of health care and the public health governance issues involved. Oxford University Press will publish a volume of the conference papers edited by Petrie-Flom Faculty Co-Director**,** I. Glenn Cohen.

Health care reform continued to take center-stage in our programming for the public. A public debated entitled "Is the Obama Health Care Reform Constitutional?" received significant media attention, and brought together the leading constitutional law experts (Larry Tribe, Charles Fried, Randy Barnett) to debate the likely fate of the Affordable Care Act. A separate panel united advocates and analysts to examine possible changes to health care payment reform. An event with Massachusetts Senator Richard Moore discussed Massachusetts health care reform process and its outcomes to try to extract lessons applicable to federal reform program efforts underway. A panel on racial disparities brought together lawyers, doctors, and economists to examine complex issues surrounding equities in health care delivery across racial and socio-economic divides.

The Center's public bioethics-oriented programming this year included a discussion of fetal and neonatal research and the legislation governing it, a panel on female circumcision that brought together doctors, academics, and human rights advocates, a panel on the treatment of children with disabilities, and an event focused on autism and its treatment in the psychiatric community that considered the views of advocates, scientists, psychiatrists, and lawyers. Our pharmaceutical/biotechnology programming included a session on challenges to pharmaceutical patents in the developing world, a panel discussion with leading FDA lawyers inside and outside of the agency on the regulation of biosimilars, emergency preparedness, and other current controversies in food and drug law, and a meeting with FDA Commissioner Margaret Hamburg during which students were able to ask the Commissioner questions about the most pressing issues in the field, which lead to a candid discussion about the day-to-day challenges the Agency faces to fulfill the obligations of its mandate to protect consumers, and how this mandate has evolved to grapple effectively with the rapid changes in technology that impact and augment the Agency's responsibilities.

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

2010-2011 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, **Michael Frakes** accepted an assistant professorship at Cornell Law School, and **Melissa Wasserman** will be an associate professor of law at the University of Illinois Urbana-Champaign. Beyond these successes in job placements, the Center's five Academic Fellow affiliates along with our Affiliated Faculty, researched and produced first-rate scholarship of national recognition in some of the premier research journals in law, ethics and science, including the **New England Journal of Medicine**, **Cell Magazine**, **Nature**, **The Journal of Law Medicine and Ethics**, **The American Journal of Bioethics** and several nationally prominent Law Reviews. The breadth of these article placements is indicative of the increasing reach beyond the disciplinary boundaries between law and medicine that the Center was founded to explore. On a day-to-day basis, our fellows' participation in the various forums associated with the Center's activities consistently enriches the intellectual experience of students and faculty who also participate, encouraging more robust discussions and exchange of ideas.

In addition to developing their own intellectual and career agendas, the Academic Fellows have played an important role in the Center's activities through mentoring students, teaching seminars and planning and participating in 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:

2009-2011 Academic Fellows

Michael Frakes earned an appointment as Assistant Professor of Law at Cornell Law School, where he will also serve as the Director of the Law and Economics Program and a Co-Editor of the Journal of Empirical Legal Studies. While a fellow at the Center, Michael conducted empirical research on the relationship between physician practices and medical malpractice law, extending research that he began at the Massachusetts Institute of Technology, where he received a Ph.D. in Economics in 2009. Among these studies is an investigation into the relationship between regional variations in medical practices and the geographical components of malpractice standard-of-care rules. Over the course of several studies, Michael's research has attempted to expand the empirical medical malpractice literature by exploring the scope and the relevancy of malpractice law's deterrent channel. Under a recent grant from the Robert Wood Johnson Foundation's Public Health Law Research Program, Michael has been conducting research on the potential deterrent impact of statutory rape laws and the degree to which the scope and severity of such laws reduces the incidence of teenage pregnancy and sexually transmitted diseases. Finally, during his tenure at the Center, Michael researched alternative policy approaches to addressing

ongoing racial disparities in the United States health care system, including an assessment of the degree to which a revamping of our civil rights laws will further reduce such disparities. He also organized a panel discussion with leading scholars and policy makers working directly on these issues. During his appointment Michael taught a seminar, *Economic Analysis of Health Care Law and Policy*, which broadly explored the economic rationales behind legal or regulatory interventions in the health care market. The seminar covered such topics as health care insurance and financing (including the interaction between health insurance and the labor market), health care cost drivers and cost-containment initiatives, quality of care and medical malpractice, and individual risky behaviors (e.g., smoking). When he begins at Cornell in the fall, Michael will teach courses in Health Law, Torts and Law and Economics. He will also become a member of Cornell University's *Field of Economics*.

Melissa Wasserman was offered an appointment as Associate Professor of Law at the University of Illinois at Urbana-Champaign. Her primary research agenda focused on the institutional design of innovation policy, including the laws and regulations that affect innovation and the public institutions that shape these legal instruments. Her scholarship explored the intersection of patent law, FDA law, and administrative law and her written work constituted an examination of the Patent and Trademark Office's (PTO) underappreciated role in shaping substantive patent law. This work identified and explained how the agency's financial incentives, as well as its relationship with the Federal Circuit, systematically push the PTO's views on substantive patent law in a patent-protective direction. Her article, *The PTO's Asymmetric Incentives: Pressure to Expand Substantive Patent Law*, is forthcoming in the Ohio State Law Journal in the Spring 2011 issue. During her appointment Melissa also taught a seminar that explored innovation policy in the biopharmaceutical industry. This seminar examined the complexities of innovation in biopharmaceutical research and development, including the mix of public and private funding that supports such research, and the intricate regulatory structure that surrounds drugs and other medical products. Melissa will teach an expanded version of this class and Patent Law at the University of Illinois.

2010 Senior Academic Fellow

We were pleased to host **Kathryn Zeiler** as Senior Academic Fellow for the fall semester of 2010. Professor Zeiler joined the Center while on sabbatical from Georgetown Law School, where she is a permanent member of the faculty. During her appointment, she worked 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 provides 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. During her fellowship, Zeiler also worked on a book chapter that will appear in the *Tort Law Handbook,* (edited by Jennifer Arlen at New York University Law School). 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. Finally, Zeiler also organized an important day-long conference on the possible effects of repealing antitrust laws governing insurance companies. The proceedings of the conference are further outlined below in this report.

2010-2012 Academic Fellows

Michelle Meyer joined the Center as an Academic Fellow in the summer of 2010. She earned a Ph.D. in religious studies, with a focus on practical ethics, 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. She has been a Research Fellow at the John F. Kennedy School of Government at Harvard, and a Greenwall Fellow in Bioethics, Health Policy and Law at The Johns Hopkins Bloomberg School of Public Health. She graduated *summa cum laude* from Dartmouth College, where she studied religious studies and philosophy.

Michelle's scholarship is interdisciplinary; in analyzing a broad range of practical legal problems, she draws pragmatically on tools from her training in philosophy, religion and law. She is particularly interested in the unorthodox use of contract and other forms of private ordering in noneconomic contexts -- such as in health care, legal practice, human subject research and other professional relationships, within families, and in forbidden markets -- as well as the implications of philosophical, theological, psychological and economic theories of human nature for such private ordering. Her work in this area is informed by her training in both ethical theory, especially utilitarianism and its critics, and existential theories of human nature, in particular their views of the possibilities and limits of individual freedom and responsibility.

Michelle explores many of these themes in her current research, which examines private ordering approaches to human subjects research (construed broadly to include not only biomedical research but also, behavioral, social science, public health, empirical legal and other types of research conducted by industry, academics and their students) in which there is room, within certain bounds, for researchers and prospective subjects to negotiate the terms of their relationship. In June 2011, Michelle was selected as one of four scholars to present at the nationally acclaimed Health Law Scholars Workshop co-sponsored by the Center for Health Law Studies at Saint Louis University and the American Society of Law, Medicine and Ethics. Her paper, *"Regulating the Production of Knowledge: From Privatization to Private Ordering in the Law and Ethics of Human Subject Research,"* was one of four judged by the committee, through a blind review of over 20 abstracts submitted by junior faculty, as "likely to produce original scholarship that will make a significant contribution to health law and bioethics scholarship."

Patrick Taylor came 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. His research explores how traditionally legal interests (such as intellectual property), traditionally ethical ones (like public benefit and social justice), and traditionally biomedical ones (such as 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. His work explores governments'

increasing use of bioethics to influence or validate policy-making, within legal systems that also must address public participation and democratic values.
During the first year of his appointment, Patrick has worked on several articles focusing on unresolved problems within cutting edge, high-impact areas of bioethics and biomedical research. During the past decade, the medical profession, regulators and society have split over how to address academic researchers' financial conflicts of interest, particularly those arising from the very sorts of partnership with industry that translational science depends upon. Defining them, resolving them, and situating their resolution within an innovation ecology that depends on academic-industry engagement, have been vexing and divisive problems. His comprehensive examination of the legal, academic, and medical literature has demonstrated both the active play of diverging incentives, and the absence of factual underpinnings essential for sound regulation. His principal scholarly research project, a law review paper pending submission, proposes radical solutions to these vexing issues.

This year, Patrick also has participated as a co-investigator in three research projects funded by the National Institutes of Health, one on institutional review of faculty consulting arrangements, and two related to designing a system to return genetic research results from whole-genome research to research participants, an area of ethical discord and practical challenge. Additionally Patrick has produced writings commissioned by the preeminent scientific journal, **Nature**, on the judicial shutdown of NIH-funded stem cell research, participated on an advisory committee of a Greenwall Foundation grant to the Kennedy School Science Technology and Society Program, participated in a major reformist project by the international Hinxton Group on intellectual property policy and its relationship to innovation and global justice; and has given several invited talks in diverse fora, both locally and internationally.

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 2010, 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 Professors **I. Glenn Cohen** and **Einer Elhauge**

I. Glenn Cohen researched and prepared four articles for publication during the summer of 2010. Three of his articles were selected for publication by the Minnesota Law Review:

The first, co-authored with **Daniel Chen**, a former Petrie-Flom student fellow, titled ***Trading-Off Reproductive Technology and Adoption: Does Subsidizing IVF Decrease Adoption Rates and Should It Matter?*****,** discusses adoption, assisted reproductive technology and insurance mandates for *vitro fertilization*. The work challenges the oft made assertion that such insurance mandates result in a decrease in adoption. The piece addresses normative claims and is supported by empirical evidence.

The second and third articles, ***Regulating Reproduction: The Problem with Best Interests***, and ***Beyond Best Interests***, are part of a larger project investigating the "best interests of the child" objection to assisted reproductive technology. *Regulating Reproduction* relies on ideas from bioethics and the philosophy of identity to present the argument that the best

interests of the resulting child argument is only valid if the state's failure to intervene would foist upon the child a "life not worth living." Professor Cohen concludes the best interest of the child objection is therefore unworkable. *Beyond Best Interests* builds upon *Regulating Reproduction* and considers the "secret ambitions" of the best interests of the child objections and discusses other substitutes for best interests objections.

Finally, ***Medical Tourism, Access to Health Care and Global Justice*** is forthcoming in the Virginia Journal of International Law. In this work, Professor Cohen is the first to comprehensively examine both the empirical question of whether medical tourism reduces the destination country poor's access to health care, and the normative question of the home countries' and international bodies' obligations, if it does.

Einer Elhauge worked on his new book, ***Re-Engineering Humans – What Limits?,*** which addresses the question of when efforts to alter human biology should be considered undesirable in a way that justifies regulatory limits. During the 2010-2011 Academic Year, Professor Elhague presented iterations of an introduction and summary of this book at a number of leading academic forums at top-ranked law schools, including several workshops at Harvard Law School, the University of Chicago Law School, and New York University Law School.

Current Affiliate Publications for 2010-2011

2010-2011 was a banner year for the production of new scholarship in health law generated by current fellows and faculty of the Center. The list of publications and their placements in leading journals attests to the vibrancy of the Center's intellectual community of the exchange of ideas that fosters the production of highly regarded work across the legal, medical and technology professions.

I. Glenn Cohen

The New England Journal of Medicine, May 2011
with Eli Y. Adashi, MD
Human Embryonic Stem-Cell Research Under Siege - Battle Won but Not the War

The Journal of Law Medicine and Ethics, April 2011
with Sadath Sayeed, JD MD
Fetal Pain, Abortion, Viability and the Constitution

The Minnesota Law Review, August 2010
with Daniel Chen, JD
Trading-Off Reproductive Technology and Adoption: Does Subsidizing IVF Decrease Adoption Rates and Should it Matter?

The Iowa Law Review, June 2010
Protecting Patients with Passports: Medical Tourism and the Patient Protective-Argument

Michelle Meyer

The American Journal of Bioethics, April 2011
The Subject-Researcher Relationship: In Defense of Contracting Around Default Rules

The Hastings Center Report, September 2010
Against a One-Size-Fits-All Research Ethics

Patrick Taylor

Cell, May 2011
Responsibility Rewarded: Ethics, Engagement and Scientific Autonomy in the Labyrinth of the Montaur

Nature, October 2010
The Long shadow of the stem-cell ruling: Why is US research stuck in the dock?

Melissa Wasserman

Ohio State Law Journal, March 2011
The PTO's Asymmetric Incentives: Pressure to Expand Substantive Patent Law

Contributions to HLS Teaching Program

Curriculum

For the 2010-2011 academic year, Harvard Law School offered fourteen 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:

•Disability Law	Prof. Field
•Economic Analysis of Health Care Law & Policy	Prof. Frakes
•Ethics, Economics and Law: Seminar	Prof. Sandel
•Health Law	Prof. Barnes
•Health Law Policy Workshop (fall and spring)	Profs. Cohen & Elhauge
•Health, Disability and Planning: Clinical	Prof. Greenwald
•Innovation Policy and Biopharmaceutical Industry	Prof. Wasserman
•Food & Drug Law	Prof. Hutt
•Intellectual Property Law: Advanced	Prof. Fisher
•Reproductive Technology & Genetics: Seminar	Prof. Cohen
•International Reproductive/Sexual Health Rights	Prof. Roseman
•Population-Level Bioethics: Reading Group	Profs. Daniels & Cohen
•Psychiatry and the Law	Prof. Stone

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. The sessions are attended by a wide range of professors and students from across all of Harvard's faculties as well as by local academics and professionals practicing health law, who are seeking insight into the most up-to-date issues in the rapidly changing field. The following is a list of the participants and the titles of their presentations:

Abigail Moncreiff
Associate Professor of Law, Boston University School of Law
A Freedom of Health: On Mandates, Death Panels, Vaccines, Obesity, and the United States Constitution

Anup Malani
Professor of Law & Aaron Director Research Scholar, University of Chicago Law School
Tort Liability and the Market for Prescription Drugs

Rebecca Eisenberg
Robert and Barabara Luciano Professor of Law, University of Michigan Law School
Patents and Regulatory Exclusivity

David Hyman
Richard W. and Marie L. Corman Professor and Director of Epstein Program in Health Law and Policy, University of Illinois College of Law
Employment-Based Health Insurance: Is Health Reform a Game Changer?

Adam Kolber
Professor of Law, University of San Diego School of Law
The Experiential Future of the Law

Nir Eyal
Assistant Professor of Global health and Social Medicine, Harvard Medical School
Deep Exclusionary Reasons: The Case of Luck Egalitarianism and Personal Responsibility for Health

Amitabh Chandra
Professor of Public Policy, Harvard Kennedy School
Identifying Provider Prejudice in Healthcare

Ernst Berndt
Louis E. Seley Professor of Applied Economics, MIT Sloan School of Management
Pricing and Reimbursement in US Pharmaceutical Markets

Patrick Taylor
Petrie-Flom Center Academic Fellow, Harvard Law School
Uniting Regulation of Research Conflicts of Interest with the Innovation Ecology

Michelle Meyer
Petrie-Flom Center Academic Fellow, Harvard Law School
Regulating the Production of Knowledge

I. Glenn Cohen
Assistant Professor of Law and Co-Director Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics, Harvard Law School
Medical Outlaws or Medical Refugees? Circumvention Medical Tourism and the Extraterritorial Application of Domestic Criminal Law

Einer Elhauge
The Carrol and Milton Petrie Professor of Law, Harvard Law School
Reingineering Humans - What Limits?

Talha Syed
Assistant Professor of Law, University of California Berkley School of Law
Distributive Justice & Disability: Theory and Applications for a New Criterion of Weighted Priority

Population Level Bioethics Reading Group

Building on existing relationships with colleagues across Harvard, we undertook a new curricular initiative this year to bring together bioethicists across the University to teach a course on population-level bioethics. This was a joint effort with the Harvard Program in Ethics and Health (PEH), which will soon be integrated into the new Harvard Global Health Institute. Enrollment in the reading group was open to Harvard Law students and to PhD candidates in the Ethics Track of the Doctoral Program in Health Policy. Following is a list of presenters and their paper topics.

I. Glenn Cohen
Assistant Professor of Law and Co-Director Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics, Harvard Law School
Medical Tourism and Migration
Population-Level Bioethics Issues with Procreation

Nir Eyal
Assistant Professor of Global health and Social Medicine, Harvard Medical School
Medical Migration
Doing versus Allowing Harm in Medical Practice
Physician Distribution
Health Worker Migration

Sadath Sayeed
Professor Global health and Social Medicine, Harvard Medical School
Valuing Life in the Neonatal Intensive Care Unit

Robert Troug
Executive Director, Institute for Professionalism and Ethical Practice at Children's Hospital Boston, Professor Division of Medical Ethics, Harvard Medical School
Health Care Rationing at the Bedside: A case study

Daniel Wikler
Mary B. Saltonstall Professor of Population Ethics and Professor of Ethics and Population Health Harvard School of Public Health
Health Promotion: Pre-commitment

Health Promotion: Paternalism and "Libertarian Paternalism" (Nudges)
Ethical Choices in Designing and Carrying out Cost Effectiveness Analysis
Research Ethics: Equipoise: Foundation of Ethical Research, or Shell Game?
Research Ethics: Outsourcing Clinical Trials and the "Standard of Care" Debate

Participation of HLS Students in Program Activities

Student engagement with the Center continued to increase in the 2010-2011 academic year. Health law and policy continues to generate high interest among the law school student body and the national focus on Health Care Reform further galvanized student interest and engagement with activities related to our program. The Center has worked to expand opportunities to work with students interested in the field and, in addition to continuing our banner Student Fellowship Program, we explored augmenting opportunities for students from Harvard Law School and from across the University to engage with us as Research Assistants and Interns, participating in developing events programming, disseminating information about our programs and scholarship, and contributing to communications related work aimed at spreading the word about the work the Center is doing to other students around the University.

Student Fellowship Program

In 2010-11 the Center sponsored seven student fellows who conducted research in a diverse range of topics related to health law. The fellows hailed from programs representing three of the Harvard University graduate schools, and were mentored on their writing projects by the Center's faculty and academic fellows, 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:

Kourtney Baltzer
Harvard Law School, JD 2012
Patent Policy Relating to Improvement of Patient Access to Genetic Testing
Kourtney's intellectual interests lie in patent policy and biotechnology. She graduated from Northwestern University in 2009 with both BS and MS degrees in Biomedical Engineering and is a registered patent agent with the United States Patent and Trademark Office. Her research project focused on patent policy relating to the improvement of patient access to genetic testing. Genetic testing can predict whether a patient will develop a particular disease years in advance, allowing a physician to prescribe certain preventative treatments. However, gene patents often create barriers to the availability of these tests. Through her research, Kourtney explored possible ways to find a balance between maximizing patient access to genetic testing while preserving the intellectual framework of our current patent laws.

Maggie Francis
Harvard Law School, JD 2011
Pilot Programs in the Patient Protection and Affordable Care Act
Maggie is interested in health policy, with a focus on health care access and delivery in the United States. She graduated *magna cum laude* from Boston University in Economics and International Relations and was the president and founder of the Undergraduate Public Health Association. Her academic interests include comparative effectiveness research,

innovative health care financing, and the delivery of health care to low-income and otherwise at-risk populations. During her fellowship, Maggie studied Congress' use of pilot programs in the Patient Protection and Affordable Care Act of 2010. Using case studies to determine how reform-oriented pilot programs have succeeded and failed in the past, she evaluated the likelihood that these pilot programs will result in any large-scale changes to the United States' health care system. She also considered whether pilot programs should be considered a viable policy tool for future health policy reforms.

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
Matthew holds a BA in economics from Northwestern University and an MDiv from Harvard Divinity School. Prior to graduate school, Matthew worked in finance and consulting and spent several years working in the nonprofit sector. His research interests focus on health insurance design and priority setting for medical resource allocation. In a recent study, he analyzed the effects of a value-based insurance design program on low-income and minority populations, supported by a grant from Mathematica Policy Research. In his Fellowship research project, Matthew considered a range of ethical issues that arise when comparative effective research is conducted and applied in health care decision making.

Lindsay Heck
Harvard Law School, JD 2011
FDA Rejection of Declaration of Helsinki for International Clinical Trials
Lindsay came to the Student Fellowship Program with a strong interest in bioethics, particularly in the areas of clinical trials involving human subjects, health disparities, reproductive health, and stem cell research. A graduate of Brown University with a BA in English Literature, she received Departmental Honors in English Literature for her thesis on Beloved and Mrs. Dalloway. In the summer of 2009 she worked at the World Health Organization in Geneva where she researched legislation and regulations related to clinical trials in 19 African countries to identify gaps in their regulatory structures. Her research as a fellow focused on the FDA's formal decision in 2008 to abandon the Declaration of Helsinki in favor of the International Conference on Harmonisation's Good Clinical Practice Guidance. Her project explored the noteworthy differences between the DoH and the ICH GCP, as well as the ramifications of the FDA's rejection of the DoH.

Arta Lahiji
Harvard School of Public Health, MS 2011
Patient Centered Medical Homes Financing and Recent Health Care Reform
Arta earned a Masters of Public Health at the Harvard School of Public Health while concurrently a Student Fellow. She completed her undergraduate degree at University of California Los Angeles with majors in Biology and Women's Studies and earned an MD from the University of Michigan. Her research interests include women's health, international health, and the medical home care model in the care of children with special health care needs. Her previous research includes undergraduate honors theses studying the family-work conflict in women physicians, female genital mutilation, and the clinical role of phytoestrogens and dietary estrogens in cancers effecting post-menopausal women. She has extensively studied the role of the patient-centered medical home in the care of children

with special health care needs and also recently further developed her interests in international health and global outreach in Haiti. During her fellowship, Arta studied the clinical, legal, and financial aspects of implementation of the patient-centered medical home into patient care and health care reform. She also organized a very successful panel on the care of children with disabilities the Center co-sponsored with the Harvard School of Public Health. Details of this event are further outlined below.

Abigail Lauer
Harvard Law School, JD 2012
Effects of Biotech Patents on the U.S. Health Care System
Abby is a second-year student at Harvard Law School. She earned a BS summa cum laude from the College of William and Mary where she majored in biology and was a Monroe Scholar and a Division I all-American soccer player. Abby's research interests focus on the relationship between science and the law. Her research agenda includes studying the costs and benefits of systems that protect intellectual property (patent, trademark, and copyright) as well as potential avenues for reforming these systems. Specifically, she is interested in looking at how the patent system affects health care in the United States and what can be done to ensure that patent protection improves rather than interferes with patient care.

Rajan Sonik
Harvard Law School, JD 2012
Understanding the Legal Needs of Low Income Youth with Sickle Cell Disease
A second year student at Harvard Law School, Rajan's primary academic interests are health disparities and the ways in which the social determinants of health model can be employed to improve advocacy for low-income populations. He is particularly concerned with the synergistic and destructive effects of poverty and chronic illness on children. This interest stems from his experiences mentoring and advocating for teenagers with sickle cell disease. His research aims to articulate better understandings of the challenges these youth face in order to determine the best ways to help them lead healthy and successful lives. He received a BA in Biochemical Sciences from Harvard, and an MPH from UC Davis. He served as a Sickle Cell Advocacy Fellow through the Richardson and Pforzheimer Fellowship Program and has a black belt in Kenpo.

Program of Study Student Fellows

This year, the Center welcomed two Program of Study Fellows, **Devin Cohen** and **Heather Whitney**. Devin and Heather were involved with building bridges between the Petrie-Flom Center and other health law-focused organizations and resources around HLS as part of the Law, Science and Technology Program of Study, one of six multidisciplinary tracks designed to give students interested in a specific area of the law information to help coordinate their curricular and extracurricular activities while at HLS.

Devin Cohen
Harvard Law School JD 2012
Devin hails from Brown University, where he studied history, philosophy, and religious studies. He began his work career in health care fundraising for 26 pediatric oncology centers, and later acted as a health intern for then-Senator Hillary Clinton. He made the leap from quality-of-care initiatives into the world of policy this past summer, working with the locally based not-for-profit organization, Health Care for All, to uphold the Drug

and Device Marketing Gift Ban in Massachusetts. His primary interests include payment reform, stem cell research, pharmaceutical marketing practices, and data mining. Devin is also active in a number of student organizations, including the Harvard Law and Health Care Society, where he served as Vice President of Policy this academic year.

Heather Whitney
Harvard Law School JD 2013
Before entering Harvard Law School as a 1L this year, Heather worked on Google's Global Ethics and Compliance Team. As an undergraduate research scholar at the UCLA Center for Society and Genetics, she explored questions related to how different narratives of identity such as ones found in science fiction, advertising, and stories about abuse and neglect, come to shape our understanding of morality and moral judgments regarding emerging biotechnologies. Against a backdrop of ethics, Heather is interested in the role of law and different institutions in shaping our understanding of psychopharmacology and other identity-shaping technologies pursued with the aim of improving quality of life. She is also interested in what these identity-altering technologies means for our duties to each other, both on local and international levels.

Student Internship Program

In an effort to respond to students' desires to engage with the Center other than through academic research projects, we this year also welcomed two student interns, **Katherine Kraschel** and **Arta Lahiji**. In addition to authoring articles on in the Center's public events contributing to the Center's marketing, communications and outreach efforts, Katie and Arta played an integral role in planning the Center's conference on the Globalization of Health Care, which provided them with the unique opportunity to interact with leading scholars in the field.

Katherine Kraschel
Harvard Law School JD 2012
Katherine is rising third year law student. She worked as a senior associate scientist at Pfizer Global Research & Development for three years after receiving her B.A. in Biochemistry from Mount Holyoke College. Katherine is a research assistant for Faculty co-Director of the Center, Professor Glenn Cohen and will be working with him on research flowing from the conference on the Globalization of Health Care. Her primary interests include assisted reproductive technologies, biomedicalization through the regulation of health care and insurance, and gender equity in health care. Katherine is also submissions editor for the Harvard Journal of Law & Gender.

Arta Lahiji
Harvard School of Public Health MPH, 2011
Arta was a 2010-2011 student fellow at the Center and is pursuing a Master of Public Health in Family and Community Health with a focus on maternal and child health at the Harvard School of Public Health. She completed her undergraduate degree at University of California Los Angeles with majors in Biology and Women's Studies and earned an MD from the University of Michigan. Arta's interests in international health, global health disparities, and global outreach in Haiti have informed her contributions and interests in the conference on the globalization of health care. Her other interests include women's health, children with special health care needs and the patient-centered medical home which has

been the focus of her research at the Center. Upon concluding her internship and receiving her MPH, Arta will return to UCLA to begin her medical residency.

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 firsthand 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.

September 20-21, 2010

Judicial Seminar on Emerging Issues in Neuroscience

In conjunction with the sponsors of the meeting, the American Association for the Advancement of Science, the Federal Judicial Center, the National Center for State Courts, the American Bar Association Judicial Division, and the Dana Foundation, the Center hosted a two-day training session for approximately 40 federal and state judges on the most recent research in neuroscience and what impact it may or may not have on the law. A particularly important and interesting topic among members of the judiciary, this training is one in a series of similar events the Center has hosted in recent years. The field is evolving at a rapid pace and there is a tremendous need for clear interpretations and careful considerations of the implications for new research in the mind sciences on the law. This workshop featured panels on neuroscience methods and technology, the latest research in understanding the development of the adolescent brain, the neuroscience of addiction, considerations of comatose, vegetative and other minimally conscious states, the neuroscience of memory, of criminality, and advances in the understanding of brain injury and recovery. Presenters included leading scholars such as **Thomas Cochrane**, Brigham and Women's Hospital and Harvard Medical School, **Carter Snead**, University of Notre Dame School of Law, **Abigail Baird**, Vassar College, **Chuck O'Brien**, University of Pennsylvania, **James Giordano**, Potomac Institute for Policy Studies, **Michael Williams**, Brain and Spine Institute, Sinai Hospital, Baltimore, **Adrian Raine**, University of Pennsylvania, **Daniel Schacter**, Harvard University, and **Michael Alexander**, Beth Israel Deaconess Medical Center and Harvard Medical School,

November 22, 2010

The Constitutional Foundations of Bioethics: A Cross-National Comparison

In collaboration with the Program on Science, Technology and Society at the Harvard Kennedy School the Center is a named recipient of a grant from the Greenwall Foundation for a project entitled The Constitutional Foundations of Bioethics: A Cross-National Comparison. The study responds to the current rapidly changing landscape of the biosciences and bioethics. In addition to Professors **Sheila Jassanoff** of the Program on Science and Technology and Society at the Harvard Kennedy School and Petrie-Flom Faculty co-Director **I. Glenn Cohen**, the Grant Advisory Committee includes representatives from the Massachusetts Institute of Technology, the Whitehead Institute, Arizona State University and the National Institutes of Health.

Departing from the historical bioethical concerns which arose around human subjects research, with subsequent extension to animal welfare, this project focuses on newer areas of concern, including stem cell biology, regenerative medicine, and synthetic biology. In recent years, these research frontiers have been producing new isolates, constructs, and tools that resist easy classification and ethical or regulatory treatment. Examples include the artificial organism Mycoplasma laboratorium, BRCA genes, "biobricks," and induced pluripotent stem cells. New approaches to oversight are emerging haphazardly around such entities, with potentially far-reaching consequences for biomedical research and development. The project brings together leading scientists, legal experts, bioethicists, and social analysts of science and technology to compare emerging ethical norms and policy responses around specific biological constructs and research domains across several countries. In November 2010, a first meeting was held at Harvard Law School to initiate the Project, and included participation of members of the faculties at the Harvard Kennedy School, Harvard Law School, Harvard Business School, the Harvard Stem Cell Institute, Children's Hospital Boston, and others from several leading national and international research universities, as well as industry representation with a participant from Pfizer, Inc. The agenda included topics concerning the balancing of innovation and precaution, and human safety, security, and integrity in biomedical research. The agenda also included planning and development of case studies concerning direct to consumer testing, chimeras, overregulation and underregulation. These case studies are being written by doctoral students and will be presented for discussion in a follow up workshop, to be held in late fall 2011.

February 20, 2011

Meeting with the Commissioner of the Food and Drug Administration

During a visit to Cambridge to participate in a University sponsored panel on the impact of the Human Genome, in light of the Human Genome Project's 10th anniversary, Food and Drug Administration (FDA) Commissioner **Margaret Hamburg** took time to meet informally with a group of Harvard Law students interested in careers in food and drug law. The Commissioner gave a brief overview her role and spoke briefly about the challenges the FDA faces in the increasingly complex and internationally focused field of food and drug regulation. The opportunity for a candid question and answer session followed the introduction, during which students and the Commissioner discussed questions ranging from issues of federal food and drug safety law preemption and the role of local level regulation (a timely topic, given a recent Supreme Court ruling on preemption in the vaccine space), to ethics and regulation of direct-to-consumer genetic testing, the relationships between the FDA and numerous other government agencies involved with health policy matters as well as matters related to cooperation with international regulatory bodies. From the perspective of her role as one of a few Presidential appointees in one of the largest federal agencies dedicated to matters concerning public health, Dr. Hamburg also shared with students her view of the challenging role politics can sometimes play.

Public Events Programming and Conferences

The events programming for the 2010-11 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 30, 2010

Massachusetts State Senator Richard Moore: National Health Care Reform and the Massachusetts Experience

Senator **Richard Moore** addressed a group of forty law students, medical students, and faculty from across the Harvard community. As Senate Chairman of the Massachusetts Legislature's Committee on Health Care Financing, Senator Moore played a pivotal role in sculpting C. 58 of the Acts of 2006, more commonly known as the Massachusetts Health Reform Law, which has become a template for other health reform efforts nationally. Senator Moore is widely known as an outspoken advocate of universal health coverage. Though he allocated most of his time to taking questions from an eager crowd, the Senator first explained how Massachusetts' health reform efforts developed into a prototype for the Patient Protection and Accountable Care Act (PPACA).

October 4-8, 2010

The Fragmentation of the US Health Care: Causes and Solutions

In collaboration with the professionally esteemed blog *Concurring Opinions*, the Center held an online symposium on the new book *The Fragmentation of U.S. Health Care: Causes and Solutions*, edited by Founding Faculty Director, **Einer Elhauge**. This book, which grew out of a conference the Petrie-Flom Center hosted in 2008, features a stellar list of contributors from law, economics, medicine, management, and other disciplines. The online symposium examined the themes and claims of the book, and in particular examined their relevance in the post health care reform world. Online symposium contributors: **John Jacobi** of Seton Hall Law, **Anup Malani** University of Chicago Law School, **Abigail Moncrieff**, Boston University School of Law, **Gwendolyn Roberts Majette**, Cleveland-Marchall College of Law, **Ani Satz,** Emory Law School, **Richard Saver,** University of North Carolina School of Law, **Vicki Williams,** Gonzaga School of Law, and **Elizabeth Weeks,** the University of Kansas School of Law. **Frank Pasquale** of Seton Hall Law School and co-editor of *Concurring Opinions* was instrumental in orchestrating the symposium.

October 14, 2010

Autism: Rights, Status, and Classification

A multidisciplinary panel discussion addressed issues ranging from the new DSM classification, neuroscience, genetics, and disability rights. Panelists included **Ari Ne'eman**, the Founding President of the Autistic Self Advocacy Network and a newly appointed member of the National Council on Disability, and **Isaac Kohane**, Lawrence J. Henderson Professor of Pediatrics and Health Sciences and Technology at Harvard Medical School, and **Harold Bursztajn**, Associate Clinical Professor of Psychiatry at Harvard medical School, and **Omar Sultan Haque**, also of Harvard Medical School. Harvard Law School Professor, and Faculty co-Director of the Petrie- Flom Center, **I. Glenn Cohen**, moderated the panel and Professor **Michael Stein** of the Harvard Program on Disabilities was the panel discussant.

October 27, 2010

Challenges to Health Care Payment Reform: A Panel Discussion

This timely panel discussion on health care payment reform was widely attended by students and faculty from across Harvard University. **Dorothée Alsentzer**, the senior fellow with HLS' Legal Services Center's Health Law and Policy Clinic, moderated a discussion with **Bob Master** from Commonwealth Care Alliance, **Georgia Maheras,** from Health Care for All, and **Joshua Greenberg** from the Children's Hospital in Boston. The panel discussed issues in current health care payment practices, and potential obstacles in implementing reform measures, and considered deeper, systemic questions about the challenges emerging from the current payment structure from multiple perspectives.

November 10, 2010

Challenging Drug Patents in Developing Countries

Tahir Amin, a co-founder of the Initiative for Medicines, Access & Knowledge (I-MAK), spoke with Harvard law students about the impact of the current patent system on global health and legal strategies that are currently being used to increase access to essential medicines. Mr. Amin leads a unique partnership between attorneys and scientists that is dedicated to identifying and challenge unmeritorious patents in India. The organization's goal is to ensure that patents do not unnecessarily obstruct access to medicines for the poor.

January 18, 2011

Current Controversies in Food and Drug Law

A panel of distinguished practitioners discussed some of the current controversies in food and drug law, including changes in the FDA's approval process for new drugs, the regulation of biosimilar products, restrictions on the marketing of therapeutics, and emergency preparedness for medical disasters. Panelists included **Peter Barton Hutt** of Covington & Burling and Harvard Law School, **Kristen Mayer** of Ropes & Gray and **Mark Raza** of the FDA. The panel was moderated by Faculty co-Director of the center, Professor **Benjamin Roin**.

February 28, 2011

Criminalizing Research: The History, Development and Revision of the Massachusetts Fetal/Neonatal Research Statute

This discussion addressed questions that have been raised about embryonic, fetal and neonatal research since the first moment the technology became available and has become a particularly hot topic with recent political developments in fetal and stem cell research. March 9, 2011 marked the second anniversary of President Obama's executive order allowing funds to be used for research on embryonic stem cells. The lively conversation outlined the various issues surrounding stem cell research. The event also featured a presentation by Petrie-Flom Center Academic Fellow **Patrick Taylor**.

March 3, 2011

Female Circumcision: Ethics and Human Rights

The practice of female genital circumcision has been at the center of health and human rights debates for decades. Public health, women's rights and child rights advocates, governments and health professional associations--in Africa, Asia, Europe and the US--have taken positions running the gamut from abolition to harm reduction. In April 2010, the American Association of Pediatrics issued a Policy Statement on female genital cutting

that was quickly retracted in the face of significant opposition. The controversy surrounding the report presents an excellent point of departure for examining the issues that still complicate our thinking about the issue. This panel explored the ethical, legal, and human rights dimensions of female genital circumcision, including dimensions of toleration, prohibition, harm-reduction, and cultural competency. This panel included **Dena Davis** of Cleveland-Marshall School of Law, **Hope Lewis** of Northeastern University School of Law, **Nawal Nour** of Harvard Medical School, and **Sarah Waldeck** of Seton Hall University School of Law. The panel was moderated by Faculty Co-Director of the Center, **I. Glenn Cohen** and **Mindy Roseman**, Academic Director of the Human Righs Program at Harvard Law. The panel was co-sponsored by the Harvard Human Rights Program.

March 24, 2011

Is the Obama Health Care Reform Constitutional?

This distinguished panel consisting of the nation's most prominent constitutional law scholars debated America's most significant health care reform initiative in over 50 years. The centerpiece of President Obama's domestic policy agenda, the Patient Protection and Affordable Care Act is currently being challenged in federal courts across the country. As of the date of the event, two district courts had already pronounced the measure (at least in part) unconstitutional, focusing on its individual mandate, while two courts had upheld the measure. Appeals are still pending before the Circuit courts, and with more litigation on the way the question may soon end up before the U.S. Supreme Court. The lively debate included Harvard Law School Professors **Charles Fried** and **Laurence Tribe**, and Georgetown University Law Professor **Randy Barnett**. The event was moderated by Petrie-Flom Faculty Co-Director, **I. Glenn Cohen**.

April 4, 2011

Racial Disparities in Health Care

Forty years after the end of the Jim Crow era and the passage of Title VI of the Civil Rights Act, there remain large racial disparities in the American healthcare system. This panel explored the strengths and weaknesses of various policies that may be employed to alleviate ongoing racial health disparities. Such policies include those that enhance the enforcement or reach of existing civil rights laws, and those that call for more direct and targeted quality-improvement initiatives. In addition, the panel discussed those aspects of the Affordable Care Act that may lead to reduced disparities in care. This panel featured participation from **David Barton Smith**, Drexel University School of Public Health, **Anup Malani**, University of Chicago Law School, **Gregg Bloche**, Georgetown Law Center and the Georgetown-Johns Hopkins Joint Program in Law and Public Health, **Amitabh Chandra**, the Harvard Kennedy School of Government, and was moderated by Petrie-Flom Academic Fellow, **Michael Frakes.**

April 28, 2011

Children with Disabilities: What's Right, What's Wrong, What's Next?

This panel discussed issues on the road for educational, legal, and health care rights for children with cognitive, social/emotional, and physical disabilities. Panelists included Professor **Tom Hehir** of the Harvard Graduate School of Education, Professor **Charles Homer** from the Harvard School of Public Health, Professor **Martha Field** from Harvard Law School, **Jaishree Capoor** from Blythedale Children's Hospital and **Mary Katherine Arbour** of the Brigham and Women's Hospital.

Conferences

November 12, 2010

Should Congress Repeal the McCarran-Ferguson Act?

In November the Center hosted a conference entitled "Should Congress Repeal the McCarran-Ferguson Act?" The Act exempts "the business of insurance" from federal antitrust regulation, except the regulation of boycott, coercion and intimidation, so long as state law regulates anticompetitive conduct. Congress adopted the Act in 1945 following a controversial holding by the U.S. Supreme Court that federal antitrust laws applied to insurance under the authority of the commerce clause. Debates over the repeal of the law date back thirty years, most recently forming part of the health reform debate. The conference panelists and attendees represented diverse backgrounds, including economics, law, health policy, and the insurance industry. The views of the panelists were also diverse, ranging from advocates of the Act's repeal, to proponents of the Act, to those who argued that repeal of the Act would have little effect, to those who believe the courts have interpreted the Act incorrectly. Each of the panelists was followed by a commentator and questions from the audience. Panelists included **Subramaniam Ramanarayanan**, Assistant Professor, UCLA Anderson School of Management; **Kathryn Zeiler**, Senior Fellow at the Center and Professor, Georgetown University Law Center; **David Balto**, Senior Fellow, Center for American Progress; **Deborah Hass-Wilson**, Professor, Smith College; **Scott Harrington**, Professor, Wharton School; **Einer Elhauge**, Founding Faculty Director of the Center and Professor, Harvard Law School; **Daniel Schwarz**, University of Minnesota School of Law; **Joseph Miller**, General Counsel, America's Health Insurance Plans; **Michael Meurer**, Boston University School of Law; and **Stephen Weiner**, of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, LLC.

May 20-21, 2011

The Globalization of Health Care: Legal and Ethical Challenges

The Center's banner conference for the 2010-2011 academic year was one of (if not the) very first to offer a comprehensive legal and ethical analysis of the most interesting and broadest reaching development in health care of the last twenty years: its globalization. This unique event brought together speakers from across the globe, from academia as well as practice, and from across disciplinary boundaries. The participants represented a wide array of disciplinary backgrounds with teaching appointments in law, philosophy, medicine, public health, government, anthropology, and geography, helping to produce an event that crossed borders and paradigms to gain insight on the vexing questions emerging from this rapidly changing field. The conference tied together the manifestation of this globalization in four related subject areas – medical tourism, medical migration (the physician "brain drain"), telemedicine, pharmaceutical research and development – and integrated them with a philosophical discussion of issues of justice and equity relating to the globalization of health care and the public health governance issues involved.

The legal and ethical issues surrounding the globalization of health care are complex, novel, interrelated, and pressing. Coming on the heels of the most expansive reform to U.S. health care in fifty years, this conference also enabled us to begin plotting the intricate map of the ways in which this globalization will develop as the reform is implemented.

Among the key questions the conference addressed were:

- Does medical tourism offer a viable and ethical way to expand access to health care to domestic patients who would otherwise face cost barriers or waiting lists to access services? How will the recent Obama Health Care Reform in the U.S. and the European Directive in the EU alter the existing industry and the legal and ethical issues it raises?

- Does medical tourism for services illegal at home – abortion, assisted suicide, reproductive technology – represent a problematic end-run around domestic criminal prohibitions, or does it instead enable value pluralism and accommodate the needs of "medical exiles" without violating the laws of their home states? What steps can home states take under domestic and international law to control the activities of their patients who travel to circumvent its criminal prohibition?

- Under what conditions can home country governments and institutions lawfully recruit physicians, nurses, and other health care professionals from developing countries that face chronic shortages of providers? Can these developing countries legally, ethically, and effectively use techniques like long-term service contracts or restrictions on migration to avoid the decimating effects of this recruitment on their health care systems?

- Should the legal rules relating to licensure of physicians, the unauthorized practice of medicine, medical malpractice, and choice of law be altered to foster a robust telemedicine industry, and how would one go about doing so? Are arbitration or other dispute system designs appropriate ways to address patient and regulatory concerns regarding injuries incurred during the use of telemedicine?

- Can countries require pharmaceutical companies to register their trials and report negative results without violating international trade law? Under what circumstances can unethical research practices conducted during pharmaceutical trials outside the United States be made actionable at law under the U.S. Alien Tort Statute?

- Do WHO member states who share their influenza strains enabling the creation of influenza vaccines have a right to certain quantities of those vaccines? In what ways should the global intellectual property regime governing pharmaceuticals be altered to conform with principles of justice? More generally, under what circumstances are health inequities between countries unjust, and when do those inequities imply duties of assistance from other countries?

The conference culminated with a public session on the global regulatory challenges on prohibiting the sale of organs that tied together the personal stories, governance challenges, and medical perspectives.

The event was a rounding success and we are pleased to announce that **Oxford University Press** has accepted our proposal to produce an edited volume of the papers presented at the conference edited by Petrie-Flom Faculty Co-Director **I. Glenn Cohen**, similar to volume edited by Petrie-Flom Center Founding Faculty Director, Einer Elhauge *The Fragmentation of U.S. Health Care: Causes and Solutions*, which emanated from our annual conference in 2008. Webcasts of the panels of this year's conference are available at: http://www.law.harvard.edu/programs/petrie-flom/events/index.html

2010-11 Plans for Activities

During 2011-2012, we plan to consolidate and continue the excellent work the Center has done.

In the fall we will be working hard to place two of our current fellows, **Michelle Meyer** and **Patrick Taylor**, into top teaching jobs, and welcoming two new fellows **Holly Fernandez Lynch** and **Jeffrey Skopek** whom we enthusiastically expect will add vibrancy to the intellectual diversity of the Center. Below are summaries of Holly and Jeff's backgrounds, and the research agendas they will bring to the Center. Also included are details concerning **Faculty Summer Research** projects, and the planned **2011-2012 Health Law Curriculum** and brief initial information about plans for our student-based initiatives.

Other of our other programmatic initiatives are still in the planning stages. We are currently in the midst of planning the lineup for the coming year's Health Law Policy Workshop, our events programming, and our annual conference. We look forward to updating you on the Center's full 2011-2012 agenda as it evolves over the summer.

Research and Scholarship

Incoming Academic Fellows

Holly Fernandez Lynch graduated Order of the Coif from the University of Pennsylvania Law School in 2006, where she was a Levy Scholar in Law and Bioethics; President of the Bioethics, Law, and Public Policy Society; and an Associate Editor of the *University of Pennsylvania Journal of Constitutional Law*. While pursuing her J.D., Holly earned her Master of Bioethics from the University Of Pennsylvania School Of Medicine. As a member of the inaugural cohort of Academic Fellows at the Petrie-Flom Center, Holly wrote *Conflicts of Conscience in Health Care: An Institutional Compromise*, published by MIT Press in 2008. The book was named Outstanding Academic Title by the American Library Association's *Choice Magazine*, and its proposal for protecting both patient access and physician conscience has been considered by organizations as diverse as the Brookings Institution and President Bush's Council on Bioethics. Holly has also published on clinical research in vulnerable populations, end-of-life care, placebo-controlled trials with pediatric subjects, and genetic privacy.

After completing her manuscript on conscientious refusal, Holly interrupted her fellowship in order to gain additional experience in the private sector, government, and policymaking. Holly practiced law at Hogan and Hartson (now Hogan Lovells) in Washington, DC, where she was a member of the pharmaceuticals and biotechnology practice group. She has also advised the NIH's Division of AIDS on international research ethics as a bioethicist for the Henry M. Jackson Foundation. Most recently, Holly served as a Senior Policy and Research Analyst staffing President Obama's Commission for the Study of Bioethical Issues.

During her resumed fellowship, Holly will continue to work on issues at the intersection of law and bioethics. She plans to examine a variety of circumstances in the clinical and research contexts in which the current norm is to seek consent from interested parties, but in which consent may actually be unnecessary or appropriately surrendered in order to promote other social goods. She also plans to undertake additional projects applying legal notions of exploitation to the realm of international clinical trials, and to extend her work on conflicts of conscience, particularly with regard to discriminatory behavior by professionals.

Jeffrey Skopek will join the Center in the summer of 2011. He earned a J.D., *magna cum laude*, from Harvard Law School, where he served on the Articles Committee of the Harvard Law Review, and a Ph.D. in the History and Philosophy of Science from the University of Cambridge, where he studied as a Gates Scholar and Fulbright Scholar. He also holds an A.B. from Stanford University. Following law school, he clerked for Chief Judge Sandra L. Lynch of the U.S. Court of Appeals for the First Circuit. His past scholarship has covered topics ranging from the history of genetics to animal rights and environmental ethics. During his fellowship, he will explore legal and ethical uncertainties tied to the emergence of a biological conception of individual identity. Using biobanks and forensic DNA databanks as a case study, he will develop an account of the competing images of the human subject that underlie different legal solutions to the problems of governance that these collections create.

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 2011, summer research grant recipients and brief descriptions of their projects are:

I. Glenn Cohen will finish edits on his three forthcoming articles, and complete a new on regarding medical tourism for services illegal in th epatient's home country, including travel for abortion, assisted suicide, and reproductive technology use.
Einer Elhauge will continue his book, *Re-Engineering Humans – What Limits**?**,* which addresses the question of when efforts to alter human biology should be considered undesirable in a way that justifies regulatory

Benjamin Roin will be working on three projects. The first is a study of how regulatory barriers (like product safety standards) can influence research and development spending by changing the comparative costs of first movers and imitators. He will also finish a project about the use of prizes for encouraging medical innovation. And his third project for the summer is to conduct research on an empirical project with Heidi Williams, a former Petrie-Flom Student Fellow who now is a professor of economics at MIT, and Eric Budish from The University of Chicago Booth School of Business on drug patent length and cancer drug research and development. This project seeks to document how the fixed patent term distorts cancer research away from treatments for early-stage cancer and cancer prevention due to the long duration of the necessary clinical trials.

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 2011-2012. Following is the list of course offerings to date:

• Disability Law	Prof. Stein
• Drug Product Liability Litigation	Prof. Grossi
• Food: A Health Law and Policy Seminar	Prof. Greenwald
• 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
• International Reproductive Health Rights	Prof. Roseman
• Insurance Law	Prof. Hay
• Patent Law	Prof. Roin
• Regulation of the Production of Knowledge	Prof. Meyer

Health Law Policy Workshop

The following is a list of the dates, workshop presenters and their affiliations as well as tentative titles for the Fall Semester presentations.

Fall Semester Schedule

September 12
Mark Hall
Fred D. & Elizabeth L. Turnage Professor of Law, Wake Forest University School of Law
Clause Challenges to Health Care Reform

Sept 23
Arti Rai
Elvin R. Latty Professor of Law Duke Law School
Administering Patent Policy across the Executive Branch: The Case of Life Science Patents

October 3
Al Roth
George Gund Professor of Economics and Business Administration Harvard Business School **&**
Judd Kessler
Assistant Professor of Business and Public Policy, the Wharton School University of Pennsylvania
Organ Allocation Policy and the Decision to Donate

October 24
Tom Baker
Deputy Dean and William Maul Measey Professor of Law and Health Sciences University of Pennsylvania Law School
Incorporating Insights of Judgement & Decision Making and Behavioral Economics into the Design of the Health Exchanges

November 7

Katherine Baiker
Professor of Health Economics Department of Health Policy and Management, Harvard School of Public Health
TBD

November 21
Maxwell Mehlman
Professor of Bioethics and of Law, Case Western Reserve University
Bio-enhanced Warfare

Spring Semester Schedule

January 23
Nita Farahany
Associate Professor of Law and Associate Professor of Philosophy Vanderbilt Law School

February 6
Richard Epstein
Professor James Parker Hall Distinguished Service Professor Emeritus of Law and Senior Lecturer, University of Chicago Law School

February 13
Russell Korobkin
Professor of Law, UCLA School of Law

March 26
Frank Pasquale
Schering-Plough Professor in Health Care Regulation and Enforcement, Seton Hall School of Law

Participation of Students in Program Activities

The following is the list of 2011-212 **Petrie-Flom Student Fellows**

Devin Cohen
Harvard Law School, JD 2012
Pills, Quills, and Dollar Bills: Pharmaceutical Marketing and Research Practices, Physician Conflicts of Interest, and the Practical Reach of Regulatory Reform

Sachin Desai
Harvard Law School, JD 2013
Improving Commercialization of Government Medical Research By Changing Funding Models Instead of Bayh-Dole Style IPR Mechanisms

Dorothy Du
Harvard Law School, JD 2013
Improving the Regulation of GM Crops: The Failure of the Coordinated Framework and Proposals for Reform

Gurjeet Singh Guram
Harvard Medical School, MD 2014
Legal Barriers Innovation in Delivery of Health Care

Rebecca Haffajee
Harvard Graduate School of Arts and Sciences, PhD 2014
Probing the Constitutional Basis for Distracted Driving Laws: Do they Actually Reduce Fatalities?

Katherine Kraschel
Harvard Law School, JD 2012
How to Tame a Part of the Wild West?: Using Existing Legal Frameworks to Inform Surrogacy Regulation

Rachel Sachs
Harvard Law School, JD, Harvard School of Public Health, MPH, 2013
The Role of Public Health In Patent Law Injunctions

In 2011-2012 we again plan to engage Harvard Law School students to work as **Program of Study Fellows** on behalf of the Center's initiatives, to disseminate information to other students and faculty at HLS about opportunities in areas at the intersection of health care and the law.

We also plan to formalize a **Petrie-Flom Internship Program** eligible to students from across Harvard University interested in engaging with the Center's activities in ways other than by independent research projects. Our plans for this program are still in development and recruiting for interns as well as for Program of Study Fellows will take place in the early fall.