



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

Annual Report of Activities 2008-2009

Executive Summary

The 2008-2009 academic year marked the third year of the Petrie-Flom Center. Under the leadership of Visiting Faculty Director, Anup Malani, the Center's curricular and public events programming brought together a highly diverse group of students, scholars and practitioners in the fields of health law, health policy, bioethics and biotechnology to further the Center's mission of generating quality research in these rapidly changing fields.

Given the potentially dramatic changes to these fields with the 2008 presidential elections, this year's programming addressed a wide array of pressing health care topics. The Center's public events tackled issues ranging from the role of dignity in medical decision making, to the competing healthcare reform proposals of the 2008 presidential candidates. The year culminated with a conference on the legal and economic challenges to research and development in the pharmaceutical industry. All of the Center's events featured participation from nationally-recognized scholars and prominent industry practitioners, as well as enthusiastic participation from members of the Law School and greater Harvard University community.

The centerpieces of the Center's curricular activities were the Health Law Policy Workshop and the first annual Colloquium of Student Research in Health Law. Responding to increasing interest from faculty and students across the University, Prof. Malani convened the Health Law Policy Workshop weekly for two semesters (rather than just one). Researchers from a wide variety of disciplines were invited to present their findings to an audience of peers and students from across Harvard University. The cross-disciplinary nature demonstrated the many different approaches scholars employ to grapple with the complex problems of our healthcare system. The Student Colloquium likewise received an enthusiastic response. This one day conference showcased health law research papers by a dozen students from across Harvard

University. Students who presented their research gained valuable experience presenting their findings, and important feedback from faculty and fellows of the Center. Our hope is that the large audience of students was inspired to pursue their own research projects and present them at next year's Colloquium.

Finally, with respect to our aim of developing new law and policy scholars specializing health law, the Center extended its track record of successful placements. Our Academic Fellows on the entry-level law professors' market landed tenure track positions at the University of California Berkeley's Boalt Law School and at the Boston University Law School. The Center continued to address the demand for health scholarship from existing professors. A greater number of Law School professors applied for and received grants to conduct summer research, and they represented specialists from a wider variety of fields of specialty than ever before, including bankruptcy, torts, patent law, and disability law.

This report describes these accomplishments in greater detail.

2008-09 Report of Activities

Research and Scholarship

Academic Fellows

The Academic Fellowship program is the focal point around which other of the Center's initiatives are built. This year's fellows have made several major successes in their long-term career objectives gaining placements at prestigious law schools as well as producing first-rate scholarship that has received 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.

Our Academic Fellows have played an important role in the Center's activities through planning and assisting with the execution of public events, and by presenting their research in various colloquia sponsored by the Center and other Harvard-based institutions. Additionally, the Academic Fellows played an instrumental role in enhancing the experience of students affiliated with the program this year through direct mentorship and guidance of student research projects. Their work and successes are individually summarized below:

After interviewing at several top-ranked law schools, **Abigail Moncrieff** accepted a tenure-track teaching position at Boston University Law School. While a Fellow, Abigail also published two articles: *Federalization Snowballs: The Need for National Action in Medical Malpractice Reform*, which was published in the *Columbia Law Review*, and *Reincarnating the Major Questions Exception to Chevron Deference as a Doctrine of Non-Interference* published in the *Administrative Law Review*. She is currently working on another full-length article tentatively entitled *The Disappearance of Private Attorneys General: Why It Matters for Health Law and What We Should Do About It*. The paper will address health law's move away from individual private enforcement of healthcare regulations and will argue that federal agencies should fill in the regulatory vacuums created by the increasing disappearance of private attorneys general.

JP Sevilla's research agenda has focused on fundamental questions of moral responsibility. His first article argued that because physical mechanisms were causally sufficient for all mental events, persons should not be held morally responsible for their actions under nonconsequentialist theories of justice. His second article argued that there is no nonreducible self but rather a series of moment-selves and explores the philosophical implications. Through presentations of his work at various workshops at the Law School and the Harvard Medical School, he has developed and is currently working on an expansion of his papers as the issues relate to the understanding of themes within the natural sciences. JP will continue these inquiries as he undertakes a position as a Research Fellow at the Harvard School of Public Health's Department of Global Health and Population in the fall.

One of the Center's Inaugural Fellows, **Talha Syed** wrapped up his appointment with the Center by accepting an entry-level teaching position at the University of California, Berkley Boalt Law School. The work he presented as a candidate, and that he has continued to develop during the year, involved the two main streams of his current research: work on pharmaceutical innovation law and policy (primarily undertaken jointly with Professor William Fisher at Harvard Law School) and independent work developing a number of critiques of and alternatives to welfarist cost-effectiveness analysis, with special reference to the allocation and distribution of healthcare resources. Talha will complete his Doctoral diploma at Harvard Law School before leaving for Berkeley and is using the latter part of his tenure as an Academic Fellow to work on his dissertation titled *Cost-Effectiveness Analysis in Law and Regulatory Policy: Three Fundamental Critiques and Two Constructive Amendments*.

Allison Hoffman is a 2004 graduate of Yale Law School where she was submissions editor for the Yale Journal of Health Policy, Law and Ethics. After graduating, she spent several years as a Corporate Health Care Associate for Ropes & Gray, LLP, and most recently has been a management consultant for The Bridgespan Group, where she counsels leading nonprofits and foundations on management strategy. During her first year in the fellowship, Allison has authored an empirical study of Massachusetts Health Care Reform, evaluating the effectiveness of individual mandates as a means toward a universal healthcare policy. The article is tentatively titled *Oil and Water: The Trouble With Individual Mandates, Fragmented Markets, and Health Reform*. Allison looks forward to submitting it for publication this summer. Additionally, her research agenda includes plans to conduct a study arguing for shifting the way we think about healthcare quality initiatives by starting with well-defined, measurable outcomes, as well as to work on a proposal on social insurance to support informal providers of long-term care. Allison plans to participate in the 2009 entry-level law professors' market in the fall.

In 2006, **Christopher Robertson** was a Petrie-Flom Student Fellow while a third-year student at Harvard Law School. His student fellow paper was a co-authored article titled *Get Sick, Get Out: The Medical Causes of Home Foreclosures*. Eventually published in the journal Health Matrix, the paper provided analysis based on original empirical data showing that half of all home foreclosures are caused in part by some sort of medical crisis in the household. This article gained widespread attention in the media having often been cited in articles on the home foreclosure crisis, and Christopher has been interviewed by several news outlets to discuss his findings. Since commencing his Academic Fellowship in September 2008, Christopher's research agenda has included projects investigating the relationship between expert advice and lay judgment under conditions of potential bias especially in judging cases of medical malpractice. This research has led to an article that has been accepted for publication in the New York University Law Review entitled *The Blind Expert: A Litigant Driven Solution to Bias and Error*. Christopher is working on two more empirical projects related to the main idea in this article. One is a laboratory experiment that will measure the ability of lay jurors in medical malpractice cases to assess the biases of expert witnesses, compared to those that are blinded. In another project he plans to measure the litigant-induced biases of doctors reviewing medical malpractice cases, compared to

experts who are blinded. While conducting research on these projects, Christopher plans to participate in the 2009 entry-level law professors' market in the fall.

Academic Fellow **Mark S. Stein** has worked on a wide ranging research agenda focusing on utilitarian theories of justice in the realm of healthcare distribution since commencing his fellowship. In the past year, he has published an article titled *Nussbaum: A Utilitarian Critique* in the Boston College Law Review. The article examines Nussbaum's distributive theory of justice particularly as they apply to healthcare. He is also working on an article tentatively entitled *Welfare Versus Autonomy in Human Subjects Research* which argues that in the regulation of human subjects research, the value of autonomy is compromised, and should be compromised, for the sake of the welfare of research subjects and the welfare of those who stand to benefit from medical research. Mark will continue this research agenda while participating in the 2009 entry-level law professors' job market in the fall.

Melissa Wasserman joined the Center in December of 2008. She earned her Ph.D. in chemical engineering from Princeton University. She is also a graduate of New York University Law School, where she was an Articles Editor of the Law Review. After graduating Melissa clerked for Judge Kimberly A. Moore on the U. S. Court of Appeals for the Federal Circuit. Her past scholarship includes work on the extraterritorial scope of patent law and the doctrine of inequitable conduct. During her fellowship Melissa has begun writing on issues involving patent law and biotechnology, including the desirability of utilizing FDA law to promote biotechnology innovation, how the judicial philosophy of the Federal Circuit influences biotechnology innovation, and the anticompetitive effects of authorized generics. Melissa plans to continue this research and participate in the 2010 entry-level law professors' market.

Faculty Research Support

An important goal of the Center has been to encourage existing Harvard faculty to use their expertise to focus on long-neglected issues falling within the Center's mandate. In 2008, 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. We received more than ten applications from a greater variety of fields of expertise than in previous years. This evidences the success with which the Center has been able to engage the interest of core Harvard Law School faculty in issues related to health law. In the summer of 2008 grants were given to:

- **I. Glenn Cohen** wrote an article entitled *Intentional Diminishment, the Non-Identity Problem, and Legal Liability* which appeared in the Hastings Law Journal. Additionally, Professor Cohen undertook research related to medical tourism.
- **Einer Elhauge** continued work on a book on how best to regulate the re-engineering of human biology
- **Martha Field** undertook research on disability and eugenics in an effort to study the intersection between these subjects and to consider how society's new interest in and knowledge about genetics will impact future policy choices. She presented her initial findings in a talk at the Harvard Humanities Center in April 2009. Additionally, Professor Field wrote an article on Parental Rights in Constitutional

Law, which is published in the Encyclopedia of Constitutional Law (2009). Portions of the article relate to parental control of children’s health decisions – in relation to state laws and in relation to children’s own choices. Another part traces the debate over compulsory vaccination laws and discusses how and why public reaction in relation to the HPV vaccine differs from past public reaction to the Hepatitis B vaccine.

- **Benjamin Roin** wrote a paper, which will be submitted to law reviews this fall, arguing that the operation of the 20-year patent term for drugs has the effect of discouraging investment in many preventative treatments and drugs for early-stage disease. The paper argues for specific reforms in the setting of patent length for drugs to correct these problems.
- **David Rosenberg** investigated the costs and benefits of a proposal to harness “e-prescription” technology and systems to improve the management of risks associated with physicians’ use of pharmaceuticals (drugs and medical devices). His proposal, in particular, envisions enactment of legislation authorizing the FDA to create and require physicians to employ e-prescription software governing all use of pharmaceuticals, approved and off-label.
- **Elizabeth Warren** to use her expertise on bankruptcy and empirical studies to study the extent to which health care costs cause bankruptcy, which has been the subject of many news articles and some of her recent Congressional testimony

Contributions to HLS Teaching Program

For the 2008-2009 academic year, Harvard Law School offered an unprecedented thirteen courses in health law, policy and bioethics. Such a diverse curriculum has proved to be instrumental to attract the most competitive students interested in health law to Harvard. This year, enrollments continued to be strong, averaging about 30 students per course. Following is a list of these classes:

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|---|-----------------|
| • Ethics, Biotechnology & Law: Seminar | Prof. Sandel |
| • Health Care Law | Prof. Malani |
| • Health Law Policy Workshop (fall and spring) | Prof. Malani |
| • Health, Disability and Planning: Clinical | Prof. Greenwald |
| • Law and Psychology | Prof. Cope |
| • Food & Drug Law | Prof. Hutt |
| • Psychiatry & the Law | Prof. Stone |
| • Bioethics: Seminar | Prof. Kamm |
| • Genetics & Reproductive Technology: Seminar | Prof. Cohen |
| • Health Law and Economic Insecurity Reading Group | Prof. Robertson |
| • Science and the Law: Competing Universals | Prof. Jassanoff |
| • Ideology, Psychology and the Law | Prof. Hanson |
| • Law Psychology and Morality: Exploration through Film | Prof. Stone |

Health Law Policy Workshop

Responding to increasing interest from faculty and students across the University, Prof. Malani, the Petrie-Flom Center’s Visiting Faculty Director for 2008-09 convened the

Health Law Policy Workshop weekly for two semesters (rather than just one). Researchers from a wide variety of disciplines were invited to present their findings to an audience of peers and students from across Harvard University. The cross-disciplinary nature demonstrated the many different approaches scholars employ to grapple with the complex problems of our healthcare system. Following is a list of the participants and the titles of their presentations for each of the year's sessions.

Sept 4 - Susan Wolf, McKnight Presidential Professor of Law, Medicine & Public Policy; Faegre & Benson Professor of Law; Professor of Medicine, University of Minnesota, *Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations*

Sept 11 - Abigail Moncrieff, Academic Fellow, Petrie-Flom Center, *Federalization Snowballs: The Need for Federal Action in Medical Malpractice Reform*; **Mark Stein**, Academic Fellow, Petrie-Flom Center, *Welfare Versus Autonomy in Human Subjects Research*

Sept 18 - Darius Lakdawalla, Director of Research, Bing Center for Health Economics, Rand Corporation; Faculty Research Fellow, National Bureau of Economic Research; Professor of Economics, Pardee RAND Graduate School of Public Policy, *The Welfare Effects of Medical Malpractice*

Sept 25 - Henry Grabowski, Professor of Economics and Director of the Program in Pharmaceuticals and Health Economics, Duke University, *Priority Review Vouchers to Encourage Innovation for Neglected Diseases*

Oct 2 - Anup Malani, Professor of Law and Aaron Director Research Scholar, University of Chicago Law School; Visiting Faculty Director, Petrie-Flom Center, Harvard Law School, *Clinical Trials, the Market for Observations and the Cost of Medical R&D*

Oct 9 -Mike Scherer, Professor of Public Policy and Corporate Management in the Aetna Chair, Harvard John F. Kennedy School of Government, *Markets and Uncertainty in Pharmaceutical Development*

Oct 16 -Ashish Jha, Assistant Professor of Health Policy and Management, Harvard School of Public Health, *How does Pay for Performance Affect Hospitals that Care for the Poor?*

Oct 30 - Mark A. Hall, Professor of Law and Public Health, Wake Forest University, *Government-Sponsored Reinsurance: Purpose and Performance*

Nov 6- Glenn Cohen, Assistant Professor, Harvard Law School; Petrie-Flom Center Affiliated Faculty, *Patients with Passports: Legal and Ethical Issues Posed by Medical Tourism*

Nov 13 - Zeke Emanuel, Chair of the Department of Bioethics, Clinical Center, National Institutes of Health, *A New Theory for the Allocation of Scarce Medical Resources: The Complete Lives Framework*

Nov 20 - Scott Hemphill, Associate Professor of Law, Columbia Law School, *Patent Settlements between Rival Drug Makers*

Dec 4 - Emily Oster, Assistant Professor of Economics, University of Chicago; Faculty Research Fellow, National Bureau of Economic Research, *Insurance Ownership and Adverse Selection: Evidence from Individuals with Huntington Disease*

Feb 4 - Jeff McMahan, Professor, Rutgers, *Radical Cognitive Limitation*

Feb 11 - Joseph Doyle, Associate Professor of Economics, MIT Sloan School of Management, *Returns to Physician Human Capital: Analyzing Patients Randomized to Physician Teams*

Feb 18 - Ben Roin, Hieken Assistant Professor of Patent Law, Harvard Law School, *The Perverse Incentives Created by the Patent Term for Drugs*

Feb 25 - Ted Marmor, Professor Emeritus of Public Policy and Management & Professor Emeritus of Political Science, Yale School of Management, *Comparative Perspectives and Policy Learning in the World of Health Care*

Mar 4 - Anup Malani, Roscoe Pound Visiting Professor of Law, Harvard Law School, *The Effect of Direct-to-Consumer Advertising on the Efficacy of Branded Drugs*

Mar 11 - Adriana Lleras-Muney, Associate Professor, Department of Economics, UCLA, *Understanding the Relationship between Education and Health*

Mar 18 - Michael Chernew, Professor, Harvard Medical School, *Value Based Insurance Design*

Apr 1 - Arti Rai, Elvin R. Latty Professor of Law, Duke University, *Biopharmaceutical Innovation in the Administrative State*

Apr 8 - Kate Baicker, Professor of Health Economics, Harvard School of Public Health, *Expanding Public Health Insurance*

Apr 15 - Alison Hoffman, Academic Fellow, Petrie-Flom Center, *Oil and Water: The Trouble with Individual Mandates, Fragmented Markets, and Health Reform*; and **Christopher Robertson**, Academic Fellow, Petrie-Flom Center, *Blind Expertise: A Practical Proposal for Litigation Experts to Render Opinions from Behind Veils of Ignorance*

Apr 22 - Alexander Capron, University Professor, Scott H. Bice Chair in Healthcare Law, Policy and Ethics, and Professor of Law and Medicine, University of Southern California, *Rethinking Informed Consent for Research*

Apr 29 - Alison Galvani, Assistant Professor, Yale School of Public Health, *Integrating Epidemiology, Psychology and Economics to Achieve the Effective Control of Influenza*

Participation of HLS Students in Program Activities

Student Involvement

Student engagement with the Center continued to increase in the 2008-2009 academic year. Not only are more and more students interested in the fields of inquiry the Center addresses, they are displaying interest in the Center's work as early as their first year in law school. For upper-level students, the quality of participation in our curriculum and the sophistication of research and writing has continued to increase. Students continue to actively engage in the Center's work through our programmatic initiatives with enthusiasm and this year, worked extensively to organize a colloquium of student research in health law to share their research projects for feedback from faculty and others.

Student Fellowship Program

In 2008-09 the Center sponsored six student fellows who conducted research in areas as diverse as patent law in the pharmaceutical industry, philosophical and social implications of the right to health, and examinations of ethnic and racial health disparities. Mentored by the Center's post-graduate fellows, affiliates and faculty, and through participation in the Center's Health Law Policy Workshop, this group of students, came together to share, develop and refine the research agendas by participating with other Harvard graduate students in the Colloquium on Student Writing in Health Law (see below). Following is a roster of this year's student fellows and titles of their final research projects.

- **Jeffrey Gritton**, Harvard Law School
Misguided Arguments Over Biologic Data Exclusivity
- **Jeffrey Jacobstein**, Harvard Law School
Proof by Genetics: Genetic Evidence and the Law of Admissibility
- **Lindsey Murtaugh**, Harvard Law School and Harvard School of Public Health
Racial and Ethnic Disparities in Healthcare Delivery
- **Carmel Shachar**, Harvard Law School and Harvard School of Public Health
Improving the Balance: The Need to Re-examine the Court/Ethics Committee Relationships through Legislative Action
- **Amie Shei**, Harvard Graduate School of Arts and Sciences

Social Safety Nets and Health: The Impact of Brazil's Bolsa Familia Program on Health

- **Heidi Williams**, Harvard Graduate School of Arts and Sciences
Estimating Marginal Returns to Medical Care: Evidence from At-Risk Newborns

Connections to the Community and Professions

Our goal of enhancing the academic formation of rising young scholars in health law, and our role to inform, mentor and engage students in this field continues to be an important focus of the Center's work. The student-focused events programming in 2008-09 fulfilled these objectives by providing students opportunities to engage first-hand with practitioners in fields from a variety of perspectives, and to learn what the current and upcoming needs and opportunities lay ahead in the realm of health law as they plan their career paths. The Center sponsored two exclusive events focusing on the careers in health law:

Health Law Practice across the Country

September 18, 2009

In conjunction with the Harvard Law and Health Care Society, and the Ethics Law and Biotechnology Society, the Center sponsored a luncheon which hosted a panel of several practicing attorneys working in health law in firms from across the country to informally discuss their work, answer student questions and compare notes about health law practice in different firms and in different cities.

Health Law Speakers Series: Neil Flanzraich '68

February 18, 2009

The Center was pleased to welcome Neil Flanzraich, JD '68, to campus as the first speaker in a new series of discussions on health law in practice. He spoke with students and faculty about his extensive experience and current work in the pharmaceutical industry. Mr. Flanzraich is particularly well known for his pioneering work in the generics sector of the industry, helping to turn IVAX into one of the largest generic-drug companies in the world. Mr. Flanzraich's talk drew upon his experience with both generic and brand-name drug companies to speak about the intellectual property and FDA regulatory issues that create value-enhancing opportunities for specialty pharmaceutical companies.

Conferences and Events Programming

The events programming for the 2008-09 academic year represented a substantial increase in the Center's visibility. The events featured involvement from several of the nation's leading experts in the fields of health policy, bioethics and industry practice. At each event we enjoyed participation from large audiences from around Harvard and the Boston area that came to share in the debates and dialogues addressing leading topics in the socio-political as well as academic realms. The events programming agenda has continued to further substantiate the Center's local and national reputation

as an active, accessible and valuable forum for education about legal aspects of health and society. Following are descriptions of this year's events.

September 24, 2008

Human Dignity and Bioethics

With the advance of medical technologies and the increasing power over life and death that they afford, discussions of "human dignity" have begun to take a more central role in bioethics. In a debate co-sponsored and organized with the President's Council on Bioethics, the advisory board charged with informing the President of the United States about complex issues at the intersection of ethics and the use of emerging biological technologies, this event sought to address a number of questions such as: Is "human dignity" a useful concept that leads to determinate answers on issues like stem cell research and care for the dying? Or, is it instead a concept prone to misuse, an empty vessel or a camouflage for unconvincing arguments and unarticulated biases? The Petrie-Flom Center examined these questions in a debate, which brought together speakers from four universities whose expertise spans the disciplines of philosophy, law, and theology and medicine. Participants included professors from Harvard Law School and Harvard Medical School, Oxford University and the Chairman of the President's Council on Bioethics, whose recent volume of essays on these issues has generated widespread public discussion.

October 2, 2008

Health Care Policy 2008: A Debate on the Obama and McCain Proposals

As healthcare promises to be a key issue in the current presidential election debates, as well as one of the most prominent initiatives for the new Presidential Administration, the Center brought together key health policy advisors to the McCain and Obama campaigns to discuss the respective candidate's proposals for reform.

October 14, 2008

Moot Court: Wyeth v. Levine: The Doctrine of Preemption Policy

Partnering with the Harvard Law School chapters of the American Constitution Society the Federalist Society, and the Harvard Law School Dean's Office, the Petrie-Flom Center held a moot court session on the case, *Wyeth v. Levine* to be heard in the Fall 2008 session of the Supreme Court. Just weeks before arguing the same case before the Supreme Court of the United States, Attorney David Frederic presented his preparation for the case before a panel of Harvard Law School professors including Prof. I. Glenn Cohen and Prof. Anup Malani of the Petrie-Flom Center.

February 18, 2009

Health Law in Practice Speakers Series: Neil Flanzraich '68

The Center was pleased to welcome Neil Flanzraich, JD '68, to campus as the first speaker in a new series of discussions on health law in practice. He spoke with students and faculty about his extensive experience and current work in the pharmaceutical industry. Mr. Flanzraich is particularly well known for his pioneering work in the generics sector of the industry, helping to turn IVAX into one of the largest generic-drug companies in the world. Mr. Flanzraich's talk drew upon his experience with both generic and brand-name drug companies to speak about the intellectual property and

FDA regulatory issues that create value-enhancing opportunities for specialty pharmaceutical companies.

February 27, 2009

Conflicts in Conscience in Healthcare

On the occasion of publication of a new book on physician conscience clauses written by PFC Academic Fellowship alumni Holly Fernandez Lynch, this panel examined the legal and ethical aspects of the current debates surrounding physicians and health care practitioner's rights to refuse to perform legally permissible medical procedures on the grounds of moral objections. Holly was joined by Prof. I. Glenn Cohen of Harvard Law School and the Petrie-Flom Center, and Prof. Daniel Brock of Harvard University's Program on Ethics and Health.

March 13, 2009

A Colloquium on Student Writing Projects in Health Law

In collaboration with the Harvard Law and Healthcare Society and the Ethics Law and Biotechnology organizations at Harvard Law School, the Petrie-Flom Center hosted an afternoon colloquium for Harvard graduate students conducting research related to health and law. The colloquium showcased some of the high-quality student research being carried out at Harvard, and provided a forum for authors to workshop their writing with other scholars.

March 13-14, 2009

National Undergraduate Bioethics Conference

The Harvard Undergraduate Bioethics Society was selected by the American Society of Bioethics and Humanities to host the 2009 National Undergraduate Bioethics Conference (NUBC). The NUBC is an annual event carried under the auspices of the American Society of Bioethics and Humanities. Planned and organized by students, the conference brought together undergraduate students and leading experts to discuss issues of current interest within the field of bioethics. The theme of this year's conference was "Bioethics: The New Issues." Speakers included some of the foremost bioethicists, economists, legal scholars and physicians, such as Robert Truog, Michelle Mello, Peter Singer, Dan Brock, Dan Wikler and Leon Eisenberg. Approximately 350 undergraduate students registered for the conference, representing 70 colleges and universities throughout the US and Canada. The Center sponsored the conference with financial support and participation of our post-graduate fellows and faculty in some of the conferences events and gatherings.

June 12-13, 2009

Pharmaceutical Research, Development and Markets

Amidst this larger debate about drug prices and pharmaceutical innovation, there is a growing consensus of a need for reform in the industry and how it is regulated. The substance of the necessary reforms remains subject to great debate, however, and the policies chosen by Congress are likely to have significant consequences for the public. This conference aimed to address a range of questions about the opportunities for greater efficiency in drug development and markets such as: Are the mergers sweeping through the pharmaceutical industry really enhancing the productivity of

pharmaceutical R&D? Do the FDA's stringent clinical-trial requirements block public access to valuable new drugs? Should the clinical-trial data submitted to the FDA be made available to the public and competing pharmaceutical companies? And what effects — if any — does patent length have on public health and public access to medication in the United States? For two half-days, leaders from industry and academia met to debate the issues and to inform one another's perspectives on this crucial but complex and often misunderstood issue in drug development.

2008-09 Plans for Activities

The Center staff and affiliates enthusiastically look forward our fourth year of activities in 2009-2010 under the leadership of Professors **I. Glenn Cohen** and **Benjamin Roin** who will serve as co- directors of the Petrie-Flom Center. Both professors know the Center well; having graduated from the Academic Fellowship Program as members of the Inaugural Cohort in 2008. Since becoming a professor at Harvard Law School in 2008, Glenn Cohen's primary research interests are in bioethics and health law. Currently, he is working on projects relating to reproductive technology and medical tourism; his past work has included projects on end of life decision-making, FDA regulation, research ethics, and commodification. Benjamin Roin is the Hieken Assistant Professor of Patent Law. Since joining the Harvard Law School faculty, Ben has continued the ambitious research agenda he started during his time as a fellow. Ben has worked on issues involving pharmaceutical innovation, FDA regulations, and the patent system and his research interests in general include patent law, trade secrecy, copyright law, trademark law, health law, food and drug law, and property law. Ben's recent scholarship includes work on why the patent system fails to achieve one of its functions, and the disclosure of patented ideas to others.

Research and Scholarship

Academic Fellows

Michael Frakes, the Center's eleventh Academic Fellow, will begin in the summer of 2009. Mike is a 2001 graduate (B.S., economics) of the Massachusetts Institute of Technology (MIT) and a 2005 graduate of Harvard Law School, where he received the John M. Olin Prize for Outstanding Paper in Law and Economics. While in law school, Michael began his PhD studies in economics at MIT and passed his general examinations in public finance and econometrics in 2004. After graduating from law school, Michael worked as an associate with the Mergers and Acquisitions group of Skadden, Arps, Slate, Meagher & Flom LLP. He returned to his PhD studies at MIT in February 2007 and was an Aging and Health Economics Fellow at the National Bureau of Economic Research from 2007-2008. His current research interests focus on exploring the association between regional variations in physician practice styles and the geographical scope of malpractice laws respecting standard of care determinations. During his fellowship period, he plans to develop a general research agenda focused on understanding how certain economic and legal incentives impact the treatment styles developed by physicians and other health care providers. With these efforts, he hopes to contribute to an understanding of the consequences attributable to, and the limitations inherent in, various health law doctrines.

Faculty Summer Research Grants

Applications for Faculty Summer Research Grants for 2009 are currently under review at the writing of this report. We look forward to sharing information on the awardees in our next communication. We anticipate having a strong applicant pool again this year, however, due to financial constraints, we expect to be able to award fewer grants than in previous years.

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 2009-2010. Following is the list of course offerings to date:

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| • Healthcare Reform: Past, Present and Future | Prof. Ruger |
| • Health Care Law and Regulation | Prof. Ruger |
| • Health Law Policy Workshop | Profs. Cohen & Elhauge |
| • Ethics, Economy and Law: Seminar | Prof. Sandel |
| • Public Health Law | Prof. Barnes |
| • Right to Health through Litigation | Profs. Yamin & Roseman |
| • Food & Drug Law | Prof. Hutt |
| • Psychiatry & the Law | Prof. Stone |
| • Health Reform Perspectives | Profs. Hoffman & Robertson |
| • Genetics & Reproductive Technology: Seminar | Prof. Cohen |

Health Law Policy Workshop

The Health Law Policy workshop will be co-taught in 2009-10 by Petrie-Flom Co-Director Professor Cohen, and the Center's Founding Faculty Director, Einer Elhauge. The Workshop is scheduled to take place every other week throughout the entire academic year, in response to enthusiastic interest from people across Harvard University and in the Boston area who wish to participate regularly but who are not able to commit to do so every week. The open format of the workshop, which permits members of the wider community to participate on a drop-in basis, has been tremendously successful in stimulating broad discussion at the sessions. Again, the schedule of presenters includes an impressive roster of leading intellectuals and practitioners in the field. To date, the following have agreed to present their works-in-progress:

- **Michael Frakes**, *Academic Fellow, Petrie-Flom Center, Harvard Law School*
- **Barak Richman**, *Professor of Law, Duke University School of Law*
- **Theodore Ruger**, *Professor of Law, University of Pennsylvania Law School*
- **Katherine Swartz**, *Professor of Health Economics and Policy in the Department of Health Policy and Management, Harvard School of Public Health*
- **Sadath Syed**, *Division of Medical Ethics, Harvard Medical School*
- **Elizabeth Warren**, *the Leo Gottlieb Professor of Law, Harvard Law School*
- **Melissa Wasserman**, *Academic Fellow, Petrie-Flom Center, Harvard Law School*

Participation of Students in Program Activities

Student Fellowship Program

Interest in the Student Fellowship Program remained strong again this year. Once again, more than twenty applications were received and the proposals represented a broad distribution of areas of focus and academic backgrounds. A number of finalists are joint degree candidates from multiple schools at Harvard which signifies the strong cross-disciplinary appeal of the program across the University. Again, the largest percentage of applicants were among rising first-year students at Harvard Law School plan to focus on health law related issues throughout their study. The core aspects of the Student Fellowship Program will remain the same as in previous years and will require participation in the Health Law Policy Workshop and undertaking an independent research project under the guidance of the Center's affiliated faculty and under the mentorship of the Center's Academic Fellows. Additionally, students are encouraged to actively participate in the Center's events and conferences through attendance and engagement in debates. In particular, by way of the major success it was for the Center in 2008, participation in a symposium of student research in health law in the spring semester will become a requisite for student fellows. The roster of student fellowship awardees for the 2009-2010 academic year is:

- **Maya Anantha Babu**, Harvard Business School and Harvard Business School
Socioeconomic Factors Underlying Trauma Center Admissions
- **Charlotte Harrison**, Graduate School of Arts and Sciences
Collective Responsibility and Governance in Organ Donation
- **Blaine Saito**, Harvard Law School and Harvard's Kennedy School
Healthcare Financing and Delivery
- **Faina Shalts**, Harvard Law School
Structural, Legal, and Ethical role of World Health Organization in Preventing and Containing Pandemics
- **Ariane Tschumi**, Harvard Law School
Conceptualizing A Right to Health Care for the Poor through Judicial Analogy
- **Yuanheng Wang**, Harvard Law School
A Novel Regulatory Scheme to Reduce Arms Race and Prisoner's Dilemma in Pharmaceutical Marketing

Collaborations with Other Schools and Departments at Harvard

Collaboration with schools and programs across Harvard University has been indispensable to the success of the Center particularly in light of the cross-disciplinary nature of the field and the broad social implications of constantly emerging developments in healthcare, science and technology. Partnering with our colleagues across the University has consisted not only in sharing research of our faculty and affiliates through weekly seminars and colloquia, but also is anchored in the development of programmatic initiatives including public debates, conferences and other events. The Center is currently planning several events and conferences for the 2009-2010 academic year to be developed and held in collaboration with a variety of groups from across Harvard University. Following is information on evolving plans for a few of the events that will make up our public programming.

When Medical Care Compromises Financial Health

Universal health insurance may be on the horizon, but a growing body of empirical research has shown that, 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. Our panel will explore these problems and debate potential solutions, including insurance regulation, paid family leave, and reforms to the tax code, the bankruptcy code and debtor-creditor laws.

Synthetic Biology

The first ever course on Synthetic Biology will be offered at Harvard Medical School in the fall 2008 semester. The far-reaching advances of genetic technology witnessed over the last decades have led to a new frontier of science where we are able to redirect the power of life forms by manipulating DNA. Synthetic biology seeks to develop better tools and technologies for engineering biological systems. With this new level of power comes fundamental social questions regarding the nature of life and the appropriate limitations that should be placed on the use of these new tools. Ultimately, debates and decisions on the proper regulation and limitations of synthetic biology will become increasingly prevalent in social discourse. The Center plans to convene leading figures in this field through collaboration with the Department of Molecular Biology and the Harvard Medical School to investigate the issues represented by this new frontier of medical science.

Moral Biology

The Center is planning to pursue a joint conference with the Harvard Program in Ethics & Health and Harvard Medical School and other partners from Harvard and related not-for-profit research institutes focusing on the emerging field of moral biology. The tentative name for the event is What If Moral Intuitions Are Biologically Hardwired?: The Legal and Philosophical Implications. It will be a cross-disciplinary endeavor and is designed to engage participation from faculty all across Harvard University.