



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

Annual Report of Activities 2007-2008

Executive Summary

The Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics is pleased to submit the report of activities 2007-2008 academic year. This year has seen the completion of our first full cycle of the Academic Fellowship Program and witnessed astounding accomplishments not only in this initiative, but across the full range of our activities. The appointment to the Harvard Law School faculty of the only two Petrie-Flom Academic Fellows on the entry-level law professor's job market, **Glenn Cohen** and **Benjamin Roin** has been the dramatic highlight of the year's successes. Our primary focus has been on using the academic fellowship program to develop a new generation of scholars interested in issues of health law policy, biotechnology and bioethics. Indeed, we expect that the scholars, affiliates and partners of the Center will contribute to the legacy of our programs for many years to come, as their careers grow and they are asked to lead the nation with their expert insights on a field that needs serious consideration. With the current and predicted growth and changes to healthcare facing our society, the Center's role will only increase in importance and prominence in the coming decades. Already the Center has served as a model for the founding of similar centers at Georgetown and other law schools, and we were recently approached by a Korean university seeking a model for how to organize its own center.

We also have considerable success to report with respect to our goals to elevate the level of rigorous scholarship in health law. Our workshop continues to offer a forum for rigorous analysis of cutting-edge scholarship, and has connected leading scholars at all of Harvard's major health centered schools and other universities from across the country. Many of the works presented at those sessions have been published in journals such as the *New England Journal of Medicine* and the *Georgetown and Michigan Law Reviews*. Also we have accomplished the goal of promoting high-level scholarship by inducing existing Harvard faculty to use their expertise to focus

on long-neglected issues falling with the Center's mandate. Our senior fellow, Professor Frances Kamm, one of the world's leading philosophers, has spent the year writing a book on bioethics, and providing invaluable mentorship to our fellows. Since the establishment of the Petrie-Flom Center, the faculty summer grants program has helped induce many Harvard Law School faculty members to write new, important research in the long unaddressed issues related to health and law. This year we have had an unprecedented eight applications for these grants, a remarkable transformation from before the Center existed.

Increasingly, students are engaging with the Center through our programmatic and curricular initiatives with enthusiasm and a level of academic maturity that is unparalleled by other specialized areas of instruction at the Law School. Recently, the Center hosted an open house for students admitted to Harvard Law School who were visiting to decide whether to matriculate. As a result of their interactions with our fellows and faculty, several students being courted by other leading law schools made the decision to attend Harvard. Additionally, this year's class of student fellows produced exceptionally sophisticated scholarship in their independent writing projects. We expect many of them will continue their pursuit of health law and perhaps be future candidates for post-graduate fellowships at the Center.

The involvement of these constituents in the Center's work, in addition to the participation of broad communities of individuals interested in our work through our events and conference programming described in further detail below, helps the Center enjoy a well regarded and firmly established reputation as one of the nation's leading institutions for the development and discourse of legal, policy and ethical issues related to healthcare and society.

2007-08 Report of Activities

Research and Scholarship

Academic Fellows

2006-2008 Cohort

The remarkable success of our first crop of Academic Fellows has dramatically helped to define the high level reputation of the Center. This year, the only two Petrie-Flom Academic Fellows on the entry-level law professor's job market, **Glenn Cohen** and **Benjamin Roin**, both got appointments at Harvard Law School, an unparalleled success rate for any fellowship program in any field. This news has traveled far and wide across the nation's law schools and will inevitably garner substantially greater attention for the Center in academic circles as the preeminent fellowship in health law.

The scholarly contributions of all our first four inaugural academic fellows was a significant source of accolades for the Center's achievements toward expanding much needed high level scholarship in the field. Glenn's article, *The Constitution and The Rights Not To Procreate*, was just released in the *Stanford Law Review*. A second part of his fellowship work, *The Right Not to be a Genetic Parent*, will be released in September in the *Southern California Law Review*, while Ben's project *Pharmaceutical Innovation and the Limits of the Patent System*, will be coming out in the *Texas Law Review*. **Talha Syed**, has decided to take another year before he goes on the job market in order to wrap up pending projects, such as his Stanford University Press book with Terry Fisher, *Drugs, Law, and the Global Health Crisis*, before getting his solo-authored work ready for the job market. We are very confident Talha will be successful in procuring multiple elite law school job offers this coming year. Our fourth inaugural academic fellow, **Holly Fernandez Lynch**, decided to enter legal practice rather than pursue the academic job market, but not before publishing *Conflicts of Conscience in Health Care: An Institutional Compromise* with MIT Press. As such a well-trained legal expert in bioethics issues entering the practicing bar, Holly will no doubt be a leader in addressing such issues.

2007-2009 Cohort

The Center's second crew of Academic Fellows made great strides in their research and participated in numerous forums to present and refine their work in preparation for competing in the entry-level law professor's job market in 2008. Additionally they have played an active role in the Center's activities through planning and assisting with the execution of events, presenting their research in various colloquia sponsored by the Center as well as other Harvard-based institutions, and through mentoring and advising students affiliated with the Center.

Abigail Moncreiff has spent this year working on an important paper addressing medical malpractice reform. Entitled *Federalization Snowballs: The Need for Federal Action in Medical Malpractice Reform*, Abby's thesis rebuts the conventional view

that medical malpractice reform is best left to state-by-state determination and implementation. Her paper argues that reform actually suffers from the fact that the states can internalize the benefits of inefficient malpractice laws without bearing the full costs of the inefficiencies. Additionally, Abby has spent her time working on author proofs for an article she wrote which will appear in *Administrative Law Review* in September 2008.

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's foundational approach to these matters lends an entirely new and unique perspective to the debates considering these questions that span the intellectual realms of health policy, law and ethics.

Academic Fellow **Mark S. Stein** has developed and fleshed out a wide ranging research agenda focusing on utilitarian theories of justice in the realm of healthcare distribution since commencing his fellowship. A recent paper critiquing University of Chicago law professor and philosopher Martha Nussbaum's distributive theory of justice has been accepted for publication by the *Boston College Law Review*. Mark recently completed a draft of a law review article entitled *Medical Necessity: The Abortion Analogy* in which he considers whether constitutional claims of medical necessity, such as for medical marijuana or experimental drugs, are supported by an analogy to abortion doctrine. As a result of his research on this article, Mark was invited to respond to a related piece published in the *Texas Law Review* which has been published in the online version of the journal. Mark is currently working on another article entitled *Welfare Versus Autonomy in Human Subjects Research* in which he plans to argue 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 others who stand to benefit from medical research.

Global Health and Human Rights Initiative Fellow

In the fall of 2007, the Petrie-Flom Center and the Human Rights Program at Harvard Law School welcomed our first joint fellow, **Alicia Ely Yamin** for her two-year fellowship under the Joseph H. Flom Global Health and Human Rights Initiative. Alicia has been an active and integral participant in both Center's activities through participation and presentations in multiple colloquia, workshops and forums. Alicia's work has been instrumental toward building connections across the Harvard community as she has leveraged her strong ties with a wide array of people in representing the Initiative as its inaugural fellow, notably the School of Public Health where she teaches a summer course in global health policy. Alicia has undertaken a

robust research agenda including the completion of eight writing projects focusing on international health policy, several of which will soon appear in print in various journals including the New England Journal of Medicine and Lancet. Alicia has also participated in multiple panel discussions as an expert on international women's health issues and health policy in Latin America. Finally, Alicia developed a panel event convening experts in international health from across the nation, held in March at Harvard Law School regarding how international health priorities are determined. The panel is described below in further detail.

Senior Fellow

In the fall of 2007, Frances Kamm became the Center's first senior fellow. Professor Kamm is a Professor of Philosophy in the Harvard Philosophy Department and Littauer Professor of Philosophy and Public Policy at the Kennedy School of Government. One of the world's preeminent moral philosophers, Frances has worked during her recent career on issues relevant to health policy, biotechnology and bioethics and is recognized as a leading authority in the field. Indeed, she is widely regarded as a genius among moral philosophers of any focus. During her fellowship, Frances has worked on a book on bioethics and provided invaluable mentorship to the Center's fellows in addition to being a leading and provocative participant in debates at many Center-sponsored events and conferences. We look forward to the eventual publication of the manuscript she has worked on this year and the outstanding contribution to the field of bioethics it will undoubtedly be.

Faculty Research Support

A central goal of the Center has been encouraging existing Harvard faculty to use their expertise to focus on long-neglected issues falling within the Center's mandate; this has also been successful. In addition to sponsoring Frances Kamm as the Center's inaugural Senior Fellow, in 2007-2008 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. In the summer of 2007 grants were given to:

- **Einer Elhauge** to begin a book on how best to regulate the re-engineering of human biology,
- **Mark Ramseyer** to use his expertise on Japanese law and empirical studies to examine how Japanese health law affects the care provided, and
- **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 Congressional testimony

Contributions to HLS Teaching Program

For the 2007-2008 academic year, Harvard Law School offered eleven courses in health law, policy and bioethics. High enrollments, averaging about 30 students per

course, demonstrated strong interest in the fields of inquiry addressed by the Center and its educational mission. Following is a list of these classes:

- Ethics, Biotechnology & Law: Seminar Prof. Sandel
- Health Care Law Prof. Sage
- Health Care Policy: Reading Group Prof. Elhauge
- Health Law Policy Workshop Profs. Elhauge & Korobkin
- Ethics & Practice in Law & Medicine Prof. Sage
- Stem Cell Research: Seminar Prof. Korobkin
- Food & Drug Law Prof. Hutt
- Psychiatry & the Law Prof. Stone
- Ethics & Health Policy Prof. Daniels
- Genetics & Reproductive Technology: Seminar Prof. Cohen
- Law & Public Health Prof. Mello

Health Law Policy Workshop

Co-taught this year by Petrie-Flom Faculty Director **Einer Elhauge** and Visiting Professor **Russell Korobkin**, the Health Law Policy and Bioethics workshop continued to hold its place as the focal point for the Center's curricular initiatives and to be a popular program attracting attention from local participants and presentations of new research by nationally acclaimed researchers in the field. The participation of local academics and researchers who attended the workshop added significantly to the depth and richness of the issues debated. Following is a list of the authors and the papers presented in the Fall 2007 session of the course.

Sept 6 – **Bill Sage**, Vice Provost for Health Affairs; James R. Dougherty Chair for Faculty Excellence in Law, University of Texas at Austin School of Law; Visiting Professor of Law, Harvard Law School, ***“Health Care Delivery Reform: A 30,000 ft. View of the 800 lb. Gorilla”***

Sept 13 – **Amitabh Chandra**, Assistant Professor, Public Policy, Harvard University Kennedy School of Government, ***“Understanding Cost Growth in US Healthcare”***

Sept 20 – **David Cutler**, Otto Eckstein Professor of Applied Economics; Dean for the Social Sciences in the Faculty of Arts and Sciences, Harvard University, ***“The Value of Medical Innovation”***

Sept 27 – **Allen Buchanan**, James B. Duke Professor of Public Policy Studies & Philosophy, Duke University Institute for Genome Sciences & Policy, ***“Enhancement and Human Development”***

Oct 4 – **Kathy Zeiler**, Associate Professor of Law, Georgetown University Law Center, ***“Empirical Health Law Scholarship: The State of the Field”***

Oct 11 – **Ted Ruger**, Professor, University of Pennsylvania School of Law, “*The Submerged Constitution of American Health Law*”

Oct 18 – **Dan Wikler**, Professor of Ethics & Population Health; Mary B. Saltonstall Professor of Population Ethics, Harvard School of Public Health, “*Research Ethics: Wrong Turn After Nuremburg?*”

Nov 1 – **David Hyman**, Professor; Galowich-Huizenga Faculty Scholar, University of Illinois at Urbana-Champaign, “*The Costs of Medical Malpractice and Other Personal Injury Litigation: Evidence from Texas, 1988-2004*”

Nov 8 – **Frances Kamm**, Senior Fellow, Petrie-Flom Center at Harvard Law School; Littauer Professor of Philosophy and Public Policy, Harvard University Kennedy School of Government; Professor of Philosophy, Harvard Philosophy Department, “*Enhancement*”

Nov 15 – **Mark A. Hall**, Professor of Law and Public Health, Wake Forest University School of Law, “*The Law and Ethics of Consumer-Driven Health Care*”

Nov 29 – **Jennifer Arlen**, Norma Z. Paige Professor of Law, New York University School of Law, “*Contracting Over Malpractice Liability*”

Dec 6 – **Russell Korobkin**, Professor of Law, UCLA Law School and Visiting Professor, Harvard Law School, “*Law and Policy of Stem Cell Research*”

Reading Group

This year, the Center changed the initial Wednesday Lunchtime Speakers Series from 2006 into a reading group carrying academic credit for student participation. The Reading group was designed to be a more casual forum than the Health Law Policy Workshop, but still of particular interest to those with intellectual or academic interests in the areas of health law policy, biotechnology or bioethics. Among academics invited to present at the reading group were **Michele Goodwin** of the University of Minnesota School of Law and Harvard Law School Visiting Professor, **Russell Korobkin**. The Reading Group also served as a constructive forum for Petrie-Flom fellows to publicly present their research-in-progress for feedback from the Center’s affiliated community.

Participation of HLS Students in Program Activities

Student Involvement

Increasingly, students are engaging with the Center through our programmatic and curricular initiatives with enthusiasm and a level of academic maturity that is unparalleled by other specialized areas of instruction at the Law School. Recently, the Center hosted an open house for students admitted to Harvard Law School who were visiting to decide whether to matriculate. As a result of their interactions with our fellows and faculty where they learned of opportunities for directed study and

mentorship in health law, afforded by the existence of the Petrie-Flom Center, several students being courted by other leading law schools made the decision to attend Harvard.

Student Fellowship Program

The 2007-2008 class of student fellows stands out for their production of sophisticated scholarship in their independent writing projects. Mentored by the Center's post-graduate fellows, affiliates and faculty, and through participation in the Center's Health Law Policy Workshop and Health Law Reading Group curriculum, this group of students, representing more than half of Harvard University graduate schools in addition to the Law School, came together to share, develop and refine the research agendas set forth in their original applications. In addition to presenting their research to Center affiliates at informal workshops during the year, many student fellows also took advantage of opportunities to introduce their research to broader communities beyond Harvard, including for example participation in a national convention on stem cell research in Boston and at the bi-annual conference of the American Society of Health Economists at Duke University. We are confident many of these students will move forward in their academic and professional careers in healthcare, health law and academia and that their experiences as fellows will have a long lasting impact of their work. Following is a roster of this year's student fellows and titles of their final research projects.

- **Jordan Amadio**, Harvard Business School and Harvard Medical School
Modern Neuroethics and our Intuitions of Agency
- **Daniel Chen**, Harvard Law School
Trading Off Reproductive Technology and Adoption: Do IVF Subsidies Decrease Adoption Rates?
- **Greta Gao**, Harvard Law School
The Moral Psychology of Emergencies
- **Matthew Gordon**, Harvard Law School
The Legal Duty to Disclose Individual Research Findings
- **Adam Jed**, Harvard Law School
A Limited Consequentialist Defense of Random Decision making in the Allocation of Scarce Health Resources Note: Adam's paper was selected as best student fellow writing project and he was awarded a \$1,000 prize announced at his graduation.
- **Eunice Kim**, Harvard Law School
The Effect of Regulatory Structures on Hospitals' Internal Organization
- **Jonathan Kolstad**, Harvard Graduate School of Arts and Sciences

Information and Quality When Motivation is Intrinsic: Evidence from Surgeon Report Cards

- **Aaron Schohn**, Harvard Law School and Boalt Hall,
The Anticommons Lurking in State-Funded Stem Cell Research
- **Neel Shah**, Harvard's Kennedy School and Brown Medical School
The Impact of Privacy Challenges Posed by Health Information Technology on Medical Practice

Summer Fellowships

Open to Harvard students interested in pursuing full-time research projects, summer fellowships provide a modest stipend, access to the Center's and Harvard Law School's research resources, and an office at the Petrie-Flom Center for two and a half months during the summer break.

In the summer of 2007, the Center accepted one summer student fellow, **Erica Hemphill**, a rising first-year graduate student in the ethics track of the Health Policy PhD program at the Harvard Graduate School of Arts and Sciences and an eventual joint degree JD candidate at Harvard Law School. Erica conducted a research project entitled *Olmstead v. L.C. and its Implications for Community-Based Care*. As a result of Erica's interaction with the Academic Fellows and participation in the Center's activities over the summer, she decided to decline an acceptance to Yale Law School in favor of applying to Harvard Law School where she was accepted and where she is confident to have the resources and support of the Petrie-Flom Center to pursue her career goals in health law policy. The Center and Harvard Law School are very lucky to have such a promising young scholar for the next several years and we are confident Erica will contribute substantially to the intellectual life of the Center.

No Summer Student Fellowships are offered in 2008 for lack of office space resources at the Center. Summer opportunities may be considered on an ad hoc basis, depending on future availability of resources.

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 is critical to our success and growth in the coming years. The student-focused events programming for this year 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 three events focusing on the careers of legal professionals from diverse backgrounds including advocacy work, government service, and venture capital.

“Legal Strategies to Promote Justice in Health: Community Based Healthcare Advocacy”

February 29, 2008

In conjunction with the Harvard Law and Health Care Society, the Petrie-Flom Center sponsored a luncheon hosting the executive directors of two Boston-based not-for-profit organizations focusing on community based advocacy for health care access and reform. **John McDonough** of Health Care for All and **Barbara Anthony** of Health Law Advocates, Inc. discussed their work combining legal expertise with grassroots organizing to advance efforts in Massachusetts toward universal health care access. The luncheon was attended by more than 40 students and faculty from across Harvard.

“Career Counseling with Former General Counsel, Department of Health and Human Services”

March 11, 2008

In the spring semester, the Center welcomed Harvard Law School alumnus **Daniel Meron**, who is the former General Counsel of the Department of Health and Human Services. Meron held a group advising session for current students from across Harvard University who expressed diverse interests in pursuing careers in health law and policy sectors. Meron shared with students advice drawn from his extensive experience in public and private realms, including not only his government appointment to head the legal team in the Nation’s primary health policy making institution, but also a role as a well known prosecutor at the Department of Justice, a long career as a partner at a major national law firm, and a judicial clerkship at the Supreme Court.

“Legal Careers at the Intersection of Venture Capital and the Life Sciences”

April 13, 2008

This panel discussion of legal careers in venture capital brought together legal practitioners and venture capitalists with backgrounds in law to discuss the intricate legal challenges involved when venture capitalists help bring the development of cutting edge scientific discoveries into the global health marketplace. Topics covered ranged from administrative transactions from establishing a company to launching an IPO, to intellectual property and competing interests for investors and company owners. The participants in this panel were: **Marc Goldberg**, General Partner, BioVentures Investors; **Susan Mazur**, Partner, Wilmer Hale; **Michael Twomey**, Senior Partner, Wilmer Hale; and **Benjamin Roin**, Academic Fellow, Petrie-Flom Center.

Conferences and Events Programming

Reaching out to academic and other local communities to promote leading scholarship at the intersection of the fields of law, science and medicine is the overarching core mission of the Petrie-Flom Center. The events and community outreach programming in the 2007-2008 academic year represented a substantial success for the Center, engaging large numbers of diverse constituencies from across the University and the local Boston area. The events featured participation from

several of the nation's leading experts in the fields of health law and bioethics. At each of the public events organized by the Center this year, audiences of more than fifty people turned out. The events programming agenda has gone far toward further substantiation of the Center's local and national reputation as an active, accessible and valuable forum for education and debate about legal aspects of health and society. Following are descriptions of this year's events.

Panel Events and Special Lectures

The events programming agenda proved to be a tremendously successful part of the Center's growth this year. Through collaboration with other organizations from within and outside of Harvard, and with student groups at the Law School, our events attracted broad participation from a wide array of constituencies and definitively added to local educational opportunities regarding leading edge issues at the intersection of health law and policy. A particular source of pride for the Center is the eagerness of some of the nation's foremost intellectuals in the field to participate in our programs. Following is a list of the events and descriptions.

Stem Cell Century: Law and Policy for a Breakthrough Technology

November 28, 2008

This nationally televised panel gathered leaders in scientific research, policy and ethical concerns related to the pursuit of stem cell research in the United States. The event was organized around the issues addressed in a recently released book by **Russell Korobkin**, a professor at UCLA School of Law, and Visiting Professor, Harvard Law School. Participants in the panel included **Kevin Eggan**, Principal Faculty of Harvard Stem Cell Institute, Assistant Professor of Molecular and Cellular Biology, Harvard University, and Investigator, Stowers Medical Institute; **Frances Kamm**, Littauer Professor of Philosophy and Public Policy, Kennedy School of Government, Professor of Philosophy, Harvard University, and Senior Fellow, Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics; **Pamela Samuelson**, Richard M. Sherman Distinguished Professor of Law, U.C. Berkeley Boalt Hall School of Law, Director, Berkeley Center for Law & Technology, and Visiting Professor, Harvard Law School; and **Brock Reeve**, Executive Director, Harvard Stem Cell Institute.

Information and Incentives Relating to Cost and Quality of Healthcare and Pharmaceuticals Legal Developments in the Debate between Market and Regulatory Forces

March 11, 2008

In this lecture delivered by **Daniel Meron**, HLS '92, former General Counsel of the United States Department of Health and Human Services, the economic and policy challenges of initiating and implementing healthcare reform were considered in light of recent legal developments. Meron explored innovative approaches to managing rising healthcare costs addressing the complexities of the issue from legal, economic and policy related standpoints.

Setting Global Health Priorities: The Role of International Human Rights Law

March 20, 2008

This panel addressed debates around the United Nations Millennium Development Goals and other international initiatives that have brought renewed attention to both the urgency and challenges of setting a limited number of global health priorities. Participants examined the role that international human rights law does or might play in guiding priority-setting, which remains open to debate through considering both normative and empirical dimensions of this question from a variety of different perspectives. The participants in this panel were: **Norman Daniels**, Harvard School of Public Health; **Lawrence Gostin**, Georgetown University Law School; **Jennifer Prah Ruger**, Yale School of Public Health; and **Alicia Ely Yamin**, Joseph H. Flom Global Health and Human Rights Initiative

Should Criminal Law Be Reconsidered in Light of Advances in Neuroscience?

April 7, 2008

In co-sponsorship with the Berkman Center for Internet and Society at Harvard Law School and the Gruter Institute for Law and Behavioral Research of Portola Valley, California the Center hosted an engaging and spirited debate on the potential legal impact of current and future advances in neuroscience. The participants in this panel were: **Stephen J. Morse**, University of Pennsylvania Law School; **Joshua Greene**, Department of Psychology, Harvard University; **Jerome Kagan**, Department of Psychology, Harvard University; **Amanda Pustilnik**, Harvard Law School; and **Oliver Goodenough**, Harvard Law School.

Federalism Implications of Healthcare Reform

April 9, 2008

This panel examined central questions concerning the administration of healthcare reform and the role that states and the federal government should respectively play. The debate addressed such questions as whether the state governments or the federal government do a better job of implementing health reforms and administering resultant health systems, whether ERISA provides a barrier to state reforms, and examined the role of constitutional principles in the articulation of federal reforms. The participants in this panel were: **Richard Epstein**, University of Chicago Law School; **Kristin Madison**, University of Pennsylvania Law School; **Timothy Westmoreland**, Georgetown University Law School; and **Kathryn Zieler**, Georgetown University Law School & Harvard Law School.

The Ethics of Creating Human-Non-Human Chimeras & Transgenesis: Should We Modify Human Nature?

April 22, 2008

In this lecture, delivered by **Julian Savulescu**, Director of the Oxford Uehiro Centre for Practical Ethics at Oxford University, philosophical questions concerning the nature of human life and the ethics of applying new technologies to dramatically modify it were examined. It has been possible since the 1980s to transfer genes taken from one species into another. Opponents to transgenesis claim that it will lead us inevitably down a slippery slope that risks altering human nature irrevocably. Prof.

Savulescu argued that this need not be the case and in fact, the use of such technologies, by allowing us to enter a new stage of evolution, 'evolution under reason', can actually strengthen our humanity. His lecture examined how transgenesis, when applied to humans, has the potential to radically enhance human beings, to produce resistance to diseases, to enhance our physical capabilities or even to slow the ageing process.

Rising Health Policy Leaders Forum Beyond 2008: Challenges and Opportunities

May 8, 2008

This event was held at the Massachusetts General Hospital and co-sponsored with the Harvard Business School Health Care Club, the Kennedy School Health Policy Professional Interest Council and the Brigham and Women's Hospital Health Policy Interest Group. A group of young scholars, including Petrie-Flom Center Academic Fellow **Abigail Moncrieff**, participated in a multi-disciplinary panel discussing the future of careers at the intersection of health policy, law, business, and the sciences. The panel was moderated by **Dr. David Blumenthal**, the highly esteemed director of the Massachusetts General Hospital's Institute for Health Policy and senior health policy advisor to Senator Barak Obama. The event also partly served as a networking opportunity for medical residents, students and graduate students from all disciplines related to health care reform and policy.

Conferences

"Our Fragmented Health Care System: Causes and Solutions"

June 13-14, 2008

At the writing of this report, the Center has just completed an enormously successful conference examining the sources, effects and possible solutions to the fragmented state of the American healthcare system. This conference convened more than twenty of the nation's leading scholars who presented new research on the problems and solutions to our disorganized and overburdened system. The conference generated significant interest from scholars, business leaders and policy makers, and was well attended, particularly for a summer scheduled event. We're delighted to report that Oxford University Press has accepted a proposal to publish the papers delivered at the conference in a compendium edited by Faculty Director Einer Elhauge to be released sometime in 2009. We are confident that making this research available to a wider public will play a part in setting the agenda for national health care reform.

2008-09 Plans for Activities

The Center staff and affiliates enthusiastically look forward to undertaking our third year of activities in 2008-2009 under the leadership of Professor **Anup Malani** who will be Visiting Faculty Director of the Petrie-Flom Center in Professor Einer Elhauge's stead while he is on sabbatical. Malani is a Professor of Law at the University of Chicago as well as a Research Affiliate for the Joint Center for Poverty Research at Northwestern University and the University of Chicago. A well-known specialist in healthcare policy, Malani teaches, among other classes, Health Law, Bankruptcy and Corporations. His research interests include law and economics, health economics, and corporate law and finance. In addition to leading the programmatic plans for the Center's activities in the coming year and actively mentoring fellows and students, Malani will teach Health Care Law in the fall semester and will lead the Health Law Policy Workshop which will be held both semesters of the 2008-2009 academic year.

Research and Scholarship

Academic Fellowships

In the fall of 2008, we will welcome the third cohort of Petrie-Flom academic fellows to the Center: **Allison Hoffman**, **Christopher Robertson**, and **Melissa Wasserman**. They are another outstanding group of scholars, whose research backgrounds show insightful and innovative approaches to health law.

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 fellowship, Allison will author an empirical study of Massachusetts Health Care Reform, evaluating the effectiveness of individual mandates as a means toward a universal healthcare policy. Additionally, she also 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.

Christopher Robertson graduated magna cum laude from Harvard Law School, where he was a Petrie-Flom Student Fellow, a Hewlett Fellow in Negotiation, a teaching fellow for Michael Sandel's classes in Justice and Bioethics, and the chief student editor for the developments section of the peer-reviewed Journal of Law, Medicine and Ethics. Previously, Christopher completed a Ph.D. in Philosophy at Washington University in St. Louis, where he also taught bioethics. Christopher has published a co-authored article in Health Matrix, titled "Get Sick, Get Out: The Medical Causes of Home Foreclosures". In that paper, Christopher and his co-authors provide original empirical data showing that half of all home foreclosures are caused in part by some sort of medical crisis in the household. Christopher has

published an article in *Jurimetrics* entitled, "From Freeriders to Fairness: A Cooperative System for Organ Transplantation". He has also published shorter pieces on embryonic stem cell policy, doctor-patient-confidentiality, and organ transplantation in the *American Journal of Bioethics* and the *Journal of Law, Medicine and Ethics*, along with scholarly works in philosophy journals. Christopher's current research focuses on consumer-oriented health care issues.

Melissa Wasserman 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 she 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 she intends to work 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.

The Center has also selected the first scholar to join the Academic Fellowship Program's 2009-2011 cohort. **Michael Frakes** 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

Currently under review at the time of this report, the applicant pool for the 2008 Faculty Summer Research Grant program includes an unprecedented eight HLS faculty seeking grants to conduct research and write in areas at the intersection health care and their respective specialties in law. This awakening of interest in the field amongst Harvard Law School's prominent scholars is a remarkable transformation from before the Center existed and is instrumental to the Center's goal of promoting the level of rigorous scholarship in health law. We look forward to reporting soon on this year's research grant awardees.

Contributions to HLS Teaching Program

The addition of former Petrie-Flom Academic Fellows Glenn Cohen and Benjamin Roin to the Harvard Law School faculty is not only the Center's crowning achievement for the 2007-2008 academic year, but is a major step forward for the long-term prospects of the health law curriculum at Harvard Law School. Specialists respectively in bioethics and intellectual property in biotechnology, Professors Cohen and Roin will be indispensable to fulfilling the demands of growing student interest in these fields. Additionally the visiting appointment of Professor **Anup Malani**, a specialist in health policy and economics, will flesh out representation of the three core fields of focus in health law that the Center was established to foster at Harvard Law School.

As in the previous two years, Harvard Law School will offer an impressive curriculum of courses in 2008-2009. Following is the list of course offerings to date:

Fall 2008

Ethics, Economy and Law: Seminar	Professor Sandel
Health Law Policy Workshop A	Professor Malani
Health, Disability and Planning: Law and Policy Clinical Workshop A	Professor Greenwald
Health Care Law	Professor Malani

Winter 2009

Food and Drug Law	Professor Hutt
Psychiatry and the Law	Professor Stone

Spring 2009

Bioethics: Seminar	Professor Kamm
Genetics and Reproductive Technology	Professor Cohen
Health Law Policy Workshop B	Professor Malani
Health, Disability and Planning: Law and Policy Clinical Workshop A	Professor Greenwald
Science and the Law: Competing Universals	Professor Jassanoff
Ideology, Psychology and Law: Seminar	Professor Hanson

Health Law Policy Workshop

As previously mentioned, the intellectual centerpiece of Petrie-Flom's curricular initiatives, the Health Law Policy Workshop will be offered in both semesters this academic year. Taught by Visiting Director, Anup Malani, the Workshop schedule for the fall semester includes an impressive roster of leading intellectuals and practitioners in the field, listed below. The Workshop will remain open to attendance by members of the greater Harvard community on a drop-in basis, an arrangement we have found to be successful in stimulating broad discussion at the sessions and

helpful to draw diverse participants into the Center's activities. The papers delivered at the workshop will again be posted on the Petrie-Flom Center's website to afford accessibility of this leading-edge research to others not able to attend the sessions in person.

Sept 4 - **Anup Malani**, Professor of Law and Aaron Director Research Scholar, University of Chicago Law School; Visiting Faculty Director, Petrie-Flom Center, Harvard Law School

Sept 11 - **Mark Stein & Abigail Moncrieff**, Academic Fellows, Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics, Harvard Law School

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

Sept 25 - **Henry Grabowski**, Professor of Economics and Director of the Program in Pharmaceuticals and Health Economics, Duke University

Oct 2 - **Susan Wolf**, McKnight Presidential Professor of Law, Medicine & Public Policy; Faegre & Benson Professor of Law; Professor of Medicine, University of Minnesota

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

Oct 16 - **Ashish Jha**, Assistant Professor of Health Policy and Management, Harvard School of Public Health

Oct 30 - **Mark A. Hall**, Professor of Law and Public Health, Wake Forest University

Nov 6 - **Glenn Cohen**, Assistant Professor, Harvard Law School; Petrie-Flom Center

Nov 13 - **Zeke Emanuel**, Chair of the Department of Bioethics, Clinical Center, National Institutes of Health

Nov 20 - **Scott Hemphill**, Associate Professor of Law, Columbia Law School

Dec 4 - **Emily Oster**, Assistant Professor of Economics, University of Chicago; Faculty Research Fellow, National Bureau of Economic Research

Participation of Students in Program Activities

Student Fellowship Program

Applications for the Student Fellowship Program increased by 20% this year. Once again, applicants represented a broad distribution of areas of focus and academic backgrounds, with eight of the ten Harvard graduate schools represented. 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. Also, the largest percentage of applicants were among rising first-year students at Harvard Law School whose plans for law school included the desire to focus on health law from the start and who have expressed fervent enthusiasm to become closely involved in the Center's programs. Interest among this group demonstrates an immediate impact the Center has had on student formation in the field.

In addition to enrollment and participation in the Health Law Policy Workshop for at least one semester, students will undertake individual research projects with the goal of submitting their final work for publication. To facilitate this goal, they will be actively mentored by Petrie-Flom Center affiliated faculty and post-graduate fellows. Student fellows will also play an integral part in the Center's events programming. In particular, by request of the students, the Center plans to hold a symposium of student research in health law in the spring semester. The colloquium will showcase student fellow writing projects in the program, further introducing the wider Harvard community to their work and to opportunities for involvement in the Center.

The roster of student fellowship awardees for the 2008-2009 academic year is:

- **Jeffrey Gritton**, Harvard Law School
Pharmaceuticals patent systems and biologics
- **Jeffrey Jacobstein**, Harvard Law School
Genetic Technology and its Legal Implications
- **Spike Loy**, Harvard Law School
Venture Capital, Life Science and Innovation
- **Lindsey Murtaugh**, Harvard Law School, Harvard School of Public Health
Legal strategies for addressing racial and ethnic health disparities
- **Amie Shei**, Graduate School of Arts and Sciences
The Use of Incentives and Personal Responsibility in Health
- **Carmel Shachar**, Harvard Law School, Harvard School of Public Health
Ethical & legal challenges of clinical medical ethics consultations
- **Heidi Williams**, Graduate School of Arts and Sciences
Causes and consequences of innovation in markets for health care

Student-Focused Events Programming and Career Exploration

The Center expects to work again with students and student organizations to coordinate events in the fields of health law, policy and bioethics.

- Several students from Harvard Law School have expressed serious interest in conducting a day long seminar featuring presentations by law students conducting research projects in health law. The Center plans to sponsor and coordinate this event in conjunction with the Law and Health Care Society and the Ethics, Law and Biotechnology Society at Harvard Law School.
- We are currently coordinating with student fellows and organizations to arrange a panel discussion about careers in health law featuring practitioners from Hogan & Hartson in Washington, DC. This event will be held in conjunction with Hogan & Hartson's recruiting efforts at Harvard Law School and will serve to draw attention to opportunities for students interested in learning more about careers in health law. We particularly look forward to the occasion it will provide to further advance Harvard Law School and the Petrie-Flom Center's reputation as the preeminent institution of health law education among the nation's top law schools through showcasing the level of sophistication and superior training of our health law students in comparison to their peers from other schools.
- Finally, several of next year's cohort of student fellows have expressed interest in helping to organize and plan the Center's events programming agenda, elaborated on below.

Collaborations with Other Schools and Departments at Harvard

Collaboration with schools and programs across Harvard University is 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 consists 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 2008-2009 academic year to be developed and held in collaboration with a variety of groups from across Harvard University. Following is information on these evolving plans.

Events

Debate on Human Dignity

Center staff have been working with the Director's Office of the President's Council for Bioethics in Washington, DC to coordinate a high level event on the question of human dignity and the role it plays in bioethical debates. Based on a recent compendium of articles written by leading practitioners and philosophers in the field,

the event will bring together four to five leading figures for a philosophical debate to be held in Harvard Law School's Ames Courtroom and open to the Harvard Community. This event will take place in September and will lead off the Center's annual events program.

Moot Court on the Doctrine of Preemption

We are planning a moot court session with the actual litigants of the upcoming Supreme Court case, *Wyeth v. Levine*. This case poses an extremely significant question concerning recovery in tort for injuries from FDA-approved drugs. The court will decide whether compliance with FDA's regulation on drug labeling and marketing preempts a state law products liability claim related to the labeling. The decision will have enormous impact on the drug industry, authorizing or preventing an entire class of tort claims. The case has garnered widespread attention both within legal circles, and in the wider world (e.g., the Wall Street Journal). By holding a moot court just before the actual case is argued in the fall, the center hopes both to highlight for students at the law school the importance and complexity of Food and Drug law and to engage the public more generally on this extremely important issue.

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.

Conferences

Moral Biology

The Center remains interested in pursuing a joint conference with the Harvard Program in Ethics & Health and Harvard Medical School 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.

Pharmaceutical Research and Development

Additionally, the Center plans to pursue a conference on pharmaceutical research and development in the spring semester. Recently there has been a substantial decline in the productivity of drug research and development. According to a recent General Accounting Office report, while drug research and development expenditures have

more than doubled since 1993, the number of new drug applications – filed or approved – have remained constant. This conference will investigate possible causes of this slowdown. In addition to bringing together leading academics from across Harvard faculties and other universities, the Center plans to include representatives from the finance, drug, and clinical research industries, and government officials as participants exploring the financing of new drug development, the conduct of clinical trials, and regulatory hurdles to drug research and development. Our goal is to understand the salient risks and impediments to drug research.

Several other potential events that will be developed and co-sponsored with colleagues from across Harvard University and other institutions in the Greater Boston area are currently under consideration. We look forward to reporting on them in the upcoming year.