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Inside this issue:

Debating the Constitutionality of Obamacare	2-3
Selected HLS Events and Commentary Related to the Affordable Care Act	4-5
PFC Annual Conference: The Future of Human Subjects Research Regulation	6-9
Discussion on "Unsex Mothering"	9
Mississippi's Failed "Personhood" Amendment	10
Parenthood for Sale: Should the U.S. Regulate Reproductive Technology?	10
Identified vs. Statistical Lives - Ethics and Public Policy	11
Symposium on Ethical, Legal, and Social Implications of Autism Research	12
Professors Debate "Embryo Ethics"	12
Federal Judicial Center Workshop: Facilitating Offender Re-Entry to Reduce Recidivism	13
News from the Center for Health Law and Policy Innovation	14
2011-2012 Health Law Curriculum	15
2011-2012 Greenwall Grant Update	15
2011-2012 Health Law Events	16-17
PFC Leadership and Affiliate Announcements	18
PFC Student Fellows 2011-2012	19-20
2011-2012 Health Law Policy Workshop	21
Recent Scholarship and Commentary from Affiliates	22
Save the Date: Institutional Financial Conflicts of Interest in Research Universities	23

From the Faculty co-Directors

This has been another great year for the Petrie-Flom Center and for health law, health policy, bioethics, and biotechnology at Harvard Law School. The Affordable Care Act – both its constitutionality, the question before the Supreme Court, and its implementation if it is upheld – continued to be a focal point of the Center and its faculty's scholarship, media commentary, and public events. We were again fortunate to work with the Federal Judicial Center to provide training to federal judges, this time by focusing on health policy aspects of offender re-entry and reducing recidivism, with a keynote from the Deputy Attorney General of the United States, James Cole. Together with the Autism Self-Advocacy Network, the Center hosted a symposium on ethical, legal, and social implications of autism research. We also hosted events on the ethics of stem cell research and reproductive technology practices. Our annual conference, this year titled "the Future of Human Subjects Research Regulation," brought together more than 80 leading thinkers on the subject to provide reflections and advice to the Department of Health and Human Services as it undertakes a revision of the main rules regulating human subjects research in the U.S. Our workshop continues to be the premiere forum for students and faculty to help develop new scholarship, and we were joined this year by (among others) Tom Baker, Richard Epstein, Mark Hall, and Al Roth. Our student fellows continue to produce top-notch scholarship under the mentorship of our faculty and academic fellows, with papers on subjects as diverse as the commercialization of health technology, the organization and regulation of surrogacy brokerages, conflicts of interest in pharmaceutical marketing, distracted driving laws, and genetically modified crops.

We are expecting another banner year in 2012-2013. On November 2, 2012, we will be hosting a major event on Institutional Financial Conflicts of Interest in Research Universities, featuring among others NIH Director Francis Collins and former Harvard President Derek Bok. With the help of our new Executive Director, Holly Fernandez Lynch, we plan to launch several new initiatives that we hope will even further extend the great work done by our students, faculty, and university. There has never been a better time to be working in these fields, and we are excited to continue to be a part of it!

Sincerely,

I. Glenn Cohen

Benjamin N. Roin

Assistant Professor of Law,
Faculty co-Director

Hieken Assistant Professor in
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Faculty co-Director

Petrie-Flom Events and Commentary

Debating the Constitutionality of Obamacare

In addition to the “health care reform law” and “Obamacare,” The Patient Protection and Affordable Care Act (ACA) might appropriately be dubbed “The Full Employment Act for Law Professors.” It certainly has been keeping Professor Einer Elhauge, founding director of the Petrie-Flom Center, and Assistant Professor I. Glenn Cohen, current Center Faculty co-Director, busy as they provide their expertise on the law’s constitutionality and their predictions as to how the Supreme Court is likely to rule.

For three days in late March, the Court heard arguments on four issues:

1. The Anti-Injunction Act: Is the penalty imposed for failure to purchase individual health insurance a tax, such that the law may not be challenged until after the tax is collected?
2. The Minimum Coverage Provision: Is the requirement to purchase individual health insurance or pay a penalty constitutional?
3. Severability: If the purchase requirement is unconstitutional, can the rest of the Act stand?
4. Medicaid: Is the requirement that states expand Medicaid coverage or lose their Medicaid funding constitutional?

The Fourth Circuit Court of Appeals dismissed challenges to the Act’s minimum coverage provision – also called the individual mandate – on standing grounds and as premature in light of the Anti-Injunction Act. However, both the Sixth Circuit and the D.C. Circuit ruled on the merits to uphold the minimum coverage requirement. Only the Eleventh Circuit held that requirement to be unconstitutional, although it declared the mandate severable from the remainder of the Act. The Eleventh Circuit also rejected a challenge to the ACA’s Medicaid expansion requirements. The Supreme Court is expected to issue its opinion later this month.

When the law was passed in 2010, few questioned its constitutionality. Indeed, prior to oral arguments, many felt confident that the Supreme Court would easily uphold the law. However, Georgetown Law Professor Randy Barnett, who has been called the “intellectual architect” of the legal challenge against the ACA, had his doubts. Barnett argues that the individual mandate is an unprecedented requirement that goes beyond the powers of Congress granted by the Commerce Clause because it

regulates economic inactivity – failure to buy health insurance – rather than activity.

Prof. Elhauge disagrees. He has argued, against Barnett and others, that there are in fact a number of precedents for a federal purchase mandate, including 18th century requirements that ship owners buy medical insurance for their seamen, that seamen buy hospital insurance for themselves, and that all able-bodied men buy firearms. Prof. Elhauge also argues that the mandate can be up-



held under either the Commerce Clause or the Constitution’s Necessary and Proper Clause. And he rejects the activity-inactivity distinction, considering that nearly everyone is active at some point in the health care market, which is closely related to the health insurance market. Further, he notes that without Obamacare, the costs of treating the uninsured would again be borne by hospitals, which effectively imposes the mandate on the insured who cover hospital costs. Thus, the issue is not really whether there will be a mandate, but whether the mandate to cover the uninsured will be imposed on the insured or on the uninsured who receive the care.

In response to those who argue that grounding the mandate in the Commerce Clause is problematic because it would eliminate any limiting principle on congressional power, permitting the government to impose mandates to buy anything from broccoli to GM cars, Prof. Elhauge argues that there is a limiting principle: under the Commerce Clause, a federal law must involve

Debating the Constitutionality of Obamacare *(continued)*

economic regulation that addresses a national problem affecting interstate commerce. Each of those criteria is satisfied for the ACA, and even if “stupid” mandates could be constitutionally enacted within these broad limits, the political process is the proper source of protection, says Prof. Elhaug.

Prof. Cohen has also weighed in on a host of issues related to the ACA, in particular offering insight on the Medicaid question, which has received less media and scholarly attention. The Act requires that state Medicaid plans cover all persons under 65 with individual or family incomes up to 133% of the federal poverty level, a significant change given that Medicaid has not previously set a baseline income level for mandatory eligibility for adults. States must accept these new requirements (along with substantially more federal matching funds) in order to remain eligible for any federal Medicaid matching funds, a trade that some states have argued is coercive. Along with co-author Jim Blumstein from Vanderbilt, Prof. Cohen has evaluated various arguments against the Medicaid expansion, expressing greatest concern as to whether the states were given sufficient notice of the change. Although some have suggested the challenge is a non-starter, Prof. Cohen acknowledges that the Supreme Court’s grant of review signals that the issue is live.

Former Petrie-Flom Center Academic Fellow Abby Moncrieff, now Assistant Professor at Boston University School of Law, has become deeply involved with the ACA litigation as well. In addition to publishing [a number of articles](#) on the federalism aspects of the law, the validity of the individual mandate, and structural protections of non-fundamental liberties, Prof. Moncrieff was also involved in two amicus briefs submitted to the Supreme Court in support of the constitutionality of the ACA’s minimum coverage provision.

As we await the Supreme Court’s ruling this summer, and once it is handed down, we look forward to continued insight and analysis from Profs. Elhaug, Cohen, and Moncrieff.



Einer Elhaug
Petrie Professor of Law, Harvard Law School,
Founding Faculty Director, Petrie-Flom Center



I. Glenn Cohen
Assistant Professor of Law, Harvard Law School,
Faculty co-Director, Petrie-Flom Center



Abigail Moncrieff
Peter Paul Career Development Professor, Associate
Professor of Law, Boston University School of Law

Selected HLS commentary related to the ACA:

Einer Elhauge

[What a Nobel Prize-Winning Economist Can Teach Us About Obamacare](#)

The Atlantic, May 23, 2012

[A Further Response to Critics on the Founding Fathers and Insurance Mandates](#)

The New Republic, April 21, 2012

[A Response to Critics on the Founding Fathers and Health Insurance Mandates](#)

The New Republic, April 19, 2012

[It's Not About the Broccoli: The False Case Against Health Care](#)

The Atlantic, April 16, 2012

[If Health Insurance Mandates Are Unconstitutional, Why Did the Founding Fathers Back Them?](#)

The New Republic, April 13, 2012

[The Roberts-Kagan Compromise on Obamacare?](#)

The National Law Journal, March 28, 2012

[Don't Blame Verrilli for Supreme Court Health-Care Stumble](#)

The Daily Beast, March 28, 2012

[Economists Argue Over the Cost of Caring for the Uninsured](#)

The Daily Beast, March 25, 2012

[The Irrelevance of the Broccoli Argument Against the Insurance Mandate](#)

The New England Journal of Medicine, January 5, 2012

[The Broccoli Test](#)

The New York Times, November 15, 2011

Glenn Cohen

[Quoted in High Court Eyes Power of Federal Funds in Health Law Row](#)

Law360, March 20, 2012

[Quoted in Medicaid Expansion 'Sleeper Issue' of Health Care Cases](#)

Bloomberg News, March 20, 2012

[Quoted in Insurers at Risk in Challenge to Health Law's Medicaid Plan](#)

Bloomberg News, March 20, 2012

[Quoted in Tax Code Ruling Could Leave Health Reform Law in Limbo](#)

Law360, March 19, 2012

[Quoted in The Supreme Court Holds the Fate of Medicaid](#)

Politico, January 17, 2012

[The Constitutionality of the ACA's Medicaid-Expansion Mandate \(with Jim Blumstein\)](#)

The New England Journal of Medicine, December 7, 2011

[Interview on the Constitutional Challenge – Podcast](#)

The New England Journal of Medicine, December 7, 2011

Profs. Cohen, Elhauge, & Moncrieff

[7 Experts Try to Read Supreme Court Health-Care Tea Leaves](#)

The Daily Beast, March 29, 2012



Selected HLS events related to the ACA:

The Patient Protection and Affordable Care Act Oral Arguments

Martha Minow & Randy Barnett

April 12, 2012

What Happens If the ACA Is Struck Down?

Featuring Einer Elhauge

March 29, 2012

Implementing the ACA

Glenn Cohen & Timothy Jost

March 29, 2012

Health Insurance Exchanges and the Affordable Care Act

Glenn Cohen & Joel Ario

November 1, 2011

The Expanded Medicaid Mandate Under the ACA

Glenn Cohen & Jim Blumstein

October 27, 2011

Commerce Clause Challenges to Health Care Reform

Mark Hall (Health Law Policy Workshop)

September 12, 2011

Is the Obama Health Care Reform Constitutional?

Glenn Cohen, Charles Fried, Lawrence Tribe, & Randy Barnett

March 24, 2011



James Blumstein

University Professor of Constitutional Law & Health Policy; Director, Vanderbilt Health Policy Center



Randy Barnett

Carmack Waterhouse Professor of Legal Theory at Georgetown University Law Center



Charles Fried

The Beneficial Professor of Law at Harvard Law School

More Events and Commentary to come following the Supreme Court's ruling

Petrie-Flom's Annual Conference, May 18-19, 2012

The Future of Human Subjects Research Regulation

In July 2011, the Department of Health and Human Services released for public comment an Advanced Notice of Proposed Rule Making (ANPRM) titled "[Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators.](#)" With a focus on calibrating regulatory burden and resources to the magnitude of potential research risks, the ANPRM floated a number of potential changes to the federal regulations governing research with human subjects, which have not been substantially amended in more than twenty years. When the comment period closed in October, the Department had received over 1100 submissions.

Also in 2011, President Obama's Commission for the Study of Bioethical Issues took on the matter of human subjects research, issuing a report on the adequacy of current regulatory protections for subjects in federally-funded research, and making a number of recommendations for improvement.

Then in January 2012, the National Institutes of Health announced a commitment of \$1 million to support research that will be used to evaluate the impact of the regulatory revisions currently under consideration. The goal: to develop an evidence-based approach to ensuring the effectiveness of human subject protections.

With these important developments, it is clear that the regulation of human subjects research is not only ripe for reevaluation, but that the regulators are primed to listen and respond. Against this backdrop, the Petrie-Flom Center used the occasion of its annual conference to convene some of the foremost experts in the field to put forth their ideas on "The Future of Human Subjects Research Regulation." As Center Faculty co-Director I. Glenn Cohen put it, "This is the kind of thing that affects billions of dollars for industry, pharma, hospitals, researchers, and universities across the world [This



conference] might be an opportunity to revisit and actually change things regarding human subjects research."

Over the course of a day and a half of panels, plenaries, and extensive Q&A, conference attendees heard from a wide range of presenters, from the former director of the Office for Human Research Protections, Greg Koski, to social science researchers, lawyers, clinicians, and federal employees. Although the ANPRM served as a jumping off point, presentations and discussions were not so limited. A driving theme, however, was the tension between whether to accept the ANPRM's approach of tweaking the current system but keeping its primary elements in tact, or simply starting from scratch.

In his opening plenary, Greg Koski argued in favor of the latter. Although there is not much evidence that the regulations as they stand are achieving their goal of protecting subjects, Dr. Koski pointed out that we do have evidence of substantial impediments to research. He argued that the foundation of the current approach is that scientists are bad, which he analogized to the TSA's approach to airline safety: every passenger is a potential terrorist. Dr. Koski argued this results in huge amounts of wasted time and money, without evidence that airline travel is safer and with several near misses caught outside this protective system. Similarly, a number of recent research tragedies have occurred despite adherence to the required regulatory process. As an alternative model, Dr. Koski pointed to the regulation of medical practice, where we do not treat every doctor as potentially bad, but instead assume they can be trusted to provide responsible care. Ultimately, Dr. Koski pro-



Leslie Wolf, (left) Professor of Law, Georgia State University, and **Gail Javitt**, (right) Research Scholar, Johns Hopkins Berman Institute of Bioethics; Adjunct Professor at the Georgetown University Law Center

posed adapting the medical profession's paradigm to research, which he argued would be every bit as effective, but less burdensome and more efficient. It will not be review committees that protect subjects, he concluded, but rather well-trained, conscientious investigators.

Following Dr. Koski's challenge, the first panel of presenters focused on research risks, addressing such questions as how to appropriately categorize them, how subjects' perspectives should influence policy, and whether the risk-benefit analysis performed by IRBs is fundamentally flawed. Annette Rid from the University of Zurich pointed out a number of initiatives in Europe to make the regulation of research more appropriately keyed to potential risks, just as American regulators have proposed to do. However, she argued that it is insufficiently nuanced to separate risks into minimal and greater than minimal risk categories, and inappropriate to rely on an intervention's marketing status as a reliable indicator of risk. Next, Rosamond Rhodes from Mt. Sinai School of

The ANPRM is "simply tinkering around the edges of a system that the bioethics community, the investigator community, and virtually every other community, sees as being somewhat dysfunctional."
-Greg Koski

Medicine emphasized the need to base regulation on ethically significant factors such as risk level, the need for general participation, and the importance and likelihood of expected benefits. She proposed a new category of research risk – de minimis risk – to cover things like biospecimen research, for which consent generally would not be required. Ana Iltis of Wake Forest took issue with the ANPRM's proposal to eliminate continuing review of previously expedited minimal risk research, given that risks and study value are not always static. Michael McDonald and his colleagues from the University of British Columbia presented results of their study evaluating how subjects experience research regulation and risk, concluding that it is essential to consider subjects' perspectives in order to assess whether review committees' predictions as to what subjects need to be protected from are in fact accurate. Finally, Michelle Meyer from the Petrie-Flom Center addressed the information and aggregation problems that plague the risk-benefit analysis currently required by the regulations. Risks, benefits, and the reasonableness of their balance depend on individual circumstances and preferences, she argued, which IRBs are simply unable to as-



Greg Koski, Former Director, HHS Office for Human Research Protections; Director of Clinical Research, Division of Cardiovascular Anesthesia, Department of Anesthesia, Critical Care and Pain Medicine, Massachusetts General Hospital

sess. Even if they could, IRBs can only make a single risk-benefit judgment, even though this calculation may differ for different subjects, creating a heterogeneity problem.

The next panel evaluated issues related to research with vulnerable populations, such as prisoners, children, and the military. First, Osagie Obasogie of UC Hastings College of Law criticized the Institute of Medicine's recommendation that it would be acceptable to increase the use of prisoners in research, arguing that more empirical data is needed. Next, Adam Braddock from UC San Diego argued that children should be included as research partners, while recognizing that there may be challenges related to maturity level, parental disruptions, and psychosocial harms. And Efthimios Parasidis from St. Louis University described an extensive history of misfeasance in military research. He argued, inter alia, that members of the military should be protected against adverse consequences for refusing to participate in research and that the existing waiver of consent applicable to military research should be abolished.

During a lunchtime plenary address, Amy Davis and Elisa Hurley of PRIM&R (Public Responsibility in Medicine and Research) reported on their organization's public comments on the ANPRM. One of their most striking, and potentially controversial points, was PRIM&R's position that efficiency itself is not a moral imperative, such that human subjects protection should not be compromised in its name. They also reiterated the need to improve the consent process for subjects without overwhelming them with details. PRIM&R disagrees, however, with the ANPRM's suggestion to import HIPAA standards into research. Instead, it emphasizes the need for a strong criminal enforcement approach to data privacy.

On that note, the third panel focused on the privacy of tissues, specimens, and data, where a common theme was concern regarding the type of consent for biospecimen research contemplated by the ANPRM. Ellen Wright Clayton of Vanderbilt Law School pointed out

Continued page 8

Petrie-Flom's Annual Conference, May 18-19, 2012

The Future of Human Subjects Research Regulation (*continued*)

that re-identification of de-identified research samples is likely to be both difficult and improbable, therefore rendering potential harms to subjects minimal. Nonetheless, she indicated that the general, one-time consent to future biospecimen research proposed by the ANPRM is not consent at all, but rather a mere signature incapable of protecting autonomy. Gail Javitt from Johns Hopkins explained that no uniform approach has emerged from the courts as to ownership and control over biospecimens, but that courts have often treated contributors as donors through decisions favoring the interests of researchers. Leslie Wolf of Georgia State University College of Law noted a conflict between permitting broad consent to biospecimen research and the requirement for specific consent to obtain a federal Certificate of Confidentiality. Carol Weil of the National Cancer Institute's Office of Biorepositories and Biospecimen Re-

"If I want to inform policy by asking questions, I have to go through IRB, but if OHRP wants to inform policy by asking questions, they don't . . ."

-Zachary Schrag

search expressed concern regarding potentially biased collections of data if certain populations refuse to provide broad consent. And finally, Suzanne Rivera from Case Western argued that the boundaries between private and public are situational and changing. She suggested that the ANPRM's concern regarding privacy is overblown considering how often people disclose information about themselves, and pointed out the various benefits to consumers and patients from sharing their data. Thus, she called for "informational altruism" – the idea that de-identified data and specimens should be seen as a national resource.

The final panel of Day 1 focused on the researcher-participant relationship. First, Seemah Shah from NIH's Clinical Center Department of Bioethics argued that the Common Rule governing most federally-funded research creates an undesirable moral division of labor in which investigators and sponsors go to IRBs to determine whether their research is ethical. Instead, she suggested that the Common Rule should impose obligations directly on investigators and sponsors to ensure the scientific validity and value of their research, reason-



Ana Iltis

Associate Professor of Philosophy, Director of Center for Bioethics, Health and Society at Wake Forest University

able risks and benefits, and respect for subjects. However, she also argued that these obligations should not be legally enforceable given the fuzziness of precisely what would be required for compliance. In his talk, Alex Capron from USC indicated that the regulatory exceptions to informed consent are in danger of swallowing the rule. He also expressed concern about "passing the buck" in the sense that IRBs sometimes view subjects as capable of protecting themselves via informed consent, while investigators simultaneously view IRBs as responsible for subject protection. Finally, Govind Persad from Stanford discussed how democratic deliberation should be used in human subjects research, for example by including greater representation of subjects on IRBs.

The second day of the conference opened with a panel on research governance, addressing such questions as whether research subjects are meaningfully different from other types of individuals exposed to risks for pay, the legitimacy of IRB decisions, and the propriety of regulating biomedical and social science research under the same framework. First, Holly Fernandez Lynch of the Petrie-Flom Center set forth the numerous similarities between research subjects and those workers protected by labor and employment law, and argued that the human subjects research regulations should be amended to permit unrestricted payment for participation, require a modified minimum wage, impose a workers' compensation system for injured subjects, and protect subjects' rights to engage in concerted activity and collective bargaining. Laura Stark of Wesleyan described the historical development of IRBs and her ethnographic research on IRB decision-making, particularly boards' use of local precedents. She concluded by arguing that IRB discretion is inevitable and appropriate, that divergent outcomes between different IRBs are not necessarily a sign of inefficiency or illegitimacy, and that models of advance peer review and precedent sharing may be

Petrie-Flom's Annual Conference, May 18-19, 2012

The Future of Human Subjects Research Regulation (*continued*)



Patrick Taylor,

Petrie-Flom Academic Fellow, 2010-12; Assistant Clinical Professor, Pediatrics, Children's Hospital Boston

worthy of further exploration. Next, Heidi Li Feldman of Georgetown University Law Center argued that application of the so-called "medical model" is not necessarily a problem when it comes to regulation of behavioral and/or qualitative research with human subjects, since all types of research with human subjects can threaten subject autonomy. Thus, she argued, IRB regulation based on protection of autonomy via informed consent is neither totalitarian nor intolerant of non-biomedical research methods and fields of study. Finally, Melissa Frumin and colleagues discussed their experience developing a central IRB for a multi-site clinical trial network.

The final two presenters of the conference each addressed the parameters of regulatory authority over human subjects research. First, Zachary Schrag from George Mason University took aim at the regulatory definition of human subjects research, using as an example the ANPRM itself, which he indicated might be appropriately cast as an attempt to collect generalizable knowledge from individually identifiable living people, rendering it subject to IRB review requirements. Ultimately, Dr. Schrag argued that regulating research based on its generalizability, systematic nature, and funding source is arbitrary and inappropriate. Next, Barbara Evans from the University of Houston Law Center questioned whether the suggested changes described in the ANPRM can be supported by statutory authority, although she cautioned against seeking greater authority from Congress.

Overall, attendees hailed the conference as a massive success, achieving its goal of bringing together leading experts to address the future of human subjects research regulation through both concrete and creative proposals. In addition to already catching the attention of federal policy makers, plans are in the works to disseminate the participants' contributions to a wider audience. In the interim, a webcast of the conference will be posted later this summer on the [Petrie-Flom conference webcast page](#).

PFC Co-Sponsors Discussion of "Unsex Mothering"

On February 13, 2012, the Petrie-Flom Center co-sponsored a panel discussion of Professor Darren Rosenblum's work "Unsex Mothering: Toward a New Culture of Parenting," which was published in the Harvard Journal of Law and Gender's Fall 2011 volume. Rosenblum's piece challenges the ways in which "mothering" and "fathering" have been "inappropriately tethered to biosex," and proposes that with the elimination of biosex tethers to specific parental roles "a parent could define herself as 'parent,' 'mother,' or 'father' with some fluidity." Further, he argues that unsexing parenting through legal regimes such as Sweden's Parental Leave Act that promote fluidity in parenting also serve normatively valuable goals such as furthering sex equality.

Panelists took up Rosenblum's work, providing praise and critique. Panelists challenged the novelty of his notion of unsexing, questioned his premise that unsexing mothering is good for women, and probed his vision of what an unsexed world would look like. The overarching theme of the discussion focused on bioethical issues at the intersections of gender/queer theory and critical legal studies.

The event featured Professors Darren Rosenblum (Pace Law School), Mary Ann Case (University of Chicago Law School), Elizabeth Emens (Columbia Law School), Suzanne Kim (Rutgers), and Petrie-Flom Center student fellow Katherine Kraschel (HLS '12). The panel provided a new forum for discussion of legal scholarship both among the panelists and members of the Harvard community in attendance. In addition, the Journal of Law and Gender hosted an on-line colloquium on the piece, including a contribution from Center Faculty co-Director I. Glenn Cohen.

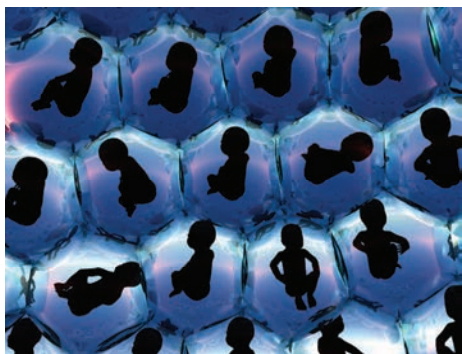
Mississippi's Failed "Personhood" Amendment

In November 2011, Mississippi voters were presented with a ballot initiative that would have defined the term "person" to include "every human being from the moment of fertilization, cloning, or the functional equivalent thereof." Supporters of the initiative hoped to curtail abortion rights, get other states to follow suit, and provoke a challenge to *Roe v. Wade*. But opponents feared that such an amendment to the state constitution could have made birth control illegal, and even rendered the performance of in vitro fertilization procedures legally tenuous.

Glenn Cohen, Petrie-Flom Center Faculty co-Director, was at the front lines of the debate. He participated in a panel discussion of the proposed amendment hosted by Mississippi College School of Law, and wrote an [op-ed for the New York Times](#) with Jonathan F. Will, a professor at Mississippi College. In that op-ed, Professors Cohen and Will argued that the amendment was profoundly ambiguous as a legal matter, and that support or opposition should not fall along traditional abortion lines. First, they pointed out that fertilization itself is a continuum that spans over two weeks from the joining of sperm and egg until the embryo implants in the uterus. Second, it was unclear whether the amendment would be self-executing or require additional action by the legislature, leading to uncertainty as to precisely what would be immediately subject to prosecutorial investigation. Such an ambiguous amendment would prove a poor vehicle to challenge existing abortion jurisprudence, they argued. Thus, whatever one's views on abortion, this amendment should be voted down – and in fact, it was. On November 8, Mississippi voters defeated the ballot initiative, although "personhood" efforts are underway in several other states.

Professor Cohen has also written on other aspects of the abortion debate, including most recently on [fetal pain](#) with Sadath Sayeed.

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



On April 17, 2012, Assistant Professor I. Glenn Cohen, Faculty co-Director of the Center, participated in a panel discussion at HLS on the regulation of reproductive technology hosted by the American Constitution Society and moderated by student fellow Katie Kraschel (JD '12). Prof. Cohen described the ways in which reproduction itself is regulated with regard to whether, with whom, and when reproduction takes place. He also set forth a number of potential reasons for regulating reproduction, such as the best interests of the resulting child and paternalism. However, Prof. Cohen finds most of these reasons unpersuasive, and argues that instead there must be some "secret ambition" behind reproductive regulations, such as eugenic motivations, requirements to enhance resulting children, or other unjustifiable grounds. These are issues that Prof. Cohen takes up in detail in two recent law review articles, [Regulating Reproduction: The Problem with Best Interests](#) and [Beyond Best Interests](#).

Alongside Prof. Cohen were Susan Crockin, an attorney focused on adoption and assisted reproductive technologies, and Prof. George Annas of Boston University. Ms. Crockin described her goal of helping clients create legally secure families that will not be challenged by future legal uncertainty regarding parental rights and responsibilities. She noted that same sex female couples generally have more in common with heterosexual couples than with same sex male couples when it comes to family law, and also identified a number of issues associated with gestational surrogacy, including the possibility that the surrogate and intended parents might disagree as to whether to abort or selectively reduce a pregnancy. Prof. Annas described a number of regulatory models for reproductive technology, including the "American way" of allowing the market to run free without government interference, state regulation, federal prohibition of various types of reproductive sales, and professional self-regulation, his preferred approach.

During the Q&A period, the panelists were asked to compare the regulation of reproductive technology to the regulation of adoption. Prof. Cohen explained that the best interest of the child standard can make sense in the realm of adoption, since there is already a child in existence with best interests to be concerned about, as opposed to the realm of both assisted and natural reproduction, where there is not yet any child to be harmed (what philosophers call the "Nonidentity Problem"). Ms. Crockin agreed that natural reproduction provides the preferable comparison to assisted reproduction, rather than adoption, noting that no home visits should be required. Finally, Prof. Annas suggested that we can have obligations to non-existent children, but argued that adoptions are in fact over-regulated. Additional discussion considered donor anonymity, private eugenics, capping donor payments, and the differences between sperm donation and egg donation/surrogacy.

Identified v. Statistical Lives – Ethics and Public Policy

On April 19 and 20, 2012, the Harvard Global Health Institute in collaboration with partner institutions at Harvard – the Petrie-Flom Center, the Edmond J. Safra Center for Ethics, the Center for Decision Science and the Center for Population & Development Studies – convened a University-wide conference focusing on the notion that we tend to feel more obligated to help “identified” people at risk than to assist “statistical” people. This notion has important implications for public policy and risk prevention. To illustrate with one recent example, the plight of the group of Chilean miners who were stranded following a 2010 mine accident mobilized worldwide support and millions of dollars for a rescue mission, but there was no public support for investing in mine safety measures that would have prevented the accident.

This issue has often been cast as the difference between the public health approach, which focuses on the health of populations, and the medical approach, which looks at the health of individual patients. This issue has also been seen as a debate about whether it is better to allocate scarce societal resources for treatment of a person’s medical condition versus the prevention of that condition in the broader population.

This two day conference was the first to take an in-depth look at this issue from across disciplinary boundaries. Six panels were organized by four Harvard faculty members from the Harvard School of Public Health, the Harvard Medical School, and the Harvard Law School: Norman Daniels, Mary B. Saltonstall Professor and Professor of Ethics and Population Health, Harvard School of Public Health; I. Glenn Cohen, Assistant Professor of Law and Faculty co-Director, Petrie-Flom Center; Nir Eyal, Assistant Professor of Global Health and Social Medicine, Harvard Medical School; and Stephen Resch, Deputy Director, Center for Health Decision Science, Department of Health Policy and Management, Harvard School of Public Health. Panelists included faculty from philosophy, economics, decision science, government and public policy, marketing and psychology, linguistics and bioethics, with lively discussions among the panelists of the six sessions and across panels.

The faculty organizers arranged panels that framed the question in more nuanced ways, as conference panelists looked more broadly at whether this bias exists and explored this question from different contexts. In the session on the whether the law tends to favor identified lives, panelists noted that certain areas of law – environmental, national security and public health law – while encouraging the protection of statistical lives with expansive state police powers that allow government to regulate activities to meet societal safety standards, also restrict those powers through protection of individual

rights in lawsuits brought by identified individuals whose rights have been infringed. Other panels examined empirical evidence and the seemingly strong psychological and neurological bases for the identified life bias, considering such questions as what factors trigger or explain attitudes and behaviors that favor people we can identify in some way. Here, presenters noted how little information about the identity of an individual is needed to change human behavior and resource allocation decisions to favor the identified life.



Faculty organizers of the Conference, from left to right: **Nir Eyal**, Harvard Medical School, **Norman Daniels**, Harvard School of Public Health, **I. Glenn Cohen**, Harvard Law School, and **Stephen Resch**, Harvard School of Public Health.

Some presenters questioned the general distinction in the literature between an identified life and a statistical life. What is required to determine when a life has been “identified” and when it is a statistical life? Other presenters examined the moral arguments used to favor identified lives over statistical ones, noting that the identified versus statistical life distinction was not valid in some of the arguments often used to justify the identified person bias. One panel looked at the modern global health approach of treatment as prevention, where arguments are made in the infectious disease context that treating identified people reduces the infection rate of others not yet identified (or statistical lives), potentially reducing overall health care costs. Other presenters considered whether this bias could be justified in some circumstances, such as appealing to empathy, encouraging people to be more social beings, noting that more successful donor appeals include the pictures and stories of individuals. These appeals often increase the resources allocated to health care, saving more lives.

Panel discussions and the question and answer sessions with the wide-ranging audience were spirited. Panelists from the various disciplines agreed that there was more work to be done to examine the important ethical and public policy implications of looking at identified lives versus statistical lives. Webcasts of the panels are available on the [Petrie-Flom Center website](#).

PFC Hosts Symposium by the Autism Self-Advocacy Network

The Ethical, Legal, and Social Implications of Autism Research

Over \$1 billion has been spent over the course of the last decade on autism research funding. During a time of constant budget cuts and increasing fiscal pressures on government, this is an astonishing sum. What have we purchased for this investment? How successful has the autism research agenda been in making the American dream a reality for autistic people and their families? Has our society adequately discussed the ethical, legal and social consequences of how autism research findings may be used?

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

Professors Debate “Embryo Ethics”

On February 1, 2012 the Petrie-Flom Center co-hosted with the HLS Federalist Society a debate on the philosophical and legal issues surrounding the field of embryonic research. The event, “Embryo Ethics and the Law,” featured Christopher Tollefsen, a philosophy professor at the University of South Carolina, and HLS Assistant Professor I. Glenn Cohen, Faculty co-Director of the Petrie-Flom Center.

Tollefsen, author of several books including “Embryo: A Defense of Human Life,” explored the professionalization of science and the stake that the state holds in research. He began the debate with the question of the regulation and governance of science, questioning whether research should be governed by scientific principles or by the morals and ethics of society.

Cohen’s position suggested that embryonic cell research could be adopted by conservatives, libertarians, pro-life, and pro-choice alike. He argued for the maximum possible liberty as long as no harm was done to others.

The question of whether embryonic research falls into the harm principle, said Cohen, cannot be answered through religious principles, as it is unethical to base state decisions in any one religious belief. He offered five sets of philosophical approaches to the question of human personhood, including the 14-day post-conception theory and the idea that humans are persons with full legal rights at conception.

The question of when embryos become persons and what legal protection this provides played heavily in the debate. “Human persons are to be morally immune from unprovoked violence, so it’s wrong, everywhere and always, to kill an innocent human being,” Tollefsen stated. “I think that this norm is violated in embryo destructive research, research in which human beings, at their earliest stages of development, are killed as part of the project of obtaining new knowledge.”



I. Glenn Cohen

Assistant Professor of Law, Harvard Law School
and Faculty co-Director of the Petrie-Flom Center



Christopher Tollefsen

Professor of Philosophy,
University of South Carolina

PFC Hosts Federal Judicial Center Workshop

Facilitating Offender Re-entry to Reduce Recidivism

For three days last September, the Petrie-Flom Center hosted a Federal Judicial Center (FJC) workshop on facilitating offender re-entry to reduce recidivism, a major priority for Attorney General Eric Holder in his review of federal sentencing and corrections policy, as well as for the multitude of jurisdictions facing unsustainable prison populations alongside dwindling corrections budgets. The Center saw this as an important issue within its purview given the need to translate the most recent advances in the social sciences, neuroscience, and criminology into practical applications and resources to support all stages of the judicial system. Moreover, given how many individuals returning to the community from prison suffer from significant cognitive deficiencies, substance abuse and dependency issues, and mental health challenges, their recidivism is in many ways an issue of health policy.

The workshop, spearheaded by Mark Sherman, Senior Education Attorney for the FJC, brought together teams of federal judges, prosecutors, defense attorneys, probation officers, and treatment providers to learn about evidence-based (rather than imitation-based) and innovative approaches to facilitating federal prisoners' transition from prison to community and reducing recidivism. These approaches include the use of actuarial risk/need instruments at the start of supervised release, cognitive behavioral interventions, and using data to drive supervision decisions and improve outcomes, particularly among individuals leaving prison who are at the greatest risk of returning and have the greatest need for support, as well as innovations like post-conviction drug and re-entry courts, and offender workforce development programs. A major theme at the workshop was the need for collaboration among a number of diverse – and sometimes traditionally adversarial – stakeholders



James M. Cole, Deputy Attorney General of the United States, delivered the keynote address.



Walter White, now a small business owner in Missouri, was one of three ex-offenders to share their experiences in the criminal justice system and their perspectives on the re-entry process. Addressing the workshop participants of judges, prosecutors, and probation officers, White began his presentation by stating 'I used to hate what you all represented.' What followed, though, was an inspiring story of transformation and gratitude.

in order to facilitate successful re-entry and avoid imposing unnecessary obstacles to the transition back to community.

Deputy Attorney General James M. Cole gave the keynote address, which emphasized the need to allocate scarce financial resources appropriately toward the most effective programs to reduce the prison population while preserving public safety. Other speakers included Hon. Ann Aiken, Chief Judge of the District Court of Oregon, who simulated a session with a previous offender in re-entry court; Scott Anders, a chief probation officer who drew a comparison between soldiers returning from war and ex-felons coming back from prison; Martha Kane, an addiction specialist who urged caution against punishing drug relapses too harshly; Kenyen Brown from the U.S. Attorney's Office in the Southern District of Alabama, who described a successful program to help ex-felons find employment; and several ex-offenders who were able to provide their perspectives on how to best achieve re-entry.

Previously, the Petrie-Flom Center had successfully collaborated with the Federal Judicial Center and others to host a training session for federal and state judges on the most recent research in neuroscience and its potential impact on the law.

Recent and Upcoming Projects from the Center for Health Law and Policy Innovation

Staff and students working in the Center for Health Law and Policy Innovation (CHLPI) collaborate with community partners throughout the US to improve access to health care and healthy food for low-income and vulnerable populations through the work that takes place in the Health Law and Policy and Food Law and Policy Clinics.

RECENT PROJECTS

Over the past 18 months, we have worked with partners in Texas to develop the comprehensive *Texas State Report: An Analysis of the Successes, Challenges and Opportunities for Improving Healthcare Access with a Focus on the Texas Medicaid Program*. CHLPI provided extensive technical assistance training to state government officials, health providers, and community-based advocates, focusing on opportunities for Texas to expand access to care to vulnerable populations living with chronic health conditions through implementation of the Patient Protection and Affordable Care Act (ACA). The Center also facilitated a dialogue between the Department of State Health Services (overseeing programs related to communicable diseases including HIV, hepatitis and Sexually Transmitted Diseases) and the Health and Human Services Commission (overseeing Medicaid), which had historically had little interaction. Because Texas has one of the most restrictive Medicaid programs in the country, this collaboration is essential in order for ACA's Medicaid expansion to meet the care and treatment needs of Texans living with HIV, hepatitis, and other chronic health conditions. Recently, Texas was one of six states selected to participate in the federally-funded Medicaid Safety Net Learning Collaborative, preparing for newly eligible Medicaid beneficiaries. Depending on the outcome of the ongoing ACA litigation, CHLPI will be working with our Texas partners this Fall to develop law and policies to support this new initiative.

This year, CHLPI also completed an advocacy toolkit on mental health and Medicaid managed care. The toolkit outlines the importance of Medicaid in providing access to mental health treatment for low-income Americans and highlights issues for advocates to consider when a state seeks to implement cost-containment approaches, which often include restricting access to mental health medications. States use approaches such as creating preferred drug lists, imposing burdensome cost-sharing requirements, and requiring patients to "fail" on older, less expensive drugs before being able to access newer

medications. These tactics can have dire consequences for people living with serious mental illness.

CHLPI put its toolkit into action in a number of states, including Illinois, Massachusetts, New York, Pennsylvania, and South Carolina. Most recently, CHLPI was part of a successful effort in Massachusetts to reverse a planned Medicaid policy that would require patients with schizophrenia or bipolar disorder to fail on two generic drugs before being able to access state-of-the-art, higher cost medications.

Finally, last fall and spring, CHLPI served as a consultant for the Southern AIDS Strategy Initiative (SASI) led by Duke Law School's AIDS Legal Project. The Center helped SASI develop research-based policy and strategy recommendations aimed at securing a federal commitment to allocate a larger part of the National HIV/AIDS Strategy resources to southeastern states, where rates of both new HIV diagnoses and HIV deaths are highest. This month the Secretary of Health and Human Services announced a new \$43.5 million initiative (\$14.5 million per year over three years) to address health disparities and mortality rates in the South.

COMING THIS FALL

During the upcoming academic year, CHLPI will start a multi-year project to develop comprehensive state law and policy recommendations for eliminating barriers to access to both health care and healthy food, with the goal of addressing obesity and improving the health outcomes of people living with type 2 diabetes. The PATHS (Providing Access to Healthy Solutions) initiative will conduct state-based pilot programs in Mississippi, New Jersey, and North Carolina, to produce state law and policy recommendations and a roadmap for supporting ongoing advocacy efforts in these states. The findings will also support a national effort to implement new law and policy regarding obesity and diabetes prevention, care, and management.

Also, in collaboration with the HLS International Human Rights Clinic and community-based partners in Zambia, CHLPI will work to mainstream HIV/AIDS, gender, and human rights law curricula in Zambian law schools and to strengthen the country's ability to address the weaknesses in these laws.

2011-2012 Harvard Law School Health Law Curriculum

- **Disability Law**, Professor Stein
- **Drug Product Liability Litigation**, Professor Grossi
- **Evolution of Gender Crimes: Seminar**, Professor McKinnon
- **Food and Drug Law**, Professor Hutt
- **Food: A Health Law and Policy Seminar**, Professor Greenwald
- **Health Law**, Professor Barnes
- **Health Law and Policy Workshop**, Professors Cohen & Elhaug
- **Health, Disability and Estate Planning: Law and Policy Clinical Seminar**, Professor Greenwald
- **International Reproductive/Sexual Health Rights: Reading Group**, Professor Roseman
- **Law and Cognition: Seminar**, Professor Kahan
- **Law and Psychology-The Emotions: Seminar**, Professor Cope
- **Law, Psychology, and Morality: An Exploration through Film: Seminar**, Professor Stone
- **Patent Law**, Professor Roin
- **Population Level Bioethics Reading Group**, Professors Cohen & Daniels
- **Real Science, Junk Science and CSI: Reading Group**, Professor Gertner
- **Regulating the Production of Knowledge: The Law and Ethics of Research**, Professor Meyer
- **Sex Equality**, Professor McKinnon



2011 Greenwall Grant Update

The Constitutional Foundations of Bioethics: A Cross-National Comparison

In collaboration with the Program on Science, Technology and Society at the Harvard Kennedy School, the Petrie-Flom Center hosted a workshop at Harvard University on November 10, 2011 entitled “The Constitutional Foundations of Bioethics: A Cross-National Comparison.”

This interdisciplinary, international workshop was the closing event in a research project generously supported by the Greenwall Foundation. Led by Professor Sheila Jasanoff, director of the Program on Science, Technology and Society, the project also involved Professor Benjamin Hurlbut of Arizona State University and Dr. Krishanu Saha of MIT as collaborators. Advisers included Professor I. Glenn Cohen and Patrick Taylor, of Harvard Law School, Professor Rudolf Jaenisch of MIT, and Dr. Robert Martensen of the National Institutes of Health.

The project was designed to explore the changing landscape of the biosciences and bioethics in Western nations, with particular emphasis on research areas and objects that challenge pre-existing legal classifications. Focusing on cross-national differences in the governance of genomics, stem cell biology, regenerative medicine, and synthetic biology, the project team sought to understand why divergence occurs and what can be learned about the deeper legal, political, and cultural foundations of the observed variations.

Four comparative case studies examined how national differences in constitutional thinking—including the web of tacit rules governing state-society relations—has affected ethical norms and policy responses with respect to: (1) direct-to-consumer genetic testing, (2) animal-human chimeras, (3) synthetic biology, and (4) discourses of over- and under-regulation in reproductive medicine and human embryo research.

The workshop brought together key experts and decisionmakers in science, industry, government, law, ethics, and science and technology studies to comment on the cases. Participants also discussed the implications of the project for future teaching and training in the biosciences, bioethics, law, and science and technology policy.

2011-2012 Academic Year Health Law Related Events

During the 2011-2012 academic year, the Center and its affiliates hosted, co-sponsored, collaborated, and participated in a wide range of events, many of which have been highlighted elsewhere in this newsletter. These events spanned from analysis of current news items, such as the Affordable Care Act, to issues of perennial interest, such as how to allocate resources among "identified" and "statistical" lives. Once again, these events brought together leading opinion-makers on matters related to health law, bioethics, and biotechnology from around the University and beyond.

September 2011– April 2012

HEALTH LAW POLICY WORKSHOP, Harvard Law School

Co-taught by **Glenn Cohen**, Petrie-Flom Center Faculty co-Director, and **Einer Elhauge**, Petrie-Flom Center Founding Director, and featuring scholars from around the country

September 7-9, 2011

FACILITATING OFFENDER RE-ENTRY TO REDUCE RECIDIVISM, a workshop in collaboration with the Federal Judicial Center

October 19, 2011

BUILDING A CAREER IN A HEALTH RELATED FIELD, HLS Alumni Health Careers Network

Featuring **Glenn Cohen**, Petrie-Flom Center Faculty co-Director, and **Daniel Vorhaus**, former Petrie-Flom Center Student Fellow

October 21, 2011

TEDxHARVARDLAW CONFERENCE ON FOOD POLICY AND PUBLIC HEALTH, Harvard Food Law Society

October 27, 2011

RECENT AND FORTHCOMING RULINGS REGARDING THE EXPANDED MEDICAID COMPONENT OF THE AFFORDABLE CARE ACT, The Petrie-Flom Center

Glenn Cohen, Petrie-Flom Center Faculty co-Director, and **Jim Blumstein**, Vanderbilt Law School

November 1, 2011

HEALTH INSURANCE EXCHANGES AND THE AFFORDABLE CARE ACT, The Petrie-Flom Center

Glenn Cohen, Petrie-Flom Center Faculty co-Director, and **Joel Ario**, previously Director, Office of Insurance Exchanges, US Department of Health and Human Services

November 10, 2011

THE CONSTITUTIONAL FOUNDATIONS OF BIOETHICS: A CROSS-NATIONAL COMPARISON, a workshop in collaboration with the Program on Science, Technology, and Society at the Harvard Kennedy School

Led by **Sheila Jasanoff**, Director, Program on STS, with a panel moderated by **Glenn Cohen**, Petrie-Flom Center Faculty co-Director

December 9-10, 2011

ETHICS IN AUTISM RESEARCH, a symposium in collaboration with the Autism Self-Advocacy Network

February 1, 2012

EMBRYO ETHICS AND THE LAW, The Petrie-Flom Center and Harvard Federalist Society

Featuring a debate between **Glenn Cohen**, Petrie-Flom Center Faculty co-Director, and **Christopher Tollefsen**, University of South Carolina

February 13, 2012

UNSEX MOTHERING, an event in collaboration with the Harvard Journal of Law and Gender
Featuring **Katherine Kraschel**, HLS '12, Petrie-Flom Student Fellow, and an [online contribution](#) from **Glenn Cohen**, Petrie-Flom Center Faculty co-Director

March 29, 2012

IMPLEMENTING THE AFFORDABLE CARE ACT: GETTING FROM 2010 TO 2014, The Petrie-Flom Center
Glenn Cohen, Petrie-Flom Center Faculty co-Director, and **Timothy Jost**, Washington and Lee University School of Law

March 29, 2012

WHAT HAPPENS IF THE ACA IS STRUCK DOWN?, HBS Health Industry Alumni Association
Featuring **Einer Elhauge**, Petrie-Flom Center Founding Director

April 3, 2012

MASSACHUSETTS AS A LABORATORY OF HEALTH CARE REFORM INNOVATION, HLS Center for Health Law and Policy Innovation

April 12, 2012

THE PATIENT PROTECTION AND AFFORDABLE CARE ACT ORAL ARGUMENTS, Harvard Federalist Society
A discussion between **Martha Minow**, Dean of Harvard Law School, and
Randy Barnett, Georgetown University Law Center

April 17, 2012

PARENTHOOD FOR SALE: SHOULD THE US REGULATE REPRODUCTIVE TECHNOLOGY?, The American Constitution Society at HLS
Featuring **Glenn Cohen**, Petrie-Flom Center Faculty co-Director

April 19-20, 2012

IDENTIFIED LIVES VERSUS STATISTICAL LIVES: ETHICS AND PUBLIC POLICY, a Harvard Global Health Institute conference in collaboration with the Program in Ethics and Health and the Petrie-Flom Center
Organized by **Norman Daniels**, Harvard School of Public Health, **Glenn Cohen**, Petrie-Flom Center Faculty co-Director, **Nir Eyal**, Harvard Medical School, and **Stephen Resch**, Harvard School of Public Health

May 18-19, 2012

THE FUTURE OF HUMAN SUBJECTS RESEARCH REGULATION, The Petrie-Flom Center Annual Conference
Featuring **Glenn Cohen**, Petrie-Flom Center Faculty co-Director, **Holly Lynch**, Petrie-Flom Center Executive Director, and
Michelle Meyer, **Jeff Skopek**, and **Patrick Taylor**, Petrie-Flom Center Academic Fellows



Announcements in Center Leadership and Affiliations

PFC Appoints Holly Fernandez Lynch Executive Director



We are pleased to announce that after a nationwide search, the Petrie-Flom Center welcomed Holly Fernandez Lynch as Executive Director on June 1, 2012. Holly will be working with the Faculty co-Directors, I. Glenn Cohen and Benjamin Roin, who remain in their existing role.

Holly has been involved with the Center since its inception, joining the inaugural cohort of fellows under the leadership of Founding Director, Einer Elhauge. At that time, she drafted the manuscript for *Conflicts of Conscience in Health Care: An Institutional Compromise*, published by MIT Press. Holly has also practiced law at Hogan & Hartson, LLP in Washington, DC (now Hogan Lovells), where she counseled pharmaceutical and biotechnology clients on complex regulatory matters involving the Food and Drug Administration. In addition, Holly has government experience as a bioethicist working with the Human Subjects Protection Branch at NIH's Division of AIDS, where she advised the Division, its clinical trial networks, and grant recipients on research ethics and human subjects regulatory issues arising in HIV/AIDS prevention, treatment, and co-infection studies. Immediately prior to returning to Cambridge as an Academic Fellow in 2011, Holly served as Senior Policy and Research Analyst for President Obama's Commission for the Study of Bioethical Issues.

Holly graduated Order of the Coif from the University of Pennsylvania Law School, where she was a Levy Scholar in Law and Bioethics. While pursuing her law degree, Holly also earned her Master of Bioethics from the University of Pennsylvania School of Medicine.

Holly's primary goal and responsibility as Executive Director will be to advance the Center's visibility and impact at Harvard and beyond, in both academic circles and the public square. In addition to the fellowships, conferences, workshops, and events that have been at the core of the Center's activities to date, she will help the Center begin a set of new initiatives. Holly will also continue to pursue independent research on issues at the intersection of law and bioethics, and will teach a seminar on bioethics in the courts in Spring 2013.

PFC Faculty Co-Director I. Glenn Cohen Awarded 2012 Radcliffe Fellowship

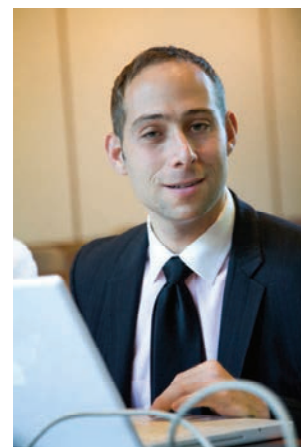
The Radcliffe Institute for Advanced Study at Harvard University has selected Faculty co-Director I. Glenn Cohen to be a Radcliffe Institute fellow for the 2012–2013 academic year. Prof. Cohen is among the 51 women and men who will pursue independent projects in the arts, humanities, sciences, and social sciences within this rich, multidisciplinary community. After a highly competitive peer-review process, Prof. Cohen is among only 5 percent of applicants who were accepted to create a diverse incoming class that includes anthropologists, chemical engineers, linguists, literature professors, molecular biologists, musicologists, and visual artists.

Radcliffe Institute Dean Lizabeth Cohen, herself a former fellow at the Institute, spoke about the incoming group: "These extremely talented individuals will arrive at different stages of their work, but whether they start exploring big new ideas or whether they complete ambitious projects, we expect that all will enjoy a year of profound growth and great productivity."

Medical tourism will be the area of focus for Prof. Cohen who will focus his fellowship on the legal and ethical issues related to patients who are residents of one country travelling to another for medical treatment.

"I am extremely honored to join luminaries in so many fields for a year of scholarly exchange and enrichment," he said. "I am grateful to Radcliffe for recognizing the importance of my project, which examines the way globalization is reconfiguring the practice of medicine, and the attendant legal and ethical issues this raises."

Harvard Law School Dean Martha Minow said: "Glenn's scholarship and also leadership of our Petrie-Flom Center demonstrate originality and bold exploration of new frontiers in health law, bioethics, and biotechnology. The recognition and resources afforded by the Radcliffe Institute fellowship are terrific for Glenn and he will marvelously represent the Law School in discussions with all the other Radcliffe fellows." Prof. Cohen will remain Faculty co-Director for the duration of his Radcliffe fellowship.



Welcoming Incoming Academic Fellow W. Nicholson Price II

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



*The Center will begin accepting applications for the 2013-2015 cohort of Academic Fellows starting August 1 until **November 16, 2012**. We seek outstanding candidates to pursue independent scholarship in the fields of health law, health policy, biotechnology, and bioethics. Past fellows have successfully placed as law professors at Harvard, UC Berkeley, BU, UCLA, Cornell, and the University of Arizona. For more information on eligibility and application requirements, refer to the [Academic Fellowship Call for Applications on the Petrie-Flom website](#).*

Petrie-Flom Student Fellows 2011-12

The Center had a great crop of student fellows this year, who researched topics from conflict of interest to distracted driving. We look forward to welcoming another cohort in the Fall and introducing them in our next issue.



Devin Cohen, HLS '12

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



Sachin Desai, HLS '13

Sachin's scholarly interests focus on improving technology commercialization and the introduction of new business models into heavily regulated industries such as health care. His fellowship project focused on how complex legal, regulatory, and administrative structures surrounding health care impact the effectiveness of traditional technology commercialization methods. Sachin entered law school after working as a strategy consultant at Deloitte, assisting numerous clients in regulated industries and health care. Sachin graduated with a Masters in Aerospace Engineering and a Bachelors in Mechanical Engineering from Cornell University.

Continued page 20

Petrie-Flom Student Fellows 2011-12

continued



Dorothy Du, HLS '13

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



Rebecca Haffajee, GSAS, PhD candidate, '13

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



Katherine Kraschel, HLS '12

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



Rachel Sachs, HLS, HSPH '13

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

*Applications for the 2012-2013 Student Fellowship Program are being accepted through **June 10, 2012**. The Center welcomes applications from students enrolled in graduate programs from across the University interested in writing on issues at the intersection of law and health policy, including issues of health care financing and market regulation, biomedical research, and bioethics. In addition to research support and mentorship from Petrie-Flom post-doctoral fellows and affiliated faculty, the Fellowship offers students opportunities to engage with scholars from a variety of disciplines working on cutting edge issues in the fields of health law, patent law, public policy, bioethics and beyond through participation in the Health Law Policy Workshop and by active participation in the Center's annual events programming. For more information on Fellowship eligibility and requirements, refer to the [Call for Applications](#) on the Petrie-Flom website.*

2011-12 Health Law Policy Workshop

The Health Law Policy Workshop is a seminar offered annually at HLS open to students from across the university, as well as interested faculty, fellows, and the general public. It features two hours of presentation and in-depth discussion of cutting edge scholarship by leading academics on topics in health law, health policy, biotechnology, and bioethics. For full text of the presentation drafts and previous years' presentations, refer to the [PFC website Workshop page](#).



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



Arti K. Rai, Elvin R. Latty Professor of Law, Duke Law School
Patentability Policy Across the Executive Branch: What the DNA Patent Controversies Teach About Institutional Choice



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



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



Katherine Baiker, Professor of Health Economics, Harvard School of Public Health
The Oregon Health Insurance Experiment: Evidence from the First Year



Max Mehlman, Professor of Bioethics and Professor of Law, Case Western Reserve University
Enhanced Warfighters: A Policy Framework



Nita Farahany, Associate Professor of Law and Professor of Philosophy, Vanderbilt Law School
Searching Secrets (Neuroscience and Criminal Law)



Russell Korobkin, Professor of Law, UCLA School of Law
Bounded Rationality, Moral Hazard, and the Case for Relative Value Health Insurance

Richard Epstein, Laurence A. Tisch Professor of Law, New York University School of Law
The Constitutional Protection of Trade Secrets and Patents under the Biologics Price Competition and Innovation Act of 2009

Frank Pasquale, Schering-Plough Professor in Health Care Regulation and Enforcement, Seton Hall Law School
From Transparency to Intelligibility: Rethinking Disclosure in Health and Finance Reform

Holly Fernandez Lynch, Executive Director, Petrie-Flom Center
Human Research Subjects as Human Research Workers

Jeffrey Skopek, Academic Fellow, Petrie-Flom Center
Anonymity Rules: Biological Identity and the Control of Human Tissue

Christopher Robertson, Associate Professor of Law, The University of Arizona James E. Rogers College of Law
The Split Benefit (Adding Skin in the Game for Insurance)



Recent Scholarship from PFC Affiliates

I. Glenn Cohen, Faculty co-Director

[Regulating Reproduction: The Problem with Best Interests](#),
96 MINN. L. REV. 423 (2011)

[Beyond Best Interests](#),
96 MINN. L. REV. _ forthcoming, 2012

[Rethinking Sperm Donor Anonymity: Of Changed Selves, Non-Identity, and One Night Stands](#),
100 GEO. L. J. 431 (2012)

[Prohibiting Anonymous Sperm Donation and the Child Welfare Error](#),
41 HASTINGS CTR. REP, Sept-Oct, 13 (2011)

[Medical Tourism, Access to Health Care, and Global Justice](#),
52 VA J. INT'L L. 1 (2011)

[How to Regulate Medical Tourism \(and Why It Matters for Bioethics\)](#),
12 DEVELOPING WORLD BIOETHICS 9 (2012)

[In the Wake of Guatemala: The Case for Voluntary Compensation and Remediation](#),
102 AM. J. PUB. HEALTH e4 (2011) (co-authored with Eli Adashi)

[Selling Bone Marrow – Flynn v. Holder](#),
366 N. ENG. J. MED. 296 (2012)

[Can the Government Ban Organ Sale? Recent Court Challenges and Future of U.S. Law on Selling Human Organs and Other Tissue](#),
12 AM. J. TRANSPLANTATION _ forthcoming, 2012

[Mississippi's Ambiguous "Personhood" Amendment](#)
New York Times, October 31, 2011 (with Jonathan F. Will)

Holly Fernandez Lynch, Executive Director

[The Rights and Wrongs of Intentional Exposure Research: Contextualising the Guatemala STD Inoculation Study](#),
J. MED. ETHICS, Online First (Mar. 2012)

[Ethical Evasion or Happenstance and Hubris? The US Public Health Service STD Inoculation Study](#),
42 HASTINGS CTR. REP. 30 (2012)

[A Lesson from the Contraception Coverage Uproar? Rethink Employer-Based Insurance](#),
Hastings Center Bioethics Forum (Feb. 2012)

Michelle Meyer, Academic Fellow

[Stem Cell Policy as Bar Room Brawl: A Round in the Courts](#),
The Nelson A. Rockefeller Institute of Government, Aug. 2011 (with James W. Fossett)

Patrick Taylor, Academic Fellow

[Disclosing Pathogenic Genetic Variants to Research Participants: Quantifying an Emerging Ethical Responsibility](#),
22 GENOME RES. 421 (2012)(with Christopher A. Cassa et al.)

[The Beliefs, Motivations and Expectations of Parents Who Have Enrolled Their Children in a Genetic Biorepository](#),
14 GENET. MED. 330 (2012)(with Erin D. Harris et al.)

[From Patients to Partners: Participant-Centric Initiatives in Biomedical Research](#),
13 NAT. REV. GENET. 371 (2012)(with Jane Kaye et al.)

[The Informed Cohort Oversight Board: From Values to Architecture](#),
MINN. J. L., SCI. & TECH. _ forthcoming, (with I. Holm)

[Innovation Incentives or Corrupt Conflicts of Interest? Rewarding the Good and Prohibiting the Bad in the Complex World of Biomedical Academic-Industry Partnerships](#),
Yale J. Health Pol'y, L. & Ethics _ forthcoming



Save the Date: Friday, November 2, 2012, at Harvard Law School

Institutional Financial Conflicts of Interest in Research Universities

Conflicts of interest are on everyone's minds (and lips) these days, but most of the attention to date has focused on individual conflicts held by doctors, researchers, and others. Institutions can also face important conflicts as a result of their various interests and allegiances, and research universities in particular are at a crossroads. President Obama has called on these universities to collaborate with industry, investors, and agencies to bolster entrepreneurship, commercialize research results, and enhance economic development – and a number of universities have pledged to do so. Should this be a welcome development, or cause for concern? How will this new role for research universities influence their traditional mission to educate and promote reliable, unbiased knowledge?



Please join us at a symposium, co-sponsored by the Edmund J. Safra Center for Ethics at Harvard, to address a number of critical and timely questions regarding institutional financial conflicts of interest in research universities. With a world-class line-up of speakers who have grappled with these issues at some of the highest echelons in which they arise, this event is not to be missed.

Opening Remarks and Welcome

I. Glenn Cohen	The Petrie-Flom Center, Harvard Law School
Lawrence Lessig	The Edmond J. Safra Center for Ethics, Harvard University
Martha Minow	Dean of the Faculty, Harvard Law School

Introduction and Overview

David Korn	Harvard Medical School; Massachusetts General Hospital
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Evolving Roles and Enduring Values of American Research Universities

Jonathan Cole	Columbia University
Ezekiel Emanuel	University of Pennsylvania
William Fisher	Harvard Law School

Institutional Conflicts of Interest in Practice

Derek Bok	Harvard University
Claude Canizares	Massachusetts Institute of Technology
Jonathan H. Marks	The Pennsylvania State University
Hunter Rawlings III	The Association of American Universities

Federal Perspectives on Institutional Financial Conflicts of Interest

Francis Collins	National Institutes of Health
Sally Rockey	National Institutes of Health
Julie Taitzman	Office of the Inspector General, U.S. Department of Health and Human Services

Concluding Panel, facilitated by

Charles Vest	National Academy of Engineering
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Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics
Harvard Law School, Cambridge, MA 02138
www.law.harvard.edu/programs/petrie-flom

Important Dates:

June 10, 2012

2012-2013 Student Fellowship Applications Due

November 16, 2012

2013-2015 Academic Fellowship Applications Due

November 2, 2012

Institutional Financial Conflicts of Interest in Research Universities

In the Next Issue:

A New Era for the Petrie-Flom Center: A Retrospective and Prospective View

A Post-SCOTUS Review of the Status of Health Care Reform

2012-13 Events

2012-2013 Petrie-Flom Student Fellows

And more...