The Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School
presents its 2013 Annual Conference

THE FOOD AND DRUG ADMINISTRATION IN THE 21ST CENTURY

May 3-4, 2013

Location: Harvard Law School
Wasserstein Hall, Milstein East ABC (Second Floor) Map
1585 Massachusetts Avenue, Cambridge, MA

AGENDA

DAY 1 – Friday, May 3, 2013

Welcome and Introduction, 9:00-9:15
• L Glenn Cohen, Faculty Director, Petrie-Flom Center
• Holly Fernandez Lynch, Executive Director, Petrie-Flom Center

PLENARY 1, 9:15-10:00
• PETER BARTON HUTT (Covington & Burling LLP), Historical Themes and Developments Over the Past 50 Years
• Audience Q&A

The FDA in a Changing World, 10:00-11:00
Moderator: Holly Fernandez Lynch (Petrie-Flom Center)
• Lewis Grossman (American University, Washington College of Law/Covington & Burling LLP), FDA in the Age of the Empowered Consumer
• Theodore Ruger (University of Pennsylvania Law School), After the FDA: A Twentieth Century Agency in a Postmodern World
• Barbara Evans (University of Houston Law Center), The Future of Prospective Medicine Under the Food and Drug Administration Amendments Act of 2007
• Audience Q&A

Break, 11:00-11:15

Preserving Public Trust and Demanding Accountability, 11:15-12:30
Moderator: David Korn (Massachusetts General Hospital)
• Mark Lange (Eli Lilly), Data Transparency and the Role of the FDA
• Genevieve Pham-Kanter (Edmond J. Safra Center for Ethics, Harvard University), Financial Conflicts of Interest and Voting in FDA Drug Advisory Committees
• Patrick O'Leary (Harvard Law School), Credible Deterrence: The Park Doctrine and the FDA in the 21st Century
• Katrice Bridges Copeland (Penn State Dickinson School of Law), The Crime of Being in Charge: Executive Culpability and Collateral Consequences
• Audience Q&A

Conference Dropbox: http://tinyurl.com/d3o6764

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Break, 12:30-12:45

LUNCH AND KEYNOTE, 12:45-1:30
- DEBORAH AUTOR (Deputy Commissioner for Global Regulatory Operations and Policy, U.S. Food and Drug Administration), with an introduction by JEFFREY SENGER (Sidley Austin)
- Audience Q&A

Break, 1:30-1:45

Protecting the Public Within Constitutional Limits, 1:45-2:45
Moderator: I. Glenn Cohen (Petrie-Flom Center)
- Aaron Kesselheim/Michelle Mello (Harvard School of Public Health), The Prospect of Continued FDA Regulation of Manufacturer Promotion in an Era of Expanding Commercial Speech
- Chris Robertson (University of Arizona James E. Rogers College of Law), When Truth Cannot Be Safely Presumed: A First Amendment Reconstruction of the Regulation of Off-Label Drugs
- Jessica Flanigan (University of Richmond), Patients' Rights, Speech, and Off-Label Marketing
- Audience Q&A

Timing Is Everything: Balancing Access and Uncertainty, 2:45-3:30
Moderator: Jeff Skopek (Petrie-Flom Center)
- Shannon Gibson/Trudo Lemmens (University of Toronto Faculty of Law), Overcoming "Pre-Market Syndrome": Advancing Post-Market Surveillance in an Evolving Drug Development Context
- Efthimios Parasidis (St. Louis University School of Law. moving to The Ohio State University Moritz College of Law), Innovative Regulating as a Public Health Imperative
- Audience Q&A

BREAK 3:30-3:45

Major Issues in Drug Regulation, 3:45-5:00
Moderator: R. Alta Charo (University of Wisconsin Law School)
- Geoffrey Levitt (Pfizer), Drug Safety Communication: The Evolving Environment
- W. Nicholson Price II (Petrie-Flom Center), The Role of Innovation Policy in Pharmaceutical Manufacturing
- Ernst Berndt (MIT Sloan School of Management)/Rena Conti (University of Chicago), Anatomy of US Cancer Drug Shortages
- Daniel Carpenter (Harvard University), Jeremy Greene (Johns Hopkins School of Medicine), Susan Moffitt (Brown University), Jonathan Warsh (Oxford University), Therapeutic and Economic Effects of Efficacy-Based Drug Withdrawals: The Drug Efficacy Study Initiative and Its Manifold Legacies
- Audience Q&A

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DAY 2 – Saturday, May 4, 2013

Welcome, 9:00-9:05
I. Glenn Cohen (Petrie-Flom Center)

PLENARY 2, 9:05-9:50
- R. ALTA CHARO (University of Wisconsin Law School), Integrating Speed and Safety
- Audience Q&A

Regulatory Exclusivities and the Regulation of Generic Drugs and Biosimilars, 9:50-11:05
Moderator: Benjamin Roin (Petrie-Flom Center)
- Kate Greenwood (Seton Hall University School of Law), Calibrated Incentives for Orphan Drug Development: Time to Experiment?
- Kevin Outterson (Boston University School of Law), Ending the Game of Shadows in Drug Regulation
- Marie Boyd (University of South Carolina School of Law), Unequal Protection Under the Law: Reforming the Regulation of Generic Drugs
- Henry Grabowski (Duke University), FDA Regulation of Biosimilars
- Audience Q&A

Break, 11:05-11:20

Major Issues in Device Regulation, 11:20-12:20
Moderator: W. Nicholson Price II (Petrie-Flom Center)
- Jeffrey Shapiro (Hyman, Phelps, McNamara PC), Why the 510(k) Pathway is the Right Approach for Most Medical Devices
- Kayte Spector-Bagdady/Elizabeth Pike (Presidential Commission for the Study of Bioethical Issues), Device-ive Maneuvers: FDA Regulation of the Bifurcation of Direct-to-Consumer Genomic Data and Information
- Thomas R. McLean (American Medical Litigation Support Services)/Alexander McLean (University of Texas at Austin School of Law), Post-Market Surveillance of Medical Devices
- Audience Q&A

Break, 12:20-12:35

LUNCH AND PLENARY 3, 12:35-1:20
- SUSAN WINCKLER (President and CEO, Food & Drug Law Institute)
  - Audience Q&A

Break, 1:20-1:30

Conference Dropbox: http://tinyurl.com/d3o6764
Major Issues in Food, Supplement, and Tobacco Regulation, 1:30-2:45
Moderator: Emily Broad Leib (Harvard Law School)

- Robin Craig, Leslie Francis, Erika George (S.J. Quinney College of Law, University of Utah), *The FDA's Authority Over Labeling: Current Ironies and Future Improvements*
- Jennifer Pomeranz (Yale Rudd Center for Food Policy & Obesity), *Food Labeling and Enforcement*
- Diana Winters (Indiana University Robert H. McKinney School of Law), *From Industrial to Artisanal: Food Regulation and the Problem of Scale*
- Joanna Sax (California Western School of Law), *The Tobacco Diaries: Lessons Learned and Applied to Regulation of Dietary Supplements*
- Audience Q&A

Addressing the Challenges of and Harnessing New Technologies, 2:45-3:45
Moderator: Frances Miller (Boston University School of Law)

- Margaret Riley (University of Virginia School of Law), *FDA's Authority to Regulate Regenerative Technology*
- Nathan Cortez (Southern Methodist University Dedman School of Law), *Is the FDA Equipped to Regulate Mobile Health Devices?*
- David Rosenberg, Andrew English, Huaou Yan (Harvard Law School), *Enhancing FDA Oversight of Medical Product Usage: A New Regulatory Role for e-Prescriptions*
- Audience Q&A

Closing Remarks, 3:45-4:00

- I. Glenn Cohen (Petrie-Flom Center)

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Guest Wireless Access: [http://www.law.harvard.edu/about/administration/its/guests/index.html](http://www.law.harvard.edu/about/administration/its/guests/index.html)