American University Washington College of Law
4300 Nebraska Ave., NW, Washington, D.C. 20016

FRIDAY, OCTOBER 19

8:30-9:30 **Registration and Continental Breakfast**
Founders Lobby, Yuma Building, Terrace Level

9:30-10:45 **Concurrent Session 1**

Session 1A **Drugs I**
Claudio Grossman Hall, Yuma Building, Terrace Level

Moderated by Grail Sipes, JD, Deputy Center Director for Regulatory Policy, CDER, FDA

The History and Political Economy of the Hatch-Waxman Amendments

Erika Lietzan, JD, MA Associate Professor of Law, University of Missouri School of Law

Commentary by Kurt Karst, JD (AUWCL '01), Director, Hyman, Phelps & McNamara, P.C.

The More Things Change: Improvement Patents, Drug Modifications, and the FDA

Dmitry Karshtedt, JD, PhD, MA, Associate Professor of Law, George Washington University Law School

Commentary by James N. Czaban, JD, Partner, Chair, FDA and Medical Products Regulatory Practice Group, DLA Piper LLP (US)

Session 1B **Food and Animal Products**
Room N102, Warren Building, First Floor

Moderated by Stuart Pape, JD, Shareholder and Practice Chair, Polsinelli

Retooling American Foodralism

Laurie Beyranevand, JD, Associate Dean for Academic Affairs, Director, Center for Agriculture and Food Systems, Professor of Law, Vermont Law School

Diana Winters, JD, PhD, MA, Assistant Director of Scholarship, Resnick Center for Food Law and Policy, University of California Los Angeles School of Law

Commentary by Jeannie Perron, DVM, JD, Partner, Covington & Burling LLP

Administrative Guidance and Genetically Modified Food

Joanna Sax, JD, PhD, E. Donald Shapiro Professor of Law, California Western School of Law

(Coauthor: Edward L. Rubin, JD, MA, University Professor of Law and Political Science, Vanderbilt University Law School)

Commentary by Sarah Roller, JD, RD, MPH, Partner, Chair, Food and Drug Law Practice, Kelley Drye & Warren LLP

Session 1C **Medical Products: Cross-Cutting Issues I**
Room Y112, Yuma Building, First Floor

Moderated by Elizabeth Jungman, JD, MPH, Director of Public Health Programs, Pew Charitable Trusts and Member, FDLI Board of Directors

Can the Food Drug and Cosmetic Act Survive the 21st Century?

Ralph F. Hall, JD, Professor of Practice, University of Minnesota Law School

Commentary by Daniel Kracov, JD, Partner and Co-chair, Live Sciences and Healthcare Regulatory Practice, Arnold & Porter LLP and Adjunct Professor of Law, American University Washington College of Law and Member, FDLI Board of Directors

Regulating Intermediate Technologies

Rachel E. Sachs, JD, MPH, Associate Professor of Law, Washington University Law School

Commentary by Gail H. Javitt, JD, MPH, Member of the Firm, Epstein Becker Green

10:45-11:15 **Break**

Founders Lobby, Yuma Building, Terrace Level

11:15-11:45 **Welcoming Remarks**
Claudio Grossman Hall, Yuma Building, Terrace Level

Lewis Grossman, JD, PhD, Professor of Law, American University Washington College of Law

Amy Comstock Rick, JD, President and CEO, Food and Drug Law Institute

Sylvia Mathews Burwell, President, American University, former U.S. Secretary of Health and Human Services

11:45-12:45 **Plenary Session 1: A Discussion with Former FDA Commissioners**
Claudio Grossman Hall, Yuma Building, Terrace Level

Hosted by Lewis Grossman, JD, PhD, Professor of Law, American University Washington College of Law

Robert Califf, MD, Vice Chancellor for Health Data Science, Duke University

Margaret Hamburg, MD, President, American Association for the Advancement of Science and Foreign Secretary of the National Academy of Medicine

David Kessler, MD, JD, Professor, University of California San Francisco

Andrew C. von Eschenbach, MD, President, Samaritan Health Initiatives, Inc.

12:45-1:15 **Lunch Buffet**
Founders Lobby, Yuma Building, Terrace Level

1:15-2:15 **Plenary Session 2: A Discussion with Former FDA Chief Counsels**
Claudio Grossman Hall, Yuma Building, Terrace Level

Hosted by I. Glenn Cohen, JD, James A. Attwood and Leslie Williams Professor of Law, Faculty Director, Petrie-Flom Center for Health Law Policy, Biotechnology & Bioethics Harvard Law School

Richard Cooper, JD, MA, Senior Counsel, Williams & Connolly, LLP

Peter Barton Hutt, LLB, LLM, Senior Counsel, Covington & Burling LLP

Gerald Masoudi, JD, Chief Legal Officer, JUUL Labs, Inc.

Daniel Troy, JD, Senior Vice President and General Counsel, GlaxoSmithKline PLC

2:15-2:30 **Break**
Founders Lobby, Yuma Building, Terrace Level

2:30-3:45 **Concurrent Session 2**

Session 2A **Drugs II**
Room YT17, Yuma Building, Terrace Level

Moderated by David J. Horowitz, Partner, Hogan Lovells

Reversal of Fortune: Moving Pharmaceuticals from Over-the-Counter to Prescription Status?

Lars Noah, JD, Professor of Law, Stephen C. O'Connell Chair, University Term Professor, University of Florida Levin College of Law

Commentary by David C. Spangler, JD, Senior Vice President, Policy, and General Counsel and Secretary, Consumer Healthcare Products Association

On Drugs: Renovating Preemption

Elizabeth Y. McCuskey, JD, Professor of Law, University of Toledo Law School

Commentary by Brian Wolfman, JD, Associate Professor of Law, Director, Appellate Court Immersion Clinic, Georgetown University Law Center

Session 2B **Medical Products: Cross-Cutting Issues II**
Room Y400, Yuma Building, Fourth Floor

Moderated by Theresa Mullin, PhD, Associate Director for Strategic Initiatives, CDER, FDA

21st Century Citizen Pharma: The FDA & Patient Focused Drug Development

Jordan Paradise, JD, Georgia Reithal Professor of Law, Loyola University Chicago School of Law

Commentary by Marc M. Boutin, JD, Chief Executive Officer, National Health Council

Non-Therapeutic Uses and the FDA

Patricia J. Zettler, JD, Associate Professor, Georgia State University College of Law

Commentary by Geoffrey Levitt, JD, Senior Vice President and Associate General Counsel for Regulatory, Environmental and Global Supply, Pfizer, Inc.

Session 2C **Other FDA Product Areas: Tobacco and Cosmetics**
Room Y401, Yuma Building, Fourth Floor

Moderated by Linda Katz, MD, MPH, Director, Office of Cosmetics and Colors, Acting Chief Medical Officer, Center for Food Safety and Applied Nutrition, FDA

Gender & the Inadequate Regulation of Cosmetics

Marie Boyd, JD, Assistant Professor of Law, University of South Carolina School of Law

Commentary by Alexandra Gerber, JD, Vice President, Assistant General Counsel, Revlon, Inc.

Is the End of Smoking in Sight?: Tobacco Control in the Trump Years and Beyond

Micah L. Berman, JD, Associate Professor, Ohio State University, Moritz College of Law and College of Public Health

Commentary by Azim Chowdhury, JD, MBA, Partner, Keller and Heckman LLP

3:45-4:00 **Break**
Founders Lobby, Yuma Building, Terrace Level

4:00-5:15 **Concurrent Session 3**

Session 3A **Medical Devices**
Room YT17, Yuma Building, Terrace Level

Moderated by Bakul Patel, MSEE, MBA, Associate Center Director for Digital Health, CDRH, FDA

FDA's Role in Governance of Black-Box Medicine

W. Nicholson Price II, JD, PhD, Assistant Professor of Law, University of Michigan Law School

Commentary by Jeffrey N. Gibbs, JD, Director, Hyman, Phelps & McNamara, P.C. and Chair, FDLI Board of Directors

Digital Health and Regulatory Experimentation at the FDA

Nathan Cortez, JD, Associate Dean for Research, Gerald J. Ford Research Fellow, Adelfa Botello Callejo Endowed Professor of Law in Leadership and Latino Studies, Southern Methodist University Dedman School of Law

Commentary by Wade Ackerman, JD, Partner, Covington & Burling LLP

Session 3B **Biological Products**
Room Y400, Yuma Building, Fourth Floor

Moderated by Peter Marks, MD, PhD, Director, Center for Biologics Evaluation and Research, FDA

Follow-On Biologics Are Set Up to Fail

Yaniv Heled, LLB, LLM, JSD, Associate Professor of Law, Co-Director, Center for Intellectual Property Law, Georgia State University College of Law

Commentary by Michael Werner, JD, Partner, Co-Leader, Healthcare & Life Sciences Team, Holland & Knight LLP

Improving Life Sciences Regulation: Solutions to the Current Impasse

Myrisha S. Lewis, JD, Assistant Professor of Law, Howard University School of Law

Commentary by Chad Landmon, JD, Partner, Chair, Intellectual Property and FDA Practice Groups, Axinn, Veltrop & Harkrider LLP

Session 3C **Beyond Traditional Drug Regulation**
Room Y401, Yuma Building, Fourth Floor

Moderated by Henry T. Greely, JD, Director, Center for Law and the Biosciences; Professor (by courtesy) of Genetics, Stanford School of Medicine; Chair, Steering Committee of the Center for Biomedical Ethics; and Director, Stanford Program in Neuroscience and Society

Cannabis for Medical Use: FDA and DEA Regulation in the Hall of Mirrors

Rebecca S. Eisenberg, JD, Robert and Barbara Luciano Professor of Law, University of Michigan Law School
(Coauthor: Deborah B. Leiderman, MD, MA, Principal, CNS Drug Consulting LLC)

Commentary by D. Kyle Sampson, JD, Partner, King & Spalding LLP

Drugs' Other Side-Effects

Craig Konnoth, JD, MPhil, Associate Professor of Law, University of Colorado Boulder Law School

Commentary by Peter Pitts, President, Center for Medicine in the Public Interest

5:15-6:45 **Reception Honoring AUWCL Food and Drug Law Alumni**
Claudio Grossman Hall, Yuma Building, Terrace Level (all attendees welcome)

Remarks by Mitch Zeller, JD (AUWCL '82), Director, Center for Tobacco Products, FDA