



The Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access

July 18, 2017

8:00 – 9:00 **Registration**

9:00 – 9:10 **Welcome**

Keith Flanagan, Office of Generic Drugs, Center for Drug Evaluation and Research (CDER), FDA

9:10 – 9:35 **Opening Remarks**

Scott Gottlieb, Office of the Commissioner, FDA

Janet Woodcock, Office of the Center Director, CDER, FDA

9:35 – 9:45 **Introduction of the Panelists**

Keith Flanagan, Office of Generic Drugs, CDER, FDA

Panelists

- *Anna Abram*, Office of the Commissioner, FDA
- *Elizabeth Dickinson*, Office of the Chief Counsel, Office of the Commissioner, FDA
- *Keith Flanagan*, Office of Generic Drugs, CDER, FDA
- *Markus Meier*, Bureau of Competition, Federal Trade Commission
- *Grail Sipes*, Office of Regulatory Policy, CDER, FDA
- *Peter Stein*, Office of New Drugs, CDER, FDA
- *Maryll Toufanian*, Office of Generic Drugs, CDER, FDA
- *Kathleen Uhl*, Office of Generic Drugs, CDER, FDA

9:45 – 11:00 **Public Presentations: The Academic/Researcher Perspective**

Michael Carrier, Rutgers Law School

Ameet Sarpatwari, Brigham and Women's Hospital

Alex Brill, Matrix Global Advisors

James Polli, University of Maryland School of Pharmacy

Ernst Berndt, MIT Sloan School and the National Bureau of Economic Research

11:00 – 11:10 **Morning Break**

11:10 – 12:00 **Public Presentations: The Payer/Provider Perspective**

Todd Ebert, Healthcare Supply Chain Association
Wayne Russell, Premier HC Solutions
Paul Eiting, Blue Cross Blue Shield Association
Richard Bankowitz, America's Health Insurance Plans
Marissa Schlaifer, Pharmaceutical Care Management Association
Tiffany McCaslin, National Business Group on Health

12:00 – 1:00 **Lunch**

1:00 – 2:40 **Public Presentations: The Pharmaceutical Product Development Perspective**

Chester (Chip) Davis, Jr., Association for Accessible Medicines
Bruce Leicher, Momenta Pharmaceuticals, Inc.
Andrew Boyer, Teva Pharmaceuticals
Gregg DeRosa, Teva Pharmaceuticals
Scott Tomskey, Teva Pharmaceuticals
John Ducker, Fresenius Kabi USA, LLC
Marcie McClintic Coates, Mylan N.V.
Kiran Krishnan, Apotex Corp.
Candis Edwards, Amneal Pharmaceuticals
Steve Caltrider, Eli Lilly and Company
Kenneth Kleinhenz, Cytori Therapeutics, Inc.
David Korn, Pharmaceutical Research and Manufacturers of America
John Murphy III, Biotechnology Innovation Organization

2:40 – 2:50 **Afternoon Break**

2:50 – 4:50 **Public Presentations: The Patient/Consumer Perspective**

James Love, Knowledge Ecology International
Jonathan Bydlak, Coalition to Reduce Spending
Jack Mitchell, National Center for Health Research
Ayeisha Cox, Center for Lawful Access and Abuse Deterrence
Steven Knievel, Public Citizen
Nellie Wild, Aimed Alliance (for Healthy Women)
Ian Reynolds, The Pew Charitable Trusts
Martha Rinker, National Organization for Rare Disorders
David Mitchell, Patients for Affordable Drugs
James Baker, Food Allergy Research and Education
Andrew Sperling, National Alliance on Mental Illness



Rodney Whitlock, ML Strategies, LLC
David Balto, Law Offices of David Balto
Robert Femia, United States Pharmacopeia
Stacey Worthy, Alliance for the Adoption of Innovations in Medicine

4:50 – 5:00 **Closing Remarks**

Keith Flanagan, Office of Generic Drugs, CDER, FDA