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

11:00 – 11:10  Morning Break

11:10 – 12:00  Public Presentations: The Payer/Provider Perspective
12:00 – 1:00  Lunch
1:00 – 2:40  Public Presentations: The Pharmaceutical Product Development Perspective
2:40 – 2:50  Afternoon Break
2:50 – 4:50  Public Presentations: The Patient/Consumer Perspective
4:50 – 5:00  Closing Remarks

Keith Flanagan, Office of Generic Drugs, CDER, FDA