



**Public Meeting on
Prescription Drug User Fee Act
(PDUFA) Reauthorization
July 23, 2020**

- 9:00 – 9:05 am **Welcome and Introduction**
Sara Eggers, Center for Drug Evaluation and Research, FDA
Meeting Moderator & Director, Decision Support and Analysis Team
- 9:05 – 9:10 am **Opening Remarks**
Stephen Hahn, FDA
Commissioner of Food and Drugs
- 9:10 – 9:25 am **PDUFA Background and Reauthorization Process**
Andrew Kish, Center for Drug Evaluation and Research, FDA
Director, Office of Program and Strategic Analysis
- 9:30 – 10:00 am **Panel 1 – Consumer Perspectives**
Sally Greenberg, National Consumers League
Executive Director
- Diana Zuckerman**, National Center for Health Research
President
- Michael Abrams**, Public Citizen
Health Researcher
- 10:05 – 10:45 am **Panel 2 – Patient Perspectives**
Rachel Sher, National Organization for Rare Disorders
Vice President, Regulatory and Government Affairs
- Marc Boutin**, National Health Council
Chief Executive Officer
- Jeff Allen**, Friends of Cancer Research
President & Chief Executive Officer
- Cynthia Bens**, Personalized Medicine Coalition
Senior Vice President, Public Policy
- 10:45 – 11:00 am **Break**

11:00 – 11:20 am **Panel 3 - Health Care Professionals Perspectives**
Karin Bolte, American Pharmacists Association
Director, Health Policy

Patrice Harris, American Medical Association
President

11:25 – 11:45 am **Panel 4 – Regulated Industry Perspectives**
Lucy Vereschagina, Pharmaceutical Research and Manufacturers of America
Vice President, Scientific and Regulatory Affairs

Cartier Esham, Biotechnology Innovation Organization
Executive Vice President, Emerging Companies

11:45 – 12:30 pm **Lunch**

12:30 – 1:10 pm **Panel 5 – Scientific and Academic Perspectives**
Kathy Giacomini, University of California, San Francisco
Professor of Bioengineering

Aaron Kesselheim, Harvard Medical School / Brigham and Women’s Hospital
Professor of Medicine

David Ridley, Duke University
Professor of Applied Economics

Russ Altman, Stanford University
Professor of Bioengineering, Genetics, Medicine, Biomedical Data Science and (by courtesy) Computer Science

1:15 – 1:25 pm **FDA Remarks**
Patrizia Cavazzoni, Center for Drug Evaluation and Research, FDA
Acting Center Director

1:30 – 2:00 pm **Open Public Comment**

2:00 – 2:05 pm **Closing Comments**