



**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	<p>Panel 3 - Health Care Professionals Perspectives</p> <p>Karin Bolte, American Pharmacists Association <i>Director, Health Policy</i></p> <p>Patrice Harris, American Medical Association <i>President</i></p>
11:25 – 11:45 am	<p>Panel 4 – Regulated Industry Perspectives</p> <p>Lucy Vereshchagina, Pharmaceutical Research and Manufacturers of America <i>Vice President, Science and Regulatory Advocacy</i></p> <p>Cartier Esham, Biotechnology Innovation Organization <i>Executive Vice President, Emerging Companies</i></p>
11:45 – 12:30 pm	Lunch
12:30 – 1:10 pm	<p>Panel 5 – Scientific and Academic Perspectives</p> <p>Kathy Giacomini, University of California, San Francisco <i>Professor of Bioengineering</i></p> <p>Aaron Kesselheim, Harvard Medical School / Brigham and Women’s Hospital <i>Professor of Medicine</i></p> <p>David Ridley, Duke University <i>Professor of the Practice of Business and Economics</i></p> <p>Russ Altman, Stanford University <i>Professor of Bioengineering, Genetics, Medicine, Biomedical Data Science and (by courtesy) Computer Science</i></p>
1:15 – 1:25 pm	<p>FDA Remarks</p> <p>Patrizia Cavazzoni, Center for Drug Evaluation and Research, FDA <i>Acting Center Director</i></p>
1:30 – 2:00 pm	Open Public Comment
2:00 – 2:05 pm	Closing Comments