9:00 a.m.  Welcome and Overview  
*Mark McClellan, Director, Duke-Robert J. Margolis Center for Health Policy and Robert J. Margolis Professor of Business, Medicine and Health Policy, Duke University*

9:10 a.m.  Keynote Address  
*Janet Woodcock, Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration*

9:20 a.m.  The Sentinel Initiative: Perspective from FDA’s Leadership  
*Moderator: Mark McClellan, Duke University*  
- *Gerald Dal Pan*, Director, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration  
- *Steven Anderson*, Director, Office of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration  
- *Gregory Pappas*, Associate Director for National Device Surveillance, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, U.S. Food and Drug Administration  
- *Janet Woodcock*, Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

10:00 a.m.  State of Sentinel Safety Surveillance Activities  
*Moderator: Mark McClellan, Duke University*  
- *Richard Platt*, Professor and Chair, Department of Population Medicine, Harvard Medical School; Executive Director, Harvard Pilgrim Health Care Institute

10:30 a.m.  Break

10:45 a.m.  Selected Sentinel Medical Product Evaluations  
*Moderator: Greg Daniel, Deputy Director, Duke-Robert J. Margolis Center for Health Policy and Clinical Professor, Fuqua School of Business, Duke University*  
- *Marsha Reichman*, Senior Advisor and Scientific Lead for Surveillance Programs, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration  
- *Azadeh Shoaiib*, Sentinel Lead, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration

11:30 a.m.  Current and Future Development of the Sentinel System  
*Moderator: Greg Daniel, Duke University*  
- *Jeff Brown*, Associate Professor, Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute  
- *Bruce Fireman*, Biostatistician, Division of Research, Kaiser Permanente Northern California  
- *Martin Kulldorff*, Biostatistician, Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital, Harvard Medical School

12:15 p.m.  Lunch
1:15 p.m.  Developing a National Resource for Evidence Generation

*Moderator: Mark McClellan, Duke University*

- **Susan Hariri**, Scientific Deputy, Prevention Branch, Division of Viral Hepatitis, U.S. Centers for Disease Control and Prevention
- **Joe Selby**, Executive Director, Patient-Centered Outcomes Research Institute
- **Catherine M. Meyers**, Director, Office of Clinical and Regulatory Affairs, National Center for Complementary and Integrative Health, National Institutes of Health
- **Troy McCall**, Chief Implementation Officer, Reagan-Udall Foundation for the FDA
- **Melissa Robb**, Associate Director for Regulatory Affairs, Office of Medical Policy, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

2:30 p.m.  Stakeholder Perspectives on Opportunities to Enhance and Modernize Postmarket Drug Safety Surveillance

*Moderator: Greg Daniel, Duke University*

- **J. Stephen Mikita**, Planning Board Member, Sentinel; Lead, Sentinel Engagement Partners Workgroup; Patient Representative, Duke Clinical Trials Transformation Initiative
- **Kathleen Blake**, Vice President, Performance Improvement, American Medical Association
- **Fran Cunningham**, Associate Chief Consultant, Medication Safety, PBM, and Director, Center for Medication Safety, U.S. Department of Veterans Affairs
- **Paul Wallace**, Chief Medical Officer and Senior Vice President, Clinical Translation, Optum Labs
- **Patrizia Cavazzoni**, Senior Vice President, Worldwide Development Operations, Pfizer, Inc.
- **Doris Peter**, Director, Health Ratings Center, Consumer Reports

3:45 p.m.  Closing Remarks

*Mark McClellan, Duke University*

4:00 p.m.  Adjournment

Funding for this conference was made possible in part by a cooperative agreement UFD005197 from Food and Drug Administration, Center for Drug Evaluation Research. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsements by the U.S. Government.