Center for Health Policy at BROOKINGS

Draft version: 20151221

Sentinel Initiative Public Workshop

February 3, 2016 • Renaissance Washington, DC Dupont Circle Hotel • Washington, DC

9:00 a.m. **Welcome and Overview**
Mark McClellan, Senior Fellow and Director of the Health Care Innovation and Value Initiatives, Center for Health Policy, The Brookings Institution

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, The Brookings Institution

- **Janet Woodcock**, U.S. Food and Drug Administration
- **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

10:00 a.m. **State of Sentinel Safety Surveillance Activities**
Moderator: Mark McClellan, The Brookings Institution

- **Richard Platt**, Professor and Chair, Department of Population Medicine, Harvard Medical School, Harvard Pilgrim Health Care Institute

10:30 a.m. **Break**

10:45 a.m. **Selected Sentinel Medical Product Evaluations**
Moderator: Greg Daniel, Fellow and Managing Director for Evidence Development and Innovation, Center for Health Policy, The Brookings Institution

- **Azadeh Shoaibi**, Epidemiology/Methodology Lead, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

11:30 a.m. **Current and Future Development of the Sentinel System**
Moderator: Greg Daniel, The Brookings Institution

- **Jeff Brown**, Associate Professor and Director of Scientific Systems, Department of Population Medicine, Harvard Medical School, Harvard Pilgrim Health Care Institute
- **Bruce Fireman**, Biostatistician, Division of Research, Kaiser Permanente Northern California
- **Martin Kulldorf**, Professor, Population Medicine, Harvard Medical School

12:15 p.m. **Lunch**

1:15 p.m. **Developing a National Resource for Evidence Generation**
Moderator: Mark McClellan, The Brookings Institution

- **Claudia Vellozzi**, Chief, Prevention Branch, Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention
  Joe Selby, Executive Director, Patient-Centered Outcomes Research Institute
- **Catherine Meyers**, Director, Office of Clinical and Regulatory Affairs, National Center for Complementary and Integrative Health, National Institutes of Health
- **Troy McCall**, Chief Implementation Officer, Innovation in Medical Evidence Development and Surveillance, Reagan-Udall Foundation for the FDA

- **Rachel Sherman**, Associate Deputy Commissioner, Office of Medical Products and Tobacco, 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, The Brookings Institution

- **J. Stephen Mikita**, Utah Assistant Attorney General
- **Kathleen Blake**, Vice President, Performance Improvement, American Medical Association
- **Fran Cunningham**, Associate Chief Consultant, PBM; Director, VA Center for Medication Safety, Veterans Affairs
- **Patrizia Cavazzoni**, Senior Vice President, Worldwide Safety Strategy, Pfizer, Inc.
- **Doris Peter**, Director, Health Ratings Center, Consumer Reports

3:45 p.m. **Closing Remarks**
Mark McClellan, The Brookings Institution

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.