

**Sentinel Initiative Public Workshop**

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

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**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 Shoaibi**, 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**

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