ENGELBERG CENTER for Health Care Reform at BROOKINGS

FDA Sentinel Initiative Strategic Review
Brookings Institution • Washington, DC
September 26 – 27, 2011

Agenda

Day 1 – September 26, 2011

2:30 p.m. **Registration – *Refreshments served***

3:00 p.m. **Welcome, Overview, and Conference Objectives**
Mark McClellan, Engelberg Center for Health Care Reform at Brookings
Janet Woodcock, U.S. Food and Drug Administration

3:15 p.m. **Perspectives on the Progress of the Sentinel Initiative: Protecting Public Health**

- Perspectives on Sentinel Initiative's progress toward meeting its public health goals as defined in FDAAA
- A vision for the fully operational Sentinel System and essential aspects that pilots (Mini-Sentinel, OMOP, and Federal Partners Collaboration) can contribute to Sentinel 's development in the next 3-5 years

Richard Platt, Harvard Pilgrim Health Care Institute and Harvard Medical School
Paul Stang, Johnson & Johnson and the Observational Medical Outcomes Partnership
Fran Cunningham, Department of Veterans Affairs
Marcus Wilson, HealthCore
Michael McCaughan, Prevision Policy LLC and The RPM Report

4:30 p.m. **Lessons Learned from Recent Mini-Sentinel Assessments**
Melissa Robb, U.S. Food and Drug Administration
Jeffrey Brown, Harvard Pilgrim Health Care Institute and Harvard Medical School

Lead Discussants:
Alec Walker, World Health Information Science Consultants, LLC
Brian J. Kelly, Aetna

6:00 p.m. **Day 1 Wrap-up**
Mark McClellan

Dinner on your own—a handout with nearby restaurant recommendations is located at the registration desk.

Day 2 – September 27, 2011

8:30 a.m. **Registration and Continental Breakfast**

9:00 a.m. **Welcome and Overview**
Mark McClellan, Engelberg Center for Health Care Reform at Brookings
Rachel Sherman, U.S. Food and Drug Administration

9:15 a.m. **Supporting Industry-Sponsored Phase IV Studies**

- Proposals for a process through which industry can sponsor and execute phase IV studies that utilize infrastructure developed by the Mini-Sentinel pilot

Nancy Santanello, Merck & Co., Inc.
Briggs Morrison, Pfizer Inc.
Elliott Levy, Bristol-Myers Squibb
Richard Platt, Harvard Pilgrim Health Care Institute and Harvard Medical School

Lead Discussants:
Paul Stang, Johnson & Johnson and the Observational Medical Outcomes Partnership
Arnold Chan, OptumInsight Life Sciences
John Santa, Consumer Reports Health Ratings Center

10:55 a.m. **Break**

11:05 a.m. **Supporting Safety Science Methods Research and Development**

- Proposal for a potential public-private partnership to support methods research and development and training

Rachel Sherman
Garry Neil, Johnson & Johnson and Board Member of the Reagan Udall Foundation

Lead Discussants:
Ronald Krall, University of Pennsylvania Center for Bioethics
Ellen Sigal, Friends of Cancer Research
Ralph Horwitz, GlaxoSmithKline

12:45 p.m. **Lunch**

1:15 p.m. **Creating a National Resource for Evidence Development**

- Perspectives on the utility of this resource for other secondary uses of data beyond FDA safety surveillance (e.g., comparative effectiveness research, biomedical research, quality measurement reporting)

Mark McClellan

Lead Discussants:
Patrick Miller, University of New Hampshire and All-Payer Claims Database Council
Dave Knutson, U.S. Department of Health and Human Services
Joe Selby, Patient-Centered Outcomes Research Institute
Rich Elmore, Office of the National Coordinator for Health Information Technology
Sean Tunis, Center for Medical Technology Policy

2:45 p.m. **Closing Remarks**

3:00 p.m. **Adjournment**