

## Sentinel Initiative Public Workshop

Marriott at Metro Center • Washington, DC Tuesday, January 14, 2014

## Agenda

9:00 a.m. Welcome and Overview

Mark McClellan, Health Care Innovation and Value Initiative, Brookings Institution

9:15 a.m. The Sentinel Initiative: The Next Steps

Janet Woodcock, U.S. Food and Drug Administration

9:35 a.m. State of Mini-Sentinel Activities

Mark McClellan - Moderator

Richard Platt, Harvard Pilgrim Health Care Institute and Harvard Medical School

Bruce Fireman, Kaiser Permanente

Katherine Yih, Harvard Pilgrim Health Care Institute and Harvard Medical School

**Panelists** 

Marsha Reichman, U.S. Food and Drug Administration Michael Nguyen, U.S. Food and Drug Administration Thomas Gross, U.S. Food and Drug Administration

10:50 a.m. Break

11:00 a.m. Overview of Enhancements Underway to Mini-Sentinel

Mark McClellan – Moderator

Jeff Brown, Harvard Pilgrim Health Care Institute and Harvard Medical School

Lesley Curtis, Duke University School of Medicine Azadeh Shoaibi, U.S. Food and Drug Administration

Elizabeth Chrischilles, University of Iowa

12:00 p.m. Lunch

1:00 p.m. Emerging National Health Information Infrastructure

Gregory Daniel, Engelberg Center for Health Care Reform, Brookings Institution – Moderator

Robert Califf, Duke University School of Medicine

Richard Platt, Harvard Pilgrim Health Care Institute and Harvard Medical School

Mark McClellan, Brookings Institution and Reagan-Udall Foundation

Joe Selby, Patient-Centered Outcomes Research Institute

2:30 p.m. Break

## 2:45 p.m. Stakeholder Feedback on Mini-Sentinel as a Tool for Evaluating Drug Safety Issues that Require Regulatory Action

Mark McClellan – *Moderator* 

Rachel Sherman, U.S. Food and Drug Administration Karen Midthun, U.S. Food and Drug Administration William Maisel, U.S. Food and Drug Administration

Michael Rosenblatt, Merck & Co. Inc.

Sally Greenberg, National Consumers League

Kimberly McCleary, FasterCures

3:50 p.m. Closing Remarks

Mark McClellan

4:00 p.m. Adjournment