ENGELBERG CENTER for Health Care Reform at BROOKINGS

Understanding and Discussing the Implications of FDA's Sentinel Initiative
Grand Hyatt Washington
1000 H Street NW • Washington, DC
October 25, 2011

9:30 a.m.	**Registration**
10:00 a.m.	**Welcome and Overview** Mark McClellan, Engelberg Center for Health Care Reform at Brookings
10:10 a.m.	**Sentinel's Progress: Past, Present, and Future** Melissa Robb, U.S. Food and Drug Administration
10:20 a.m.	**Mini-Sentinel's Current Active Surveillance Capabilities** Richard Platt, Harvard Medical School and Harvard Pilgrim Health Care Institute
10:40 a.m.	**Stakeholder Roles in Sentinel** Rachel Sherman, U.S. Food and Drug Administration
10:50 a.m.	**Discussion**
11:20 a.m.	**Proposed Role of Medical Product Developers in the Execution of Safety Surveillance Activities** Briggs Morrison, Pfizer Inc.
11:35 a.m.	**Discussion**
12:00 p.m.	**Proposal for Medical Product Developers to Support Safety Science Methods Research and Development** Elliott Levy, Bristol-Myers Squibb Garry Neil, Johnson & Johnson
12:30 p.m.	**Lunch**
1:00 p.m.	**Remarks from the Director of FDA's Center for Drug Evaluation and Research** Janet Woodcock, U.S. Food and Drug Administration
1:10 p.m.	**Discussion of Safety Science Proposals and Additional Issues**
2:00 p.m.	**Closing Remarks and Adjournment** Mark McClellan

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