Sentinel Initiative: Structure, Function, and Scope

December 16, 2008
9:00am – 3:30pm

Omni Shoreham Hotel
2500 Calvert St., NW
Washington, DC 20008
Phone: (202) 234-0700

Format:
A public workshop co-sponsored by The Food and Drug Administration and the eHealth Initiative Foundation, convened in cooperation with the Brookings Institution.

Objectives:
1. To provide an update on the current status of the Sentinel Initiative and allow for comment from all stakeholders
2. To discuss potential governance models and their implications
3. To discuss approaches to ensuring continued involvement of all stakeholders as the initiative evolves

Agenda:

9:00 to 9:10	**Welcome, Introductions, and Meeting Objectives**	**Janet Woodcock**
9:10 – 9:20	**Current Status of Sentinel**	**Janet Woodcock**
9:20 – 9:30	**Question and Answer Session**	**Janet Woodcock**
9:30 – 9:45	**Workshop Plan**	**Mark McClellan**
9:45 – 10:00	**Overview of Governance Options**	**Rachel Behrman** **Janet Marchibroda**
10:00 – 10:15	**Break**	
10:15 – 11:55	**Perspectives on the Potential Functions and Structures of Sentinel**	
10:15 – 10:30	Data and Informatics	Lead: Shawn Murphy
10:30 – 10:40	Participant Discussion and Views	
10:40 – 10:55	Legal and Privacy	Lead: Marcy Wilder
10:55 – 11:05	Participant Discussion and Views	
11:05 – 11:20	Communications	Lead: Marc Boutin
11:20 – 11:30	Participant Discussion and Views	
11:30 – 11:45	Scientific Operations	Lead: Rich Platt
11:45 – 11:55	Participant Discussion and Views	

11:55 – 12:00 Recap of Charge for the Day **Mark McClellan**

12:00 – 12:45 Break for Lunch

12:45 – 1:45 Breakout Groups

1. What is your vision for a nation-wide safety network in the short term (1-2 years) and the long term (10 or more years)? Please discuss who might use it and under what "rules," predicated on the following:
    - FDA will build Sentinel to support its statutorily mandated functions
    - Medical product safety is a multi-stakeholder national concern
    - Privacy and security are paramount
2. Given there are a spectrum of options for governance, how do you best feel that this vision could be accomplished?
3. As FDA continues to work toward establishing Sentinel, what are some major risks that you can foresee and how would you guard against them?
4. What are the most productive ways to engage stakeholders in establishing Sentinel? Does this differ depending on the stakeholder group?

1:45 – 2:00 Break

2:00 – 3:20 Report-out of Breakout Groups **Mark McClellan** (Facilitator)

2:00 – 2:20 Discussion of Question 1
2:20 – 2:40 Discussion of Question 2
2:40 – 3:00 Discussion of Question 3
3:00 – 3:20 Discussion of Question 4

3:20 – 3:30 Summary and Next Steps **Janet Woodcock**