Sentinel Initiative: Structure, Function, and Scope

Janet Woodcock, MD
U.S. Food and Drug Administration
Senior Executive Sponsor, Sentinel Initiative
and Director, Center for Drug Evaluation and Research

Meeting Objectives

- To provide an update on the current status of the Sentinel Initiative
- To elicit a broad ranging discussion among all stakeholders on topics, including
  - Potential governance models and their implications
  - Approaches to ensuring continued involvement of all stakeholders as the initiative evolves

Current Status of Sentinel

FDAAA Creates New Authorities and Entities

New FDA postmarket safety mandates, e.g.,

- Section 905 requires FDA to collaborate with public, academic, and private entities to develop methods to obtain access to disparate sources of data and validated methods to link and analyze safety data from multiple sources
  - Access to data from 25 million patients by July 1, 2010
  - Access to data from 100 million patients by July 1, 2012

Reagan-Udall Foundation — a private, independent, nonprofit entity, to advance the mission of FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety

Initial FDA Vision of Sentinel

- Develop a nation-wide electronic safety monitoring system
- Data sources remain with original owners behind existing firewalls
  - Owners would run queries—FDA-requested or other—(or could opt out) and convey the results of their queries to the network for analysis according to strict privacy and security safeguards
  - System will enable FDA to partner with existing data owners (e.g., insurance companies with large claims databases, owners of electronic health records)
- New system
  - will strengthen FDA's ability to monitor postmarket performance of a product
  - will augment, not replace, existing functionality

Broad Perspective

- Sentinel Initiative—a long-term project; will be implemented in stages and will necessarily evolve
- Work in progress—concurrently working on the "how and what"
  - Create broad public forum for discussion of issues related to developing and implementing the system
  - Delineate structure and functions leading to foundational documents for establishing entity
  - Develop cohesive structure for shared learning from on-going related activities (scientific and methodologic projects)
  - Identify steps necessary to ensure strict privacy and security safeguards
  - Evaluate and establish risk communication principles
- New system must provide increased safety capacity for FDA and others, while acknowledging FDA regulatory role

“Governance” can mean many things

- For the purposes of this meeting, governance defines responsibilities for:
  - Developing and implementing policies and procedures for administering certain aspects of the initiative (e.g., scientific operations and infrastructure)
  - Designing and maintaining identified capabilities and needed functions (e.g., scientific methods, data and infrastructure, communication, privacy)

Learning From Multiple Related Activities Now Underway

- Those conducted by the FDA including pilots with the VA, DoD, and CMS/ASPE
- Those conducted in the private sector with FDA serving in an advisory role (listed in the FDA May 22, 2008, Sentinel report)

Expertise and Guidance From Several Organizations and Initiatives

Several initiatives, including those in the public and private sector, can inform FDA's work, including (but not limited to)

- AHRQ's Effective Health Care Program
- Brookings forums on postmarket evidence
- CBI MIT work
- CERTS
- eHI's drug safety collaboration
- HMO research network
- ISPE
- OMOP
- Operational and pilot efforts conducted by numerous health plans (I3 and Wellpoint) and numerous integrated delivery systems (Kaiser, Vanderbilt, etc.)

Work Conducted Under FDA Contracts Will Provide Important Input

1. Defining and Evaluating Possible Database Models
   (Harvard Pilgrim Healthcare)
2. Evaluation of Existing Methods for Safety Signal Identification for the Sentinel Initiative
   (Group Health Cooperative Center for Health Studies)
3. Evaluation of Timeliness of Medical Uptake for Surveillance in Health Care Databases
   (IMS Government Solutions)
4. Evaluation of Potential Data Sources for Sentinel Initiative
   (Booz Allen Hamilton)

Work Conducted Under FDA Contracts Will Provide Important Input, *cont.*

5. Evaluating Potential Sentinel Network Data Sources for Blood and Tissue Product Safety Surveillance and Studies

   (Pragmatic Data)

6. Evaluation of Potential Data Sources for a National Network of Orthopedic Device Implant Registries

   (Outcome Sciences, Inc.)

7. Engagement of Patients, Consumers, and Health Care Professionals in Sentinel Initiative

   (eHealth Initiative)

8. Developing a Governance and Operations Structure for Sentinel Initiative

   (eHealth Initiative)

Input Through a Transparent, Inclusive Process

- Our Goals
  - Create a transparent, inclusive process for sharing work in process
  - Gain input on the many components related to Sentinel (the substance and the process)

Next Steps

- Outcome from this meeting will help define initial foundational structure of Sentinel
- Timeframe: create draft documents for establishing partnership; governance; policies and procedures over next 6 months
- Several of FDA's contracts are now getting underway, and more are expected. These will contribute to thinking on how to structure above
- FDA will launch a transparent, inclusive process for both sharing and gaining input on key aspects related to Sentinel