Update on FDA's Sentinel Initiative

Judy Racoosin, MD, MPH
Sentinel Initiative Scientific Lead
US Food and Drug Administration
January 12, 2011

Agenda

- Background
- Pilot programs under way since Oct '09
  - Mini-Sentinel
  - Federal Partners' Collaboration
- Convener Activities on Active Medical Product Surveillance
- Observational Medical Outcomes Partnership (OMOP)

FDA Amendments Act of 2007

Section 905: Active Postmarket Risk Identification and Analysis

- Establish a postmarket risk identification and analysis system to link and analyze safety data from multiple sources, with the goals of including
  - at least 25,000,000 patients by July 1, 2010
  - at least 100,000,000 patients by July 1, 2012
- Access a variety of sources, including
  - Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs)
  - Private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data)

Sentinel Initiative

- Improving FDA's capability to identify and evaluate safety issues in near real time
- Enhancing FDA's ability to evaluate safety issues not easily evaluated with the passive surveillance systems currently in place
    - Expanding FDA's access to subgroups and special populations (e.g., the elderly)
    - Expanding FDA's access to longer term data
    - Expanding FDA's access to adverse events occurring commonly in the general population (e.g., myocardial infarction, fracture) that tend not to get reported to FDA through its passive reporting systems

**Will augment, not replace, existing safety monitoring systems

Mini Sentinel

Under Contract to Harvard Pilgrim Healthcare

- Develop the scientific operations needed for the Sentinel Initiative.
- Create a coordinating center with continuous access to automated healthcare data systems, which would have the following capabilities:
  - Provide a "laboratory" for developing and evaluating scientific methodologies that might later be used in a fully-operational Sentinel Initiative.
  - Offer the Agency the opportunity to evaluate safety issues in existing automated healthcare data system(s) and to learn more about some of the barriers and challenges, both internal and external.

Federal Partners Collaboration

- An active surveillance initiative via intra-agency agreements with CMS, VA, DoD
- Small distributed system
  - Each Partner has unique data infrastructure
  - No common data model being utilized
- FDA proposes medical product-adverse event pairs to evaluate
- Develop a shared protocol
- Evaluate active surveillance methodologies
- Assess interpretability of query findings resulting from a decentralized analytic approach

Convener Activities on Active Medical Product Surveillance

Brookings Institution

- Expert stakeholder conferences
  - Distributed Data Networks
  - Legal issues
  - Methods for Signal Refinement
  - Communicating Findings from Active Medical Product Surveillance
- Medical Product Surveillance “Roundtables”
  - H1N1 vaccine safety surveillance (PRISM and others)
  - South Carolina Health Information Exchange
  - DELTA System and Massachusetts Interventional Cardiology Device Safety Surveillance Pilot Project
  - Observational Medical Outcomes Partnership
  - SafeRx: a medical product safety collaboration between FDA and CMS
- Active Surveillance Implementation Meetings
- Public Workshops

Observational Medical Outcomes Partnership

http://omop.fnih.org

A public-private partnership between industry, FDA and FNIH to inform the appropriate use of observational healthcare databases for active surveillance by:

- **Conducting methodological research** to empirically evaluate the performance of alternative methods on their ability to identify true drug safety issues
- **Developing open source tools and capabilities** for transforming, characterizing, and analyzing disparate data sources
- **Establishing a shared resource** so that the broader research community can collaboratively advance the science

Next steps

- Long-term, complex initiative
  - Implement in stages as scientific methodologies and data infrastructure evolves
  - Ensure maintenance of privacy and security within the distributed system
  - Continue to address the concerns of all FDA stakeholders
- Address how the eventual Sentinel System will function as a national resource and complement other HHS initiatives using distributed systems for comparative effectiveness and quality assurance