FDA Sentinel Initiative

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Summary

- FDA Sentinel Initiative
  - Background
  - Vision
  - Current status
- Potential impact on corporate compliance departments

Sentinel Initiative: HHS Secretary Request to FDA (2005)

- Expand current system for monitoring medical product performance
- Explore possibility of working in collaboration with multiple healthcare data systems
- Augment capability of identifying and evaluating product safety information beyond existing voluntary reporting systems
- Strengthen ability to monitor product throughout entire life cycle

Sentinel Initiative: HHS Secretary Request to FDA (2005)

- Create public-private partnership
- Use increasingly available large, electronic healthcare databases
- Use emerging technologies and build on existing systems, rather than create new systems
- Also requested by IOM report “The Future of Drug Safety – Promoting and Protecting the Health of the Public” (2006)

FDA Amendments Act (FDAAA) of 2007

- Reagan-Udall Foundation
- Expansion of the existing ClinicalTrials.gov registry
- New FDA postmarket safety authorities

FDAAA Section 905

- Develop methods to obtain access to disparate sources of data
- Develop validated methods to link and analyze safety data from multiple sources
  - ≥ 25 million pts by July 1, 2010
  - ≥ 100 million pts by July 1, 2012
- Collaborate with public, academic, and private entities

FDA Sentinel Initiative: Vision

- FDA Sentinel Initiative report (May 2008)
- FDA's current vision of nationwide electronic safety monitoring system
  - Data remain with original owners behind existing firewalls
  - Owners run FDA-requested queries (or could opt out) and convey the results of their queries to the FDA for analysis (under strict privacy and security safeguards)
  - FDA may able to partner with existing data owners (e.g., Centers for Medicare & Medicaid Services, VA, DoD, insurance companies with large claims databases, owners of electronic health records)
- Reagan-Udall Foundation to be ultimate host
- Long-term project to be implemented in stages

FDA Sentinel Initiative: Current Status

- Earliest stages – will necessarily evolve
- Create broad public forum to discuss issues related to developing and implementing the system
  - FDA-initiated meetings
    - Federal partners
    - Data holders
    - Academics and experts
    - Patient representatives
    - Consumers
    - Industry
    - Vendors
  - Brookings Institution

FDA Sentinel Initiative: Current Status

- Eight contracts recently awarded
  - Governance
    - Access, controls, business models, secondary uses, etc
  - Epidemiologic (6)
    - Data sources (3) – general, orthopedic device registries, blood and tissues
    - Signal detection
    - Medical product uptake
    - Database models
  - Engaging stakeholders

FDA Sentinel Initiative: Current Status

- Epidemiologic pilots
  - Test and validate methods to study known drug-adverse event associations to avoid regulatory actions based on invalid results
    - CMS
    - Observational Medical Outcomes Partnership
    - electronic Health Initiative

FDA Sentinel Initiative: Potential Implications for Compliance

- National resource that will serve as another tool for drug safety evaluation/surveillance
- Will not replace current adverse event reporting systems
- May help companies comply with current reporting requirements
  - 21 CFR § 314.80, 21 CFR § 314.81, 21 CFR § 803
  - Post-marketing commitments
  - Drug safety monitoring as requested by FDA and/or initiated by MFRs, other potential users