An Analysis of Legal Issues Related to Structuring the FDA Sentinel Initiative Activities

Kristen Rosati, Esq.
Coppersmith Schermer & Brockelman PLC
January 2010

Legal Issues Facing Potential Data Sources

- Food and Drug Administration Amendments Act of 2007
- Privacy compliance
- Human subject research compliance
- Tort liability under the common law for failure to warn patients

Recommendations:

- To reduce privacy concerns, Sentinel should be structured to reduce disclosure of individually identifiable health information
- Participating entities would benefit from FDA/OHRP guidance on public health surveillance vs. research
- A central IRB at the national level would reduce the cost and variability of IRB review for drug safety research
- FDA model procedures would be helpful to establish standard of care regarding reporting drug safety findings
- Limited statutory immunity would increase participation in Sentinel

Phases of the Sentinel Initiative

- Phase I: Data will be held and managed by the data sources, which will send only aggregated de-identified information to the FDA or the FDA's "qualified entities" in response to Sentinel System queries
- Possible future phases: Data sources will send some individual data to the FDA or the FDA's qualified entities for analysis
  - This will permit data sources to participate, even if they don't have the expertise to analyze drug safety data
  - This may also permit more rigorous data analysis by linking individuals across data sources

Food and Drug Administration Act of 2007

- Statute prohibits FDA and it qualified entities from releasing individually identifiable health information in results of analysis of drug safety data or in response to queries
- Statute does not prohibit data sources from releasing individually identifiable health information to the FDA or its qualified entities for analysis

Privacy Compliance: A Maze of Laws

- HIPAA applies both to internal use and external disclosure of individually identifiable health information
- HIPAA permits:
  - Use or disclosure of de-identified information
  - Use or disclosure of a “Limited Data Set” with Data Use Agreement in place
  - Disclosure of individually identifiable health information for public health purposes to FDA or its qualified entities
  - Use of individually identifiable health information for “health care operations”
  - Use or disclosure of individually identifiable health information for research (with IRB approval and waiver of HIPAA authorization)

Privacy Compliance (cont.)

- Federal alcohol and substance abuse treatment regulations (the "Part 2" regulations)
  - Covers information that identifies an individual as a substance abuser
  - If this information is included, only option under current regulations is to structure as a research protocol, which then will be subject to special research restrictions (approval by the substance abuse treatment program director)
- Medicare Part D regulations
  - Part D Claims Data regulation prohibits CMS from releasing beneficiary, prescriber, or pharmacy identifiers to other agencies or to external researchers unless those identifiers are necessary for the study, such as to link to another database
  - PDP Sponsors may participate directly in drug safety surveillance programs (consistent with other law)

Privacy Compliance (cont.)

- Federal Privacy Act
  - Applies to a federal agency's disclosure of "identifiable" information from a system of records maintained by that agency; "identifiable" information includes only direct identifiers, such as name, address, picture, voice recording, telephone or fax numbers, or other "identifying particulars"
- Federal Freedom of Information Act (FOIA)
  - Contains exception for "medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy"

Privacy Compliance (cont.)

- State medical record confidentiality statutes: our report provides a framework for analyzing *categories* of state laws that provide more protection for "special" health information, such as:
  - Genetic testing
  - Mental health information
  - HIV/communicable diseases
  - Most state laws do not regulate internal use
  - For disclosure to the FDA or its qualified entities, even the most restrictive state laws generally permit release for research and permit release of aggregated, non-identifiable information

Human Subject Research Protection

- What is research versus public health surveillance?
  - FDA/OHRP guidance needed
  - Our analysis: it is research if the activities seek to determine whether a specific drug potentially caused a specific event (etiologic analyses); it is public health surveillance merely to collect reports of drug safety events or trends, but not to determine the causation of those events
- Common Rule/FDA regulations
  - Research is “human subject research” if protocol requires use or release of identifiable personal information (i.e. the information would enable an investigator to readily ascertain the identity of a subject)

Human Subject Research Protection (cont.)

- Who is doing the "human subject research"?
  - If a data source releases identifiable information to the FDA or its qualified entities, but is not otherwise involved in the analysis or manipulation of that information, the data source itself would not be "engaged" in research
  - Entities analyzing information may be "engaged" in research
- IRB review
  - IRB waiver of HIPAA authorization likely where database research accesses large number of patient records and adequate privacy protection in place
  - If each participant is "engaged in research," then creation of central IRB at the national level to provide primary review will improve quality and reduce cost and variability of IRB decisions

Tort Liability for Failure to Warn Patients

- Liability risk during "gray zone" between drug safety signal and confirmation (or refutation) of the signal's validity
  - Potential liability for failure to warn patients and physicians
  - Potential liability to manufacturers for false warnings
- Courts generally have imposed duty to warn of known drug risks on manufacturers and physicians, but have not addressed whether others have a duty to warn or how to discharge that duty
- Courts likely will weigh a variety of public policy factors
  - The degree of certainty of injury to the individual
  - The magnitude of potential harm to the individual
  - The feasibility and burden of reporting
  - The potential harm to the public by over-reporting
  - The possibility that finding a duty to report would negatively impact willingness to participate in the Sentinel Initiative

Tort Liability for Failure to Warn Patients (cont.)

- Recommendations
  - FDA model procedures would be helpful about when, how and to whom to report findings to produce reliable data to guide drug safety decisions (including when direct reporting to patients is recommended), to create a standard of care for pharmacovigilance that would be applied by courts
  - Limited statutory immunity from liability for Sentinel participants that follow the FDA model procedures

Recommendations

- To reduce privacy concerns, Sentinel should be structured to reduce disclosure of individually identifiable health information
- Participating entities would benefit from FDA/OHRP guidance on public health surveillance vs. research
- A central IRB at the national level would reduce the cost and variability of IRB review for drug safety research
- FDA model procedures would be helpful to establish standard of care regarding reporting drug safety findings
- Limited statutory immunity would increase participation in Sentinel

Questions?

Kristen Rosati, Esq.
Coppersmith Schermer & Brockelman PLC
2800 N. Central Ave., Suite 1200
Phoenix, Arizona 85004
602.381.5464
krosati@csblaw.com

ENGELBERG CENTER for Health Care Reform at BROOKINGS

Sentinel Initiative Public Workshop

Monday, January 11, 2010