

# Legal Issues in Active Medical Product Surveillance

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775 12<sup>th</sup> Street, NW • Washington DC  
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# Active surveillance of medical product safety and disclosure of protected health information

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# Surveillance: The elevator talk version

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- **GOALS:**
  - Earliest possible evaluation of adverse outcomes caused by medical products
  - Quantify actual risk of an outcome and the maximum amount that might exist

# Surveillance: The elevator talk version

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- **STRATEGY:**
  - Use existing electronic health data to identify exposures and outcomes
  - Use data from many millions of people
    - For speed
    - To identify high risk groups

# Surveillance: The elevator talk version

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- **IMPLEMENTATION:**

- Multiple data holders, e.g., health plans
- **Each keeps its own data**
- Each provides summary information
  - **Number exposed to product** with/without outcome of interest
  - **Number not exposed** with/without outcome (for comparison)
  - Separate summaries for groups at special risk, e.g., children, pregnant women
- Combine results from different data holders for an overall answer









The image shows the interior of an elevator with green walls and a red carpet. A white rectangular box is centered in the frame, containing the text "Sentinel Initiative" in a blue serif font. The text is partially cut off on the right side. A blue swoosh underline is positioned above the word "Initiative" and below the word "Sentinel".

Sentinel  
Initiative

# Not mentioned on the elevator

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- Early evaluation implies working with small numbers of events
- Data holders rarely have all of the necessary data
- Data holders can't do every required analysis
- Data holders may become targets of legal action forcing data disclosure

**Each may require disclosure of protected health information**

# Protected health information examples

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- Name, street address, Social Security number
- Date of birth
- Zip code of residence
- Month and year of medical service

# The fine print: Small numbers\*

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- A data holder might have monthly counts like this:

<b>Data holder 1</b>	<b>Hospitalized with intestinal bleed in past month</b>		
Treated with Drug A	Yes	No	Total
Yes			<b>5,000</b>
No			<b>995,000</b>
			<b>1,000,000</b>

# The fine print: Small numbers\*

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- A data holder might have monthly counts like this:

Data holder 1	Hospitalized with intestinal bleed in past month		
Treated with Drug A	Yes	No	Total
Yes	<b>4</b>	4,996	<b>5,000</b>
No			<b>995,000</b>
			<b>1,000,000</b>



# The fine print: Small numbers\*

- A data holder might have monthly counts like this:

Data holder 1	Hospitalized with intestinal bleed in past month		
	Yes	No	Total
Treated with Drug A			
Yes	<b>4</b>	4,996	<b>5,000</b>
No	<b>396</b>	994,604	<b>995,000</b>
			<b>1,000,000</b>

- Two-fold excess risk for Drug A (0.08% vs 0.04%)

- **Need to disclose small counts**
- **Some consider these counts to be protected**

# Fine print: Assembling essential data

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- **Between health care organizations**
  - Insurers' claims are often best to identify potential cases
  - Providers' medical records are often needed to confirm
  - Insurers and providers are usually different HIPAA covered entities
- **Need to disclose protected health information about a small fraction of individuals**

# Fine print: Assembling essential data

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- **Between health care organizations and others**
    - Insurers may have exposure data
    - National, state, or private registries may have outcomes, e.g., cancer diagnosis and stage
- **Need to disclose protected health information about many individuals\***

# Fine print: Shared information for analysis

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- Some analyses need to combine person-level data across data holders
  - To adjust for multiple risk factors
- Some person-level data is identifiable

- **Need to disclose protected health information to understand whether an apparent association is real\***

# Protecting protected health information

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- Plaintiffs in a class action law suit requested protected health information from data holders who had participated in a government supported study of vaccine safety

- **Need ability to avoid disclosing protected health information**



# In closing

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- Active safety surveillance requires relatively little disclosure of protected health information
- Disclosure is needed to
  - Identify potential risks (small counts)
  - Confirm diagnoses (medical charts)
  - Assemble complete exposure and outcome data (link to a registry)
  - Determine whether an apparent association is real (pooled analysis)
- Potential to become an innocent bystander in legal action may be a disincentive to participation

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Sentinel  
Initiative

# Panel I Discussion

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- Paul Stang  
Johnson & Johnson and  
Observational Medical Outcomes Partnership
- Judy Racoosin  
Office of Medical Policy, Center for Drug Evaluation and  
Research, Food and Drug Administration

# Protecting Patient Privacy in Medical Product Safety Surveillance

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Kristen Rosati, JD  
Coppersmith Schermer & Brockelman PLC

March 8, 2010

# Sentinel Initiative Phases

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- Initial phase:
  - Data sources will run drug safety queries against the information they hold, but will release only aggregate data to FDA or its partners for analysis
  - Aggregate data may or may not be fully identifiable (within the meaning of HIPAA)
- Later phases?



# Food and Drug Administration Act of 2007

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- Statute prohibits FDA and its “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
  - This will permit data sources to participate, even if they don’t have the expertise to be a qualified entity

# HIPAA Privacy Rule

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- HIPAA permits:
  - Use or disclosure of de-identified information
  - Use or disclosure of “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 (and potential internal use if under contract to the FDA)
  - Use of individually identifiable health information for “health care operations” (which includes “population-based activities relating to improving health”)
  - Use or disclosure of individually identifiable health information for research (with IRB approval and waiver of HIPAA authorization)

# Federal Privacy Act

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- 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 Alcohol and Drug Abuse Treatment

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- The “Part 2” regulations apply to federally-assisted substance abuse treatment programs and to entities that receive covered information from programs
- Regulations protect individually identifiable information that also identifies an individual as a substance abuser or someone who has applied for or received treatment (“covered information”)
- Regulations would prevent disclosure of covered information for Sentinel, unless the disclosure is structured 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

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- 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)

# Federal Freedom of Information Act

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- Individually identifiable information produced for FDA for Sentinel would be protected from FOIA request
  - FOIA contains an exemption for “medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy”

# State Medical Records Confidentiality Laws

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- Many state medical record confidentiality laws provide more protection for “special” health information:
  - Genetic testing
  - Mental health information
  - HIV/communicable diseases
  - Other categories
  - Under even the most restrictive state laws, it may be feasible to release aggregated, non-identifiable information to FDA or its qualified entities, or to structure the evaluation as a research protocol

# Observations

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- Existing federal statutes and regulations do not pose barriers to data source participation in Sentinel (unless data source will release information covered by the substance abuse treatment regulations)
- State medical record confidentiality statutes and regulations *may* pose barriers to some data sources' participation in Sentinel, particularly if sources are releasing information to FDA



# Preliminary Recommendations

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- Sentinel should be structured to minimize data source release of individually identifiable health information where possible
- Sentinel should consider protection of de-identified and aggregated information disclosed through contracts with data recipients
- Genetic Information Nondiscrimination Act should be extended beyond employers and health insurers
- Other suggestions?

# Panel II Discussion

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- Deven McGraw  
Health Privacy Project,  
Center for Democracy and Technology
- Joy Pritts  
Office of the National Coordinator for Health Information  
Technology
- Donald O. Beers  
Office of Chief Counsel, Food and Drug Administration

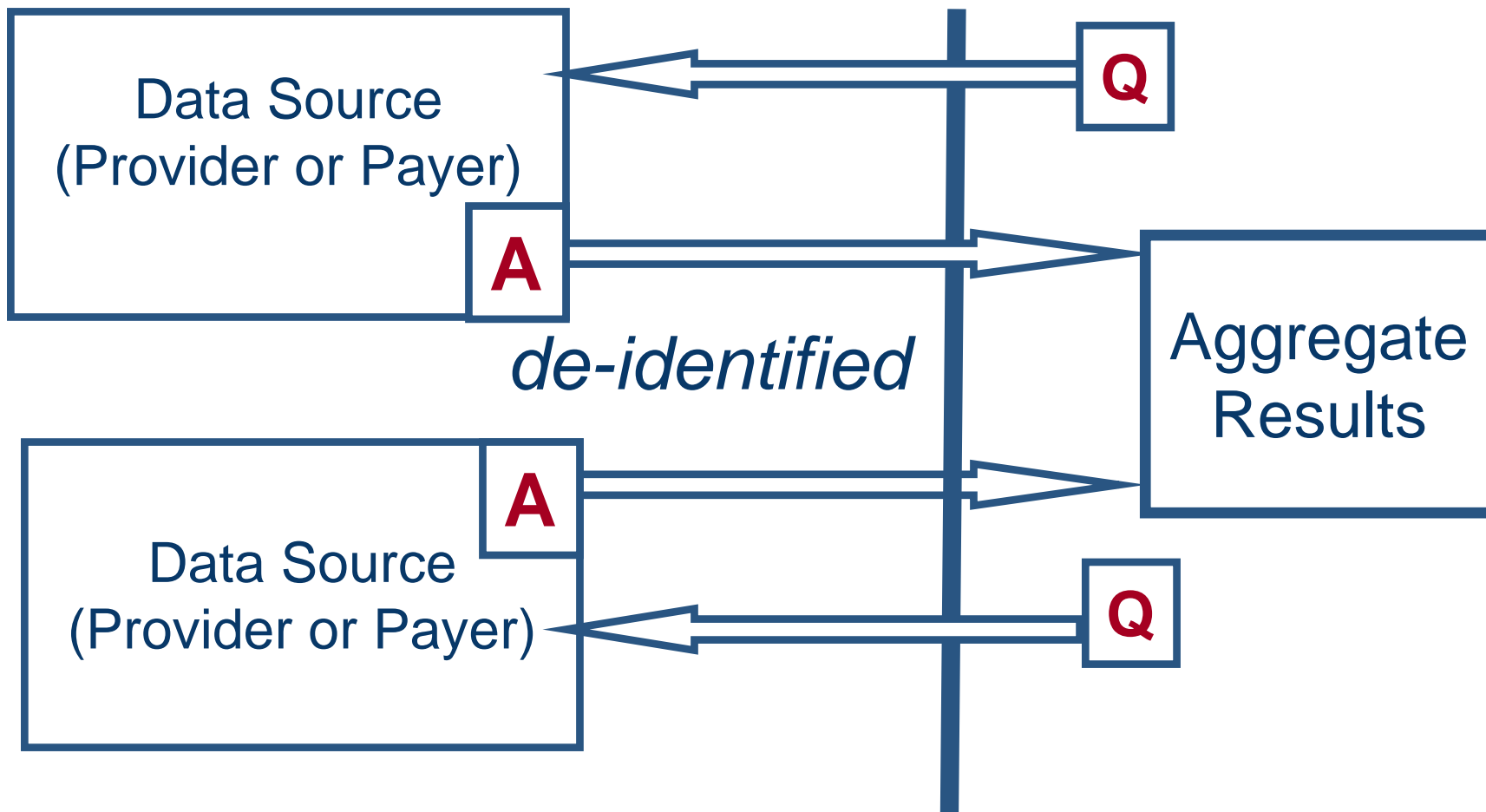
# Appropriate Human-Subject Protections for Research with Sentinel System Data

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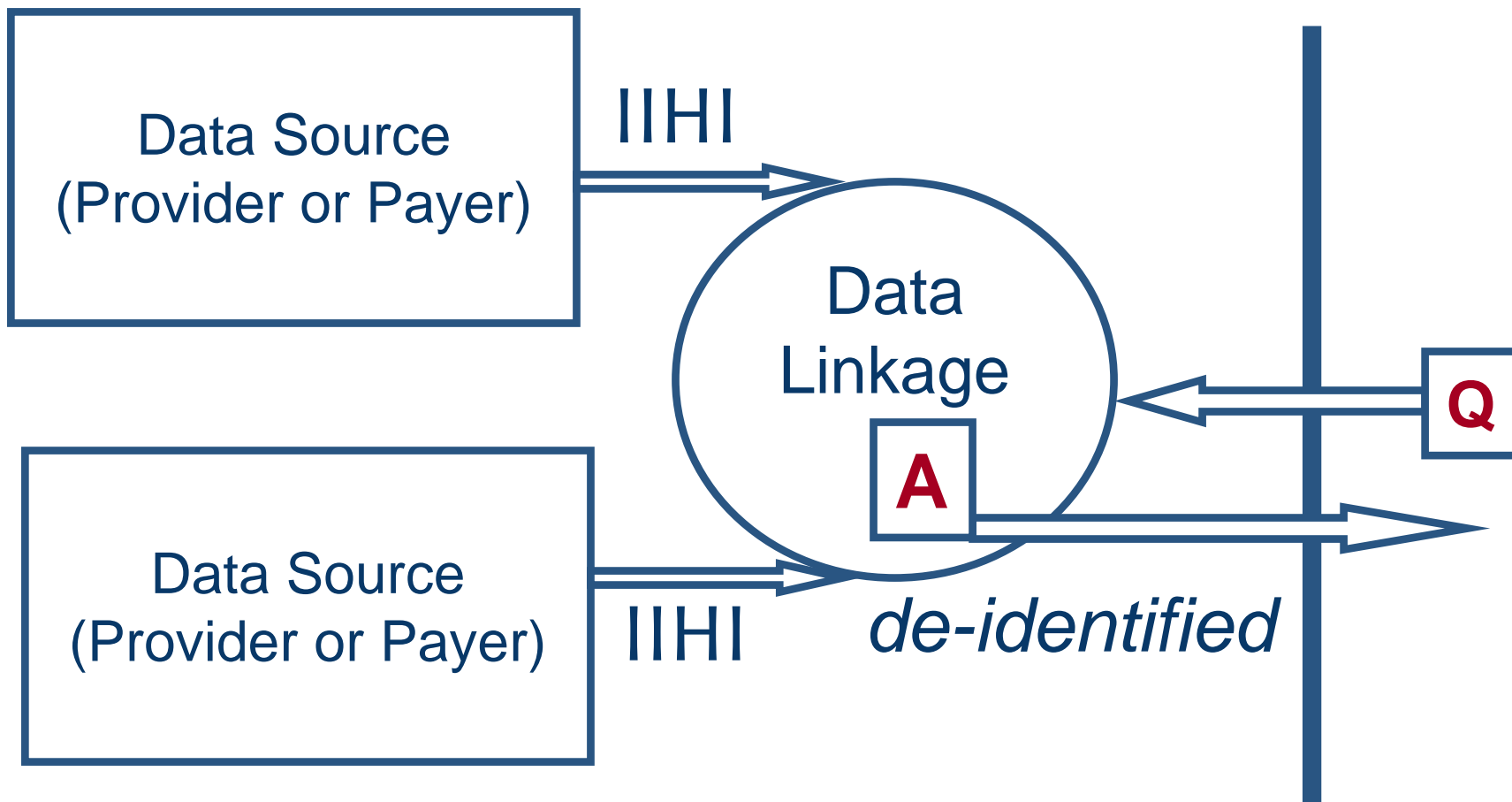
Barbara J. Evans, Ph.D., J.D., LL.M.  
Associate Professor  
Co-director, Health Law & Policy Institute  
University of Houston Law Center

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# Decentralized Query Structure



# Decentralized Structure with Data Linkage



IIHI = individually identifiable health information

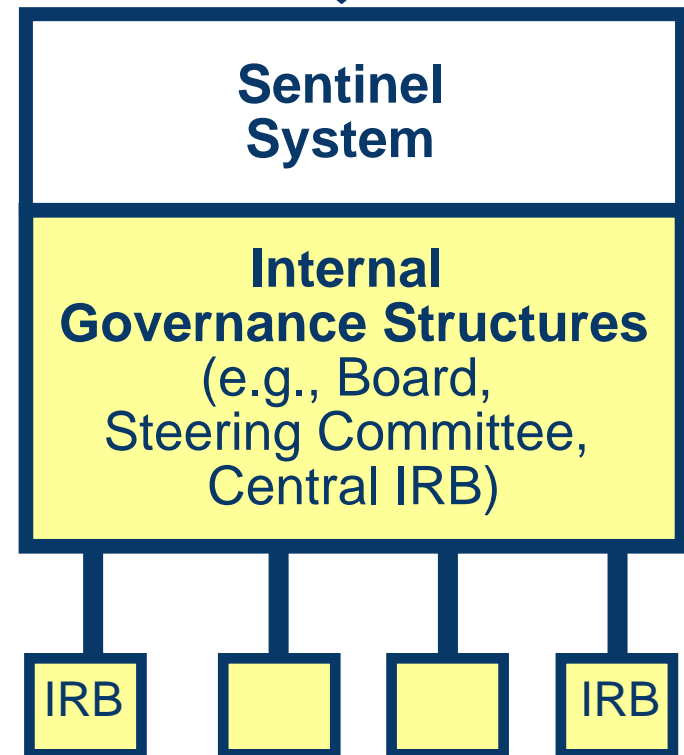
# Scenarios for Sentinel System Research



QUERIES



- FDA's own queries
- Investigators under contract with FDA (funded by FDA)
- Investigators under contract with FDA (externally funded)
- Investigators not under FDA contract



**Participating Data  
Environments**

# Pathways for Nonconsensual Use of Data under the Common Rule and HIPAA Privacy Rule

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- Definitional pathways
  - “not regulated research” under the Common Rule (e.g., exempt research, public health uses)
  - “healthcare operations” and authorization exceptions under HIPAA
- Waiver of consent and privacy authorization
- De-identification, coding, and structural pathways
- Contractual pathways

# Ensuring Ethical Use of Networked Data Resources

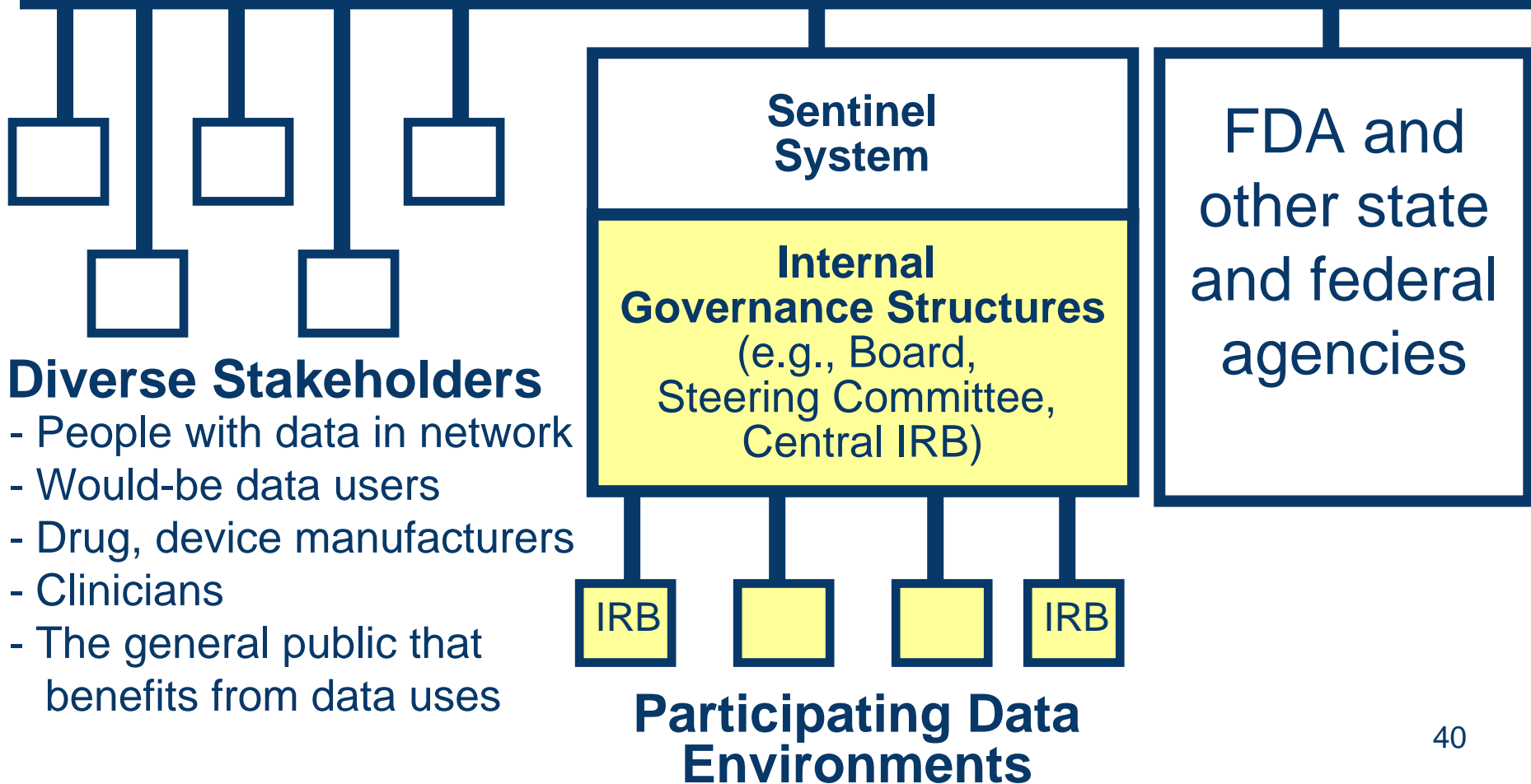
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- Decisions whether to include a data environment in a larger health data network
- Decisions about data security, privacy, de-identification, and other standards for the network
- Decisions about the types of use for which data access will be granted, and the terms governing such uses
- Decisions by IRBs/Privacy Boards to grant access under the various pathways for nonconsensual use



# Protecting Human Subjects Within the Framework of Sentinel System Governance

## Comprehensive Governance Framework



# Panel III Discussion

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- Jerry Menikoff  
Office for Human Research Protections
- Kenneth Goodman  
University of Miami Bioethics Program
- Laura Youngblood  
National Center for Emerging and Zoonotic Infections  
Diseases, Centers for Disease Control and Prevention
- Kate Cook  
Office of the Center Director, Center for Biologics  
Evaluation and Research, Food and Drug Administration

# Addressing Legal Liability in Medical Product Safety Surveillance

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Kristen Rosati, JD  
Coppersmith Schermer & Brockelman PLC

March 8, 2010

# Tort Liability

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- “Gray zone” between the first drug safety signal and confirmation (or refutation) of the signal’s validity
- Failure to warn patients or physicians may pose risk of liability to Sentinel participants
- But warning too soon raises:
  - Risk of alarming patients, potentially causing them to stop medication therapy that may have real benefit to them
  - Risk of liability for product disparagement, for negative effect on a drug manufacturer’s product and reputation

# Tort Liability for Failure to Warn

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- Courts tend to impose a duty to warn of potential drug risks on the entities that have been in the best position to evaluate the risk and take action to protect users of prescription drugs—drug manufacturers and physicians
- What standards will evolve as others gain knowledge of potential drug risks? Ordinarily, a person does not owe a duty to others to protect them for conditions not created by that person, but:
  - Courts have imposed a general duty on hospitals to warn about outcomes of care provided to patients
  - Courts have imposed a duty to warn when one party is aware that another could be harmed by a third party

# Tort Liability for Failure to Warn

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- Courts have recognized claims where a defendant assumed an undertaking on which a plaintiff reasonably relied, resulting in physical harm to the plaintiff
- Potential liability is uncertain, as it depends on a variety of public policy factors that could be weighed differently by courts in different states:
  - The degree of certainty of injury to the individual
  - The magnitude of potential harm to the individual
  - The feasibility of reporting to patients and the reasonableness of the burden imposed by reporting
  - The potential harm to the public by reporting
  - The possibility that finding a duty to report would negatively impact the Sentinel System as a whole

# Preliminary Recommendations

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- What could be helpful to reduce potential liability for Sentinel participants for failure to warn?
  - FDA guidance about when, how and to whom to report findings to produce reliable data to guide drug safety decisions (including when direct reporting to individuals is recommended), to create a standard of care for pharmacovigilance that would be applied by courts
  - Limited statutory immunity from liability for Sentinel System participants that follow the FDA guidance on reporting (with preemption of state law)
  - Contractual language that prevents participants from releasing preliminary results before confirmation through Sentinel System
  - Other suggestions?

# Panel IV Discussion

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- Stanley Watson  
Kaiser Foundation Research Institute
- Heidi Garwood  
Humana
- Dan Troy  
GlaxoSmithKline



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Thank you for your participation!