ENGELBERG CENTER for Health Care Reform at BROOKINGS

Sentinel Initiative Public Workshop

Monday, January 11, 2010

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The Brookings Institution

Welcome

- The Food and Drug Administration is committed to developing the Sentinel Initiative through an open and transparent process.

- An active partner on Sentinel, the Engelberg Center for Health Care Reform at Brookings is convening meetings and workshops to discuss issues, challenges, and solutions to developing better post-market evidence.

Objectives of Today's Workshop

- Communicate the current status and future vision of the Sentinel Initiative.

- Engage stakeholders in discussion of implementation activities, key issues, and potential solutions.

  Today's meeting is intended to be an interactive discussion – we look forward to your participation.

Agenda

Session I: Reports from Selected Sentinel Contractors

Session II: Update on FDA's Current Medical Product Safety Initiatives

Session III: Issues of Broad Interest in Implementing Active Surveillance

- Ensuring Patient Privacy While Meeting Public Health Needs
- Sentinel as a National Resource for Safety Science
- Building a Multi-Purpose Network for Enhanced Use of Health Information

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Keynote Address

Margaret Hamburg, MD
Commissioner of Food and Drugs

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Session I: Reports from Selected Sentinel Contractors

Kristen B. Rosati
Coppersmith Schermer & Brockelman PLC

Jeffrey S. Brown
Harvard Medical School, and
Harvard Pilgrim Health Care Institute

Jennifer Nelson
Group Health Research Institute, and
School of Public Health, University of Washington

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Session II: Update on FDA's Current Medical Product Safety Initiatives

Janet Woodcock
Food and Drug Administration

Patrick Ryan
GlaxoSmithKline

Richard Platt
Harvard Medical School and
Harvard Pilgrim Health Care Institute

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Session III: Issues of Broad Interest in Implementing Active Surveillance

Panel Discussions:

1. Ensuring Patient Privacy While Meeting Public Health Needs
2. Sentinel as a National Resource for Safety Science
3. Building a Multi-Purpose Network for Enhanced Use of Health Information

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Panel: Ensuring Patient Privacy While Meeting Public Health Needs

Verne Rinker
Office for Civil Rights, U.S. Department of Health & Human Services

Jeffrey C. Torres
Lathrop & Gage LLP, and Qual-Rx, Inc.

Deven McGraw
Center for Democracy and Technology

Kristen B. Rosati
Coppersmith Schermer & Brockelman PLC

Donald Beers
Office of Chief Counsel, Food and Drug Administration

Ensuring Patient Privacy While Meeting Public Health Needs

What approaches are available for protecting patient privacy, while also ensuring that the potential public health benefits of Sentinel are fully realized?

- Initially, little or no transfer of person-level data is needed to evaluate many safety questions.
- For the near term, what are the necessary protections to assure data privacy in compliance with federal and state laws?
- As Sentinel becomes more sophisticated, there may be benefits to confirming results through chart reviews and/or linking databases (eg, claims, EHRs, registries) at the patient level.
- Is it possible to protect patient privacy while linking datasets and validating findings from Sentinel?

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Panel: Sentinel as a National Resource for Safety Science

Ronald Lee Krall
University of Pennsylvania Center for Bioethics,
and retired GlaxoSmithKline

Arthur L. Holden
Pharmaceutical Biomedical Research Consortium, and
Serious Adverse Event Consortium

Francesca Cunningham
Department of Veterans Affairs

Judy Racoosin
Food and Drug Administration

Sentinel as a National Resource for Safety Science

What opportunities and challenges are involved in building Sentinel in a way that it can both support FDA efforts to better assess the safety of its regulated products, as well as serve as a national resource for safety surveillance conducted by other government and private sector organizations?

- FDA will develop the Sentinel Initiative to fulfill its regulatory mandates. Once the infrastructure is in place, there will be broad interest in using the system to answer safety science questions and develop new methods.
- What are the potential benefits of making Sentinel a national resource for use by qualified safety scientists?
- Is there a way to develop Sentinel to serve FDA's regulatory mission while at the same time allowing Sentinel to be leveraged as a tool by a broader community?

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Panel: Building a Multi-Purpose Network for Enhanced Use of Health Information

Carolyn Clancy
Agency for Healthcare Research and Quality

Paul Stang
Johnson & Johnson

Rachel E. Behrman
Food and Drug Administration

Building a Multi-Purpose Network for Enhanced Use of Health Information

What challenges must be addressed in order to create a distributed network that can be used for not only conducting safety surveillance, but also for comparative effectiveness research, quality measurement, and other public health matters?

- The data, infrastructure, and methods upon which Sentinel will be built overlap substantially with that needed for comparative effectiveness research and quality measurement.
- A variety of federal initiatives are focused on developing multi-purpose electronic data networks that make “enhanced use” of health information.
- Should Sentinel be designed to accommodate other uses in the future? What steps should be taken now to make this possible?

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