

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0016]

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Certifier A. Corbin

Sentinel Network To Promote Medical Product Safety; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to explore opportunities to link private sector and public sector postmarket safety efforts to create a virtual, integrated, electronic "Sentinel Network." Such a network would integrate existing and planned efforts to collect, analyze, and disseminate medical product safety information to health care practitioners and patients at the point-of-care. It would be established through multiple, broad-based, public-private partnerships. We are seeking input on a number of specific questions regarding opportunities for collaboration, the efficient use of information technology, and the collection and analysis of medical product safety information.

Dates and Times: The public meeting will be held on March 7 and 8, 2007, from 8 a.m. to 5 p.m.

Location: The public meeting will be held at the University System of Maryland Shady Grove Center, 8630 Gudelsky Dr., Rockville, MD 20850.

ADDRESSES: Submit written registration and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic registration to <http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/>

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meetingdocket.cfm. Submit electronic comments to *http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm*. Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at *http://www.fda.gov/ohrms/dockets* approximately 21 days after the meeting.

For Registration to Attend and/or to Participate in the Meeting: Seating at the meeting is limited. People interested in attending should register at *http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm* or submit written registration to the Division of Dockets Management (see **ADDRESSES**) by close of business on February 7, 2007. Registration is free and will be on a first-come, first-serve basis. Written or electronic comments will be accepted until April 5, 2007, at the Division of Dockets Management (see **ADDRESSES**).

If you wish to make an oral presentation during the open session of the meeting, you must state your intention on your registration submission (see **ADDRESSES**). To speak, submit your name, title, business affiliation, address, telephone number, fax number, and e-mail address. FDA has identified questions and subject matters of special interest in this notice. You should identify by number each question you intend to address in your presentation, although presentations do not have to be limited to those questions. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA may require joint presentations by persons with common interests. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.

If you require special accommodations due to a disability, please inform Erik Mettler or Nancy Stanisic.

For Information On the Meeting Contact: Erik Mettler, Office of Policy (HF-11), Food and Drug Administration, 5600 Fishers Lane, rm. 14-101, Rockville, MD 20857, 301-827-3360, FAX: 301-594-6777, e-mail: erik.mettler@fda.hhs.gov; or Nancy Stanisic, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0149, e-mail: nancy.stanisic@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Each year many Americans experience an adverse event due to the use or misuse of a medical product. Medical products, for purposes of this meeting, include human drugs, biological products, and medical devices. Sometimes it is an adverse event known to be associated with the product and sometimes it is not. Patients may experience an adverse event because of errors in the prescribing, selection, or use of a medical product, or because of the inherent properties of a medical product or a problem with the product's manufacture.

When medical products are not used optimally, the public health can be affected in many ways. First, there can be direct injuries to patients. Second, the public's trust in the health care system and in governmental oversight of medical products can be eroded. Finally, patients and health care professionals can become overly cautious in their use of treatments, thus diminishing the usefulness of effective therapies.

To make informed decisions about how to use the products safely and effectively, health care professionals need up-to-date and accurate information about the medical products they may be prescribing. Without this information,

treatments, preventatives, and diagnostics may not be utilized optimally. Efforts now underway to develop and harmonize health information standards, such as for electronic health records, and to make use of available health information technologies, are giving the public and private sectors a new array of tools to help improve the safe and effective use of medical products.

Premarket clinical trials cannot identify all potential risks from a medical product. FDA and other Federal agencies conduct a variety of postmarket surveillance efforts to monitor the safety of medical products once they have been approved for marketing in the United States. These include adverse event reporting systems used to assess known risks and to identify potential previously unknown risks, and the use of population-based data sets to help assess whether such risks are related to specific medical products. However, the effectiveness of these postmarket safety activities has been constrained due to limitations in the quality, quantity, and timeliness of the available data as well as limitations in the existing capacity to rapidly conduct postmarket safety studies when needed. The development of new information technology tools and the growing interest of the private sector in creating the necessary capacity to conduct postmarket safety assessments provide an opportunity to address these limitations through better integration of the nation's postmarket medical product safety activities.

Therefore, FDA is exploring opportunities to link existing and planned private and public sector postmarket safety efforts to create a virtual, integrated, electronic network — a “Sentinel Network”. The Network would foster the seamless, timely electronic flow of medical product safety information from electronic databases and surveillance reporting systems, through risk identification and analysis processes, to health care practitioners

and patients at the point-of-care while protecting patient privacy. The Network would use national and international standards adopted by the Department of Health and Human Services, but would not involve health information technology standards development. The Network would include three principal types of activities: (1) Data collection, (2) risk identification and analysis, and (3) risk communication.

As a first step in beginning a national dialogue regarding actions that can be taken to assemble the Sentinel Network, FDA will hold a 2-day public meeting to discuss the envisioned Network. At the meeting we will engage the private sector in a discussion of opportunities for public sector and private sector collaboration on activities to help develop the data collection and risk identification and analysis components of the Network. In particular, we would like to hear from those who have established or have access to large, electronic, population-based data sets that are, or could be, used for postmarket safety activities. We also want to hear from those with experience in risk identification and analysis.

The objectives of the Sentinel Network public meeting to be held in March are to:

- Evaluate current needs in postmarket medical product adverse event data collection and risk identification and analysis;
- Identify the obstacles to facilitators, and incentives for developing the data collection and risk identification and analysis components of the Sentinel Network; and
- Identify opportunities for public-private collaborations for building the data collection and risk identification and analysis components of the Network.

To help achieve these objectives, FDA would like to focus the meeting discussion on the following questions:

General

1. What are the obstacles to facilitators, and incentives for developing the Sentinel Network?

2. How can postmarket medical product safety data collection be integrated into the workflow of clinical practice at the point-of-care while avoiding the imposition of undue burdens on health care practitioners, patients, and health care institutions?

3. How can electronic health records serve as an effective data collection tool for medical product safety data without imposing undue burden on health care practitioners and patients at the point-of-care? What would be needed to facilitate this effort?

4. What steps should be taken to ensure the privacy of patient information used by the Network?

Current Needs

5. What are the current gaps in postmarket medical product safety data collection and risk identification and analysis?

6. What are the existing data collection systems and methodologies that could be used to fill these gaps in postmarket medical product safety data collection and risk identification and analysis? Please present a comprehensive description of the systems, including the types of questions that they have and have not been able to address and that they have the potential to address.

7. How readily can existing systems be used or be modified to serve as dynamic surveillance loops (e.g., constant integration of data collection from,

analysis, and feedback of information to health care practitioners and patients at the point-of-care)?

Future Opportunities

8. What are the opportunities for public-private collaborations for building the data collection and risk identification and analysis components of the Sentinel Network?

9. Given that building the Network will be a complex undertaking, are there worthwhile small-scale projects that could be readily achievable? If appropriate, please address what your organization can contribute to these programs.

10. What types of opportunities are there for conducting prospective testing of existing systems (e.g., in real time) to determine their validity for medical product safety risk identification? What benchmarks, both inside and outside the health care environment, are optimal for comparison?

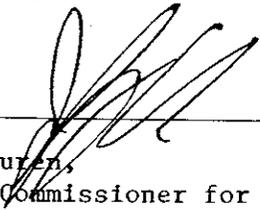
On the first day of the meeting, a panel of experts from Federal agencies will provide an overview of the vision of the Sentinel Network and the gaps they see that the Network might fill. Then a second panel of invited private sector experts will make presentations on the systems and programs they are involved in that are already in use or under development, and will address the questions presented in this notice. Afterwards, members of the public who registered to speak will make their presentations. On the second day of the meeting there will be a moderated discussion between the two panels about the questions presented in this notice. There also will be an opportunity for attendees to provide feedback on the presentations and any additional thoughts during a designated open session. While we are interested in learning about specific technologies being (or already) developed, specific proprietary

commercial products are not the focus of this meeting. An opportunity to display such commercial products will be provided in a separate, adjacent area that will be open for viewing on both days of the meeting. Because of space limitations, any vendor wishing to display its product should register (see **ADDRESSES**) to reserve space. The display area will provide vendors an opportunity to fully explain their products to interested parties. Descriptions or materials regarding commercial products can be submitted in writing to the Division of Dockets Management. Vendors are also welcome to comment on the specific substantive questions raised at the meeting.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic notices of participation and comments for consideration. To permit time for all interested persons to submit data, information, or views on this subject, the docket for the meeting will open 14 days prior to the meeting and remain open for 30 days following the meeting. Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management (see **ADDRESSES**). You should annotate and organize your comments to identify the specific numbered questions in this notice to which they respond. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Transcripts of the meeting also will be available for review at the Division of Dockets Management.

Dated: 1/11/07
January 11, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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