



January 14, 2009

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2008-N-0612, Sentinel Initiative: Structure, Function and Scope; Public Workshop; Request for Comments

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the Sentinel Initiative public workshop. For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students.

ASHP commends the Food and Drug Administration (FDA) and the eHealth Initiative Foundation for sponsoring the public workshop on December 16, 2008 titled *Sentinel Initiative: Structure, Function, and Scope*, and the Engelberg Center for Health Care Reform at the Brookings Institution for convening the meeting. In our comments, the Society will address the following five topics relating to implementation of the Sentinel Initiative: financing, data and scientific operations, communications with consumers and providers, privacy issues, and the risks and obstacles to implementation.

Financing of the Sentinel Initiative

ASHP recommends that FDA finance the Sentinel Initiative. However, the Society recognizes that the agency is already hindered in carrying out its public health mission by the lack of available resources. ASHP firmly believes that increases in FDA resources are necessary, and these increases should be made available and funded through federal appropriations, rather than through user fees. As an active member of the Alliance for a Stronger FDA (the Alliance), ASHP was pleased to see the fiscal year 2008 appropriations funding increases provided to the agency through the congressional appropriations process, and Congress' continuing resolution for fiscal year 2009 that provided FDA with additional funding. ASHP will continue to work with the Alliance to advocate for further increases in funding for the Agency and we strongly encourage FDA

leaders to work assertively through the federal budget process to increase budgetary requests to Congress.

Data and Scientific Operations

ASHP recognizes the difficulties inherent in aggregating data from multiple sources and recommends that FDA encourage contributors to the Sentinel database to submit information in a structured format. To comply, many entities will need to restructure their databases, a necessary step toward making the information collected from Sentinel more usable for improving drug safety and moving more generally toward the creation of a national health record. ASHP encourages the FDA to adopt national standards such as those established by RxNorm and SNOMED-CT for drug names, diagnosis, and side effects, and to work with electronic health record software vendors to create and test interoperable linkages to the Sentinel database.

ASHP recommends that FDA develop standardized processes and training for the organizations that will be involved in performing queries and/or research on behalf of FDA for the Sentinel Initiative. The use of a defined group of organizations, such as AHRQ's Centers for Education and Research on Therapeutics (CERTs) program, would help further standardize the process and allow FDA to implement quality control over the work that is completed. Since small research organizations and independent researchers play a significant role in assessing drug safety, the data should be available to all researchers who wish to evaluate a drug's safety. To improve the quality of that independent work, FDA should offer programs and tools to train interested researchers. FDA could use AHRQ's Healthcare Cost & Utilization Project (HCUP) as a model for implementing these programs and tools.

Communication with Consumers and Providers

ASHP recommends that FDA use a standardized format to report information developed by Sentinel to consumers and providers. Information reported by FDA or its contractors to consumers and providers should not only contain the risks and benefits of the specific medical product, but should also recommend specific actions for clinicians or patients to take based on the information. At a minimum, FDA-sanctioned reports should outline next steps, for example, requesting the manufacturer complete postmarketing studies to determine the validity of query results. A correlation between a drug and an adverse event does not necessarily indicate causation, so information reported to consumers and providers should be provided in context, to ensure a greater understanding of the impact of the findings.

Privacy

ASHP believes that the public and private entities who own and contribute data to the Sentinel Initiative should be responsible for ensuring protection of privacy. The Society

recommends that FDA provide oversight to ensure entities adhere to privacy requirements.

Risks/Obstacles to Implementation

One of the largest barriers to the implementation of the Sentinel Initiative is ensuring that organizations and individuals see value in the information that results from the Initiative, otherwise participation will quickly diminish. Organizations will spend significant time submitting relevant data to Sentinel, and if the resulting information is not useful to the organizations or their patients, these organizations likely will not participate. The Initiative's value will also be limited unless a sufficient number of private insurers participate, so FDA should address recruitment issues related to these organizations.

ASHP recommends that FDA seek stakeholder input as the agency determines the types of information, the format, and the timing for the release of data that results from the Sentinel Initiative.

The Society appreciates this opportunity to present its written comments on the Sentinel Initiative public workshop. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,



Justine Coffey, JD, LLM
Director, Federal Regulatory Affairs