

Patient and Consumer Engagement in FDA's Sentinel Initiative

Introduction

With passage of the Food and Drug Administration Amendments Act of 2007 (FDAAA), Congress authorized the U.S. Food and Drug Administration (FDA) to develop a system for postmarket risk identification and analysis using existing electronic health data. As a result, in 2008, FDA launched the Sentinel Initiative. Since then, FDA has made significant progress in developing this system for conducting active surveillance of FDA-regulated medical products. Much of the Sentinel Initiative's success stems from productive and broad collaborations among stakeholders from both public and private institutions. Future successes will depend upon continuing and expanding this collaboration.

Patient and consumer advocacy organizations have provided valuable perspectives and input into the Sentinel Initiative. This expert workshop aimed to engage representatives from a variety of patient and consumer advocacy organizations and FDA in a dialogue about ways in which patients and consumer are currently involved and opportunities for furthering their engagement. Specific objectives of the workshop included the following:

- Providing patient and consumer advocates with an overview of the Sentinel Initiative;
- Discussing opportunities for further patient and consumer engagement; and
- Discussing concrete next steps for expanding patient and consumer engagement.

Approximately 30 attendees from more than 20 patient and consumer advocacy organizations attended the workshop.

The Need to Communicate about the Sentinel Initiative

While some patients, consumers, and advocacy organizations may already be aware of the Sentinel System, FDA wants to understand the kind of information about Sentinel that would be most useful to the public. Meeting participants suggested that it would be valuable to educate patients, consumers, and advocacy organizations about the following aspects of Sentinel:

- **Mini-Sentinel:** Meeting participants suggested FDA inform the public that the Sentinel Initiative is currently advancing development of the Sentinel System via FDA's pilot program called Mini-Sentinel. Understanding that the Mini-Sentinel pilot provides only one source of information is important; other sources include the adverse event reporting system, preclinical (animal data) and clinical trial data, relevant medical literature, and other post-market safety studies. FDA assesses all of these sources prior to making regulatory decisions. Participants also suggested it is important to clarify that Mini-Sentinel responds to queries—which are requests for data—from FDA, and not to specific safety questions. FDA then takes these data into consideration along with other safety information on that particular medical product to inform a regulatory decision.
- **Communicating Mini-Sentinel results:** FDA uses the Mini-Sentinel website to compile an ongoing record of all uses of the Mini-Sentinel System (see further discussion below). However, as mentioned above, Mini-Sentinel generates data that may not be informative to the general

public, as it is only part of the data that contributes to regulatory decision-making by FDA. Any relevant safety information obtained via the Sentinel System is communicated via FDA's existing communication tools to inform patients and providers how to use a medical product safely. FDA actively uses a number of avenues for communicating information about drug and medical product safety, including information obtained using the Sentinel System. For example, FDA's Center for Drug Evaluation and Research uses Drug Safety Communications to communicate important drug safety information to the public. FDA's Office of Special Health Issues (OSHI) has undertaken initiatives to communicate information to and obtain feedback from patient communities. OSHI efforts include recently creating the FDA Patient Network website, which includes educational resources that explain FDA's approval process, a newsletter that provides regular updates on FDA activities, and an annual conference to engage patients and advocates on specific issues.

- Potential roles of third-party organizations: Third-party organizations, such as patient and consumer advocacy organizations, can also play an important role helping patients and consumers understand Sentinel and its capabilities. Some meeting participants suggested that these organizations are an effective vehicle for directing patients to FDA's resources and helping to disseminate information from FDA to a wider audience.

Spectrum of Patient and Consumer Information Needs

The amount of information that patients and consumers desire about their medication varies. Patients and consumers at one end of the spectrum would like to receive only the most pertinent and actionable information. Patients and consumers on the other end are interested in understanding the larger body of information that informs FDA's regulatory decisions. Meeting participants recognized the importance of accommodating the spectrum of information needs and highlighted the benefits of making more drug safety information, including intermediate data points that inform final regulatory decisions, available.

In order to foster transparency and to meet Congressional mandates included in FDAAA, Mini-Sentinel makes information about the pilot's assessments, such as study protocols and results from assessments, publically available. Thus, patients and consumers who are interested in having more information can access these findings. However, Mini-Sentinel's website is especially technical and may not be informative to those without a scientific background (e.g., familiarity with epidemiology, biostatistics, etc). It is important that individuals that access information from the Mini-Sentinel website understand that this information does not represent a final decision about the product's safety but is only one piece of data that helps FDA better understand a product's safety. Patients should continue with their course of treatment unless directed by their physician to discontinue treatment.

- Patient and consumer advocacy organizations have scientific experts that can interpret the technical data available from Mini-Sentinel and communication experts that can translate this into a form that is digestible to a general audience. As such, these organizations can play an important role in ensuring that patients and consumers who choose to access Mini-Sentinel data understand and interpret it appropriately.

Next Steps

Participants expressed an interest in increasing the level of public awareness and understanding of Sentinel and its role in safety surveillance, and particularly among patient advocacy groups. Participating organizations discussed potentially developing activities to share information about Sentinel with their members, and creating "best practices" to inform the public.

Since this meeting, FDA has been working to act upon and implement the ideas discussed. In an effort to raise the national understanding of Sentinel, FDA recently held a public webinar to explain Mini-Sentinel. The webinar covered several of the themes that workshop participants thought would be of interest to patients and consumers in a manner that was accessible to a general audience. These themes included what Mini-Sentinel is, what sort of information Mini-Sentinel provides, how FDA uses this information, and how FDA communicates drug safety information. FDA is considering other avenues to help disseminate this information to general audiences.

In an effort to better articulate what information is made available and why, FDA has revised its disclaimer about the posting of Mini-Sentinel data. This disclaimer has been modified to encompass the various audiences that may be visiting the website.

FDA has also expressed interest in continuing to engage with patients and consumers to inform them about and develop ways to meaningfully involve them in the Sentinel Initiative. Some of the issues raised during this meeting may be explored further in a future expert workshop hosted by the Engelberg Center.