

New FDA/CMS Medical Product Safety Initiative and Its Implications for Industry

U.S. Health and Human Services Secretary Mike Leavitt recently announced initial details about the “Sentinel Initiative,” a public-private effort being led by the Food and Drug Administration (FDA) and the Center for Medicare & Medicaid Services (CMS).¹ The Sentinel Initiative is intended to create a national, integrated, electronic system for monitoring the safety and efficacy of medical products.² While its objective is straightforward, in practice the initiative may trigger unintended consequences for industry, both positive and negative.

WHAT IS THE SENTINEL INITIATIVE?

The Sentinel Initiative is a staged, long-term effort with the ultimate objective of creating and implementing the “Sentinel System,” a national, integrated, electronic safety system capable of tracking the performance of a drug or medical product, beginning with the earliest stages of clinical research through its effects on the millions of Americans who may use it to treat or to recover from an illness or condition. The initiative will draw data from multiple, existing databases (*e.g.*, electronic health records, medical claims) to monitor products on the market, identify post-market adverse events more rapidly, support research and epidemiology studies, and enhance existing risk identification and analysis processes.

The three focus areas of the Sentinel Initiative are:

Risk Identification

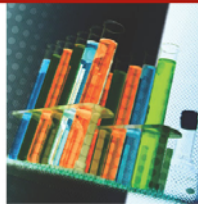
- Improving upon the current systems’ inherent limitations by reducing underreporting of suspected adverse events and providing information to enable better assessment of causality.

Risk Assessment

- Improving existing processes for monitoring medical product performance by seeking formalized access to non-agency experts and data sources instead of relying on the voluntary reporting system.

Risk Minimization

- Creating targeted education and outreach tools to increase appropriate knowledge and behaviors of individuals (*e.g.*, health care practitioners and consumers) who have the capacity to prevent or minimize product risks.
- Establishing reminder systems to prompt, remind, double-check or otherwise guide health care practitioners and/or patients in prescribing, dispensing, receiving or using a product in a way that minimizes risk.



- Using performance-linked access tools to connect product use to laboratory testing results or other documentation.

For more details, please see www.fda.gov/oc/initiatives/advance/reports/report0508.pdf.

WHAT IS THE RATIONALE BEHIND THE SENTINEL INITIATIVE?

The Sentinel Initiative is intended to remedy limitations in the existing system to capture medical product safety data. Although FDA has a rigorous pre-approval and product clearance system, post-market surveillance is important to expanding knowledge regarding products. For instance, clinical trials may not be large or diverse enough to ensure adequate representation of the patient population. In addition, clinical trials may not detect rare, serious adverse events that occur with long latency or in subpopulations who have not participated in studies. Furthermore, as new medical products enter the market, the potential for interactions with other drugs, biologics, medical devices and foods increases.

FDA's current safety and monitoring efforts rely primarily on three sources: (1) self-reports by health professionals or patients who experience serious problems that they suspect are associated with the drugs and medical devices that they prescribe, dispense or use; (2) case reports published in the medical literature; and (3) results of post-approval and other clinical studies.

The Sentinel Initiative is designed to go beyond existing FDA efforts by capitalizing on access to data on millions of Americans contained in government health records from Medicare Part D, private hospital and medical service provider databases.³ The intent of the initiative is to gain access to the data from the web of public and private databases already in existence.⁴

WHEN AND HOW WILL THE SENTINEL INITIATIVE BE IMPLEMENTED?

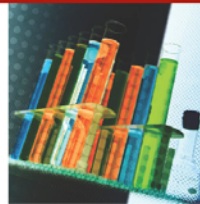
The Sentinel Initiative is underway and is being implemented in stages. Under Section 905 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), the Health and Human Services Secretary is required to identify methods to obtain access to disparate data sources and to establish a post-market risk identification and analysis system to analyze such health care data. Per FDAAA, the secretary should ensure access to data from 25 million patients by July 1, 2010, and 100 million patients by July 1, 2012.⁵

The Sentinel Initiative is being phased in through separate but interrelated initiatives by FDA and CMS. For instance, CMS just published a final rule allowing federal and state agencies access to claims data under Medicare Part D.⁶ FDA will start mining the Part D claims database when the regulation takes effect on June 27, 2008.⁷

CMS has already gathered prescription drug data on 25 million Medicare beneficiaries covered under the Medicare Part D program.⁸

INDUSTRY RESPONSE?

The Pharmaceutical Research and Manufacturers of America (PhRMA) issued a strong endorsement of the Sentinel Initiative as an important initiative that shifts post-marketing safety monitoring from reliance on voluntary reporting to active monitoring by FDA.



UNINTENDED CONSEQUENCES FOR INDUSTRY?

While many details are still pending, based on what we know to date, there are several ways in which the initiative may impact industry that may not be apparent from its description. Some of these are summarized below:

More information, or more good information?

- The increase in information access is a double-edged sword. More information generally promotes more informed treatment decisions. More information is helpful, however, only to the extent that it is accurate and not misleading. With the current voluntary reporting system, the patients and/or health care providers personally familiar with the circumstances submit adverse event reports. This process allows an eyewitness to the event to assess whether the event was product-related, unlike the more detached system of the Sentinel Initiative. While FDA plans to validate the Sentinel system, its efforts may or may not demonstrate an ability to distinguish among possible sources of causation.
- With the Sentinel Initiative, many more adverse events likely will be recorded, but the analysis linking events to the use of a specific drug may be less reliable and could create misleading results. Manufacturers should prepare for a probable increase in reported events and the scrutiny that such reports may generate.

Fuel for the product liability fire?

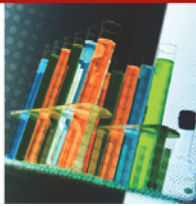
- Plaintiffs' attorneys will use the data compiled under the Sentinel system to create new or bolster existing product liability and consumer protection law claims. The concern for industry is twofold: (1) plaintiffs' attorneys will have access to more extensive but unreliable data to support their claims than they do under the current MedWatch system; and (2) the Sentinel system will facilitate plaintiffs' attorneys' ability to gather information and pursue litigation.

Impact on federal preemption arguments?

- The existence of the Sentinel Initiative may lend support to arguments in favor of federal preemption of drug and device labeling. The Sentinel Initiative will provide FDA greater access to product safety and efficacy information than it has had in the past. With that greater knowledge comes a stronger argument that courts should defer to the opinion of FDA as the expert agency regarding adequacy of product labeling.

Harbinger for heightened market entry and reimbursement standards?

- Greater linkage between product safety profiles and claims data may indirectly result in a higher bar for product entry and product reimbursement. FDA oversees the safety and efficacy of drugs and devices and CMS oversees the reimbursement of drugs and devices under government health care programs. With the agencies' growing collaboration, however, FDA may be influenced (consciously or subconsciously) to expect a greater showing of uniqueness and/or lower cost of products approaching market. Even if FDA is not so influenced, CMS's desire to control health care costs, combined with its access to data regarding existing products, may render CMS more restrictive in its reimbursement standards. Either way, the collaboration may serve to discourage market entry and render market success less predictable.



FOR MORE INFORMATION

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¹ HHS press release, <http://www.hhs.gov/news/press/2008pres/05/20080522a.html>.

² The CMS final regulation applies to Medicare Part D claims for prescription drugs. Databases including additional categories of FDA-regulated products could be added later.

³ Examples of databases that Sentinel currently has access to include Veterans Health Administration, Medicare Part D, University Health Systems Consortium, Patient Safety Net, CDC, Severe Adverse Events Consortium, etc. A comprehensive list can be found in the appendix to the Sentinel Initiative report.

⁴ See Sentinel Initiative report, www.fda.gov/oc/initiatives/advance/reports/report0508.pdf.

⁵ Food and Drug Administration Amendments Act of 2007, P.L. 110-85, § 905(a)(3)(B)(i)-(ii).

⁶ See <http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PartDDataReg.pdf>.

⁷ *Id.*

⁸ HHS press release, <http://www.hhs.gov/news/press/2008pres/05/20080522a.html>.