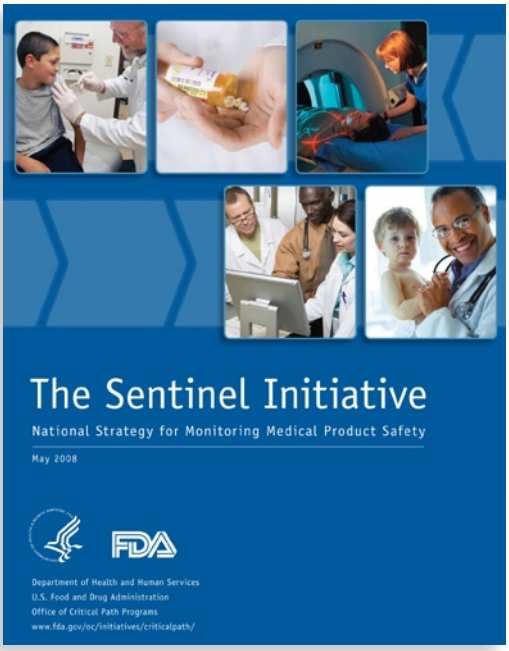
Sentinel System

to Monitor Medical Product Safety



Cover of the Sentinel Initiative report.

The Food and Drug Administration (FDA) has unveiled plans for the Sentinel Initiative, a strategy to create and implement a national, integrated, electronic system for monitoring medical product safety.

The resulting "Sentinel System" will strengthen FDA's ability to track how drugs and medical products perform once they go on the market. Ultimately, this system will help monitor medical products throughout their entire life cycle and thus better ensure the protection and promotion of public health.

The Sentinel Initiative is one of the efforts announced by Health and Human Services (HHS) Secretary Mike Leavitt on May 22, 2008, to improve and enhance patient safety and the quality of medical care into the 21st century.

The Sentinel System will

- enable FDA to have access to a variety of electronic data sources to identify possible adverse events once a drug or medical product has been approved for use, while protecting patient privacy.
- use tools and processes that ensure the protection of personal and proprietary information
- support research and epidemiology studies, as well as FDA's existing risk identification and analysis processes

Building on Existing Systems

The Sentinel System will be created through public/private partnerships. These partnerships will make it possible for the agency to access large, existing electronic databases without compromising patient privacy.

The system has unparalleled potential for supporting many other activities critical to a modern health care system. For instance, health researchers may be able to one day use the query system to evaluate the outcomes of various treatments given to different patients in different locations.

Meeting FDAAA Requirements

The Sentinel System will fulfill some requirements of the Food and Drug Administration Amendments Act of 2007 (FDAAA), which includes provisions calling for the development of such a system.

In addition to creating the new system, the Sentinel Initiative will also explore joining the emerging Nationwide Health Information Network (NHIN). The NHIN will connect clinicians across the health care system and enable the sharing of data as necessary with public health agencies. It will help ensure that treatment decisions are supported by the most current and complete data.

FDA has been meeting with a variety of potential partners with the goal of exploring how best to establish the public/private partnership. There will be a number of forums for public discussion of this initiative.

The Initiative is described in an FDA report titled, "The Sentinel Initiative—A National Strategy for Monitoring Medical Product Safety." It is available online at *www.fda.gov/oc/initiatives/advance/sentinel/*