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FDA Sentinel Initiative Expands to Support Clinical Research

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By Jill Wechsler

After eight years in development, FDA's Sentinel system is poised to play a more visible role in assessing medical product efficacy, as well as safety. There are plans to expand it to gather information on the performance of medical products in real world settings, which may assist researchers and clinicians in answering broader questions about treatment use.

Sentinel has been a big investment for FDA, commented Janet Woodcock, director of the Center for Drug Evaluation and Research (CDER), at the 8th Annual Sentinel Initiative Public Workshop in early February. A future pay-off, she noted, will enable other groups to utilize the system to "assess product performance beyond safety." FDA intends to expand the use of Sentinel by leveraging its data for additional research, public health and quality improvement activities.

The Sentinel program was launched in 2008 to expand FDA's capacity to actively identify and assess postmarket risks for medical products. It now has become an "integral part of routine safety surveillance" for drugs, biologics, and other medical products, Woodcock noted at this conference organized by the Duke University/Margolis Center for Health Policy headed by Mark McClellan. This has involved establishing an infrastructure and governance policies that are transparent and respect patient privacy. Health plans and providers participating in the Sentinel network now provide access to patient electronic health records and claims data on some 193 million individuals. An important recent addition is the Hospital Corp. of America, which can provide patient records from 168 hospitals and 113 surgery centers across the United States. Data from the Medicare Virtual Research Center, moreover, will significantly increase information related to older patients.

In addition to building Sentinel use by CDER, the system is expanding surveillance and analysis of vaccines and blood products by the Center for Biologics Evaluation and Research (CBER). A Sentinel "Tree Scan" project involves assessing vaccine safety and outcomes in pregnancy. Another CBER project will tap added hospital data to evaluate if there is a relationship between blood transfusion and lung injury and death.

Sentinel also seeks to improve coordination with the Center for Devices and Radiological Health (CDRH) to track medical device safety. CDRH is examining the use of Sentinel in conducting rapid pre-market studies for new products and to support registries of implantable devices.

To achieve its broader research goals, FDA is partnering with the research network established by the Patient-Centered Outcomes Research Institute (PCORI), which was formed to assess the safety and comparative effectiveness of medical products and practices. Similarly, FDA has set up a process for sharing information with the academic clinical research centers participating in networks established by the National Institutes of Health (NIH). The Sentinel "guardian system" is being developed to support development of new research methods for conducting studies. A collaboration with the Clinical Trials Transformation Initiative (CTTI) is developing a protocol for a randomized trial to assess the relationship between atrial fibrillation and use of anticoagulants.

Additional projects aim to monitor and assess the impact of biosimilars on patients in collaboration with a consortium formed by the Academy of Managed Care Pharmacy. And the Regan-Udall Foundation is exploring a partnership with Sentinel that would permit non-FDA stakeholders to use the system for active surveillance and medical product safety evaluations.

These developments reflect Sentinel's broader goal of providing a more active national system for biomedical safety monitoring. Important projects have weighed outcomes comparing Warfarin to newer blood thinner treatments, and have explored possible links between flu vaccines and febrile seizures. A new initiative plans to examine the impact of switching medications between brand and generic drugs.

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