FDA Launches Drug-Safety Surveillance System

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New York Bureau

The Food and Drug Administration has developed a new national electronic surveillance system that will allow it to search and analyze claims data and other clinical databases for possible postmarket adverse events for drugs and medical devices.

The Sentinel Initiative is designed to bring safety concerns from approved drugs and other medical products to the FDA's attention faster than the traditional MedWatch adverse event reporting system alone.

"We are moving from a reactive dependence on voluntary reporting of product safety concerns to a proactive surveillance of medical products that are currently on the market," Health and Human Services Secretary Mike Leavitt said during a press conference to announce the initiative. "The result will be much-improved safety and protections for the American people."

During the first phase of the project, the FDA will rely on Medicare data. As part of a pilot collaboration with the Centers for Medicare and Medicaid Services, FDA officials will use the Sentinel system to query Medicare Part D prescription drug claims data, which will be linked to Medicare inpatient and outpatient claims data. The Part D database currently holds information on medications used by more than 25 million beneficiaries, according to Health and Human Services.

The FDA will begin to look into the data in 30 days, following the publication of a final regulation that will allow federal agencies, states, and academic researchers to use claims data from the Part D program for safety research and quality initiatives.

In the future, FDA officials hope to be able to query data from other government agencies, such as the Department of Defense and the Department of Veterans Affairs, as well as from large private health plans, said Dr. Andrew C. von Eschenbach, FDA commissioner. He added that the Sentinel Initiative includes patient privacy protections. The system queries existing databases without actually acquiring the data. Essentially, the system asks questions and gets answers without identifying patient information.

The Sentinel system will work in conjunction with the existing FDA surveillance systems. For example, if the FDA receives a report of an adverse event following the use of a drug, officials will be able to query data on a large number of subjects who have taken the drug. And, in the future, agency officials may even be able to compare data from patients taking the drug with a control group of similar patients who have not taken the drug. This will allow FDA officials to give physicians better information about what particular groups of patients may be at higher risk for a specific adverse event, said Dr. Janet Woodcock, director of FDA's Center for Drug Evaluation and Research. ■

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