# FDA Launches Sentinel Surveillance System

BY MARY ELLEN SCHNEIDER
*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 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 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, 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 HHS.

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**MR. LEAVITT**

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.

Starting with the Medicare population will provide valuable data on the elderly and disabled population, said Kerry N. Weems, acting CMS administrator. Drug safety and efficacy data is usually limited in this group because they are excluded from clinical trials. This population also is at greater risk for medication side effects because of polypharmacy and many chronic diseases, according to CMS.

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, Dr. von Eschenbach said.

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.

"Although it won't answer all the questions, it will provide us with a tremendous new source of information," Dr. Woodcock said.

The Institute of Medicine called on the FDA in a 2006 report to create an active surveillance system to improve the safety of drugs. In addition, the Food and Drug Administration Amendments Act of 2007 (FDAAA) directs the FDA to develop a proactive surveillance system.

The Sentinel Initiative has garnered the support of the Pharmaceutical Research and Manufacturers of America. The group issued a statement praising the movement from voluntary reporting alone to a system that incorporates proactive monitoring of drugs and other medical products. "This program should improve the efficiency of postmarket surveillance of medicines and, in the end, the beneficiaries will be the many patients using these products," said Ken Johnson, senior vice president of PhRMA. ■

# Genetic Nondiscrimination Bill Enacted, Protecting Patients

BY MARY ELLEN SCHNEIDER
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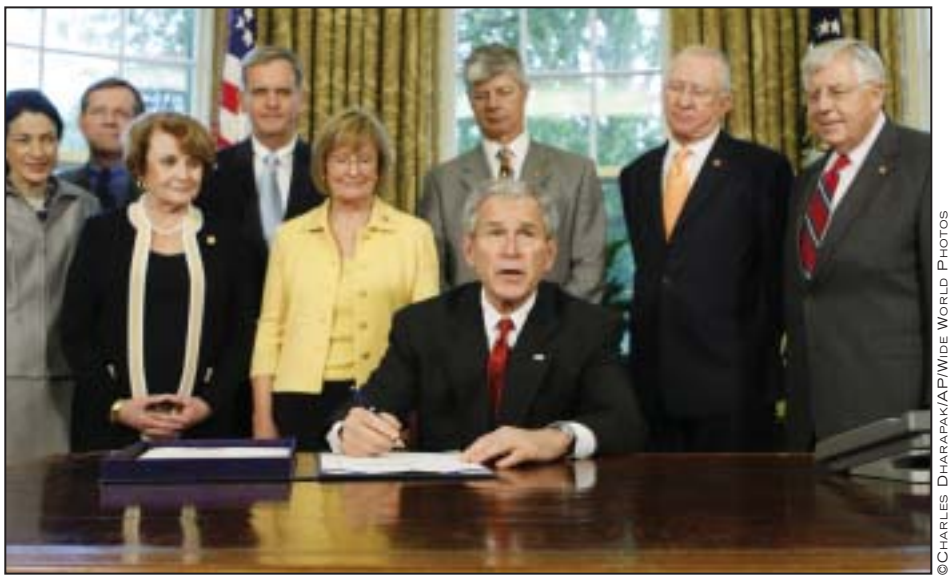
Patients will soon be able to undergo genetic testing without fear of discrimination from either their health insurers or their employers, thanks to a new law signed in May by President Bush.

The Genetic Information Nondiscrimination Act (H.R. 493), which passed both houses of Congress by wide margins, prohibits health insurers from using genetic information in determining eligibility or setting premiums and forbids employers from using that information for decisions about hiring, firing, job assignments, or promotions. The law also prohibits health insurers and employers from requesting or requiring that individuals take a genetic test. The health insurance provisions in the law will go into effect in 12 months, and the employment provisions will take effect in 18 months.

"Genetic testing holds great promise for improving public health, and patients must be able to trust that their genetic information will be protected from inappropriate and discriminatory uses," Dr. Edward Langston, board chair of the American Medical Association, said in a statement. "This new law will allow patients to take advantage of scientific advances in genetics, such as screenings and therapies, without worrying that their personal health information could be used against them by insurers or employers."

Supporters of the law are hailing it as the first civil rights legislation of the new millennium. In practice, experts say that it will mean that patients who might have been hesitant to undergo testing for fear of discrimination may be more willing. Some patients who would be good candidates for genetic testing have been refusing the tests, or in some cases taking them under an assumed name, said Sharon Terry, president of the Coalition for Genetic Fairness, and CEO of the Genetic Alliance.



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**Despite broad support, the signing of the Genetic Information Nondiscrimination Act by President Bush was a long time coming, advocates say.**

The frequency of genetic discrimination has been difficult to document, but it's clear that fear of discrimination has been a barrier to genetic services for some patients, said Dr. Matthew Taylor, director of adult clinical genetics at the University of Colorado in Denver. For example, last year the Genetics and Public Policy Center at Johns Hopkins University, Baltimore, conducted a survey of 1,199 U.S. adults on genetic testing and discrimination. The researchers found that 92% of respondents expressed concern that the results of a genetic test for disease risk could be used against them in some way.

One of the biggest impacts of the law may be its potential to alleviate concerns about genetic discrimination among both patients and physicians, Dr. Taylor said.

Another area where the law is likely to have a significant impact is in research. Many informed consent forms for clinical trials include statements warning participants that they could be discriminated against on the basis of their genetic information, according to Ms. Terry. The Coalition for Genetic Fairness plans to mount an educational campaign to make patients and physicians aware of the new protections in the law in the hopes of increasing participation in research, she said.

The law was a long time coming, according to supporters. Legislation on genetic nondiscrimination was first introduced in 1995. The bill has had broad support in Congress for many years but couldn't get to the House floor under the Republican leadership, according to Susannah Baruch, associate director of the Genetics and Public Policy Center at Johns Hopkins University. The other change that propelled the legislation forward was the explosion in the number of genetic tests available, she said.

About 1,200 genetic tests can be used to identify thousands of health conditions, according to the Coalition for Genetic Fairness. Only about 100 genetic tests were available a decade ago.

Over time, the legislation has garnered support from a broad coalition of groups, including the health insurance industry. "With this landmark bipartisan legislation, Congress and the President have taken strong action to prohibit discrimination based on a person's genetic makeup and to protect patients' privacy as they pursue genetic evaluations," Karen Ignagni, president and CEO of America's Health Insurance Plans, said in a statement. "This legislation also ensures that patients can continue to benefit from health plans' innovative early detection and care coordination programs that improve the safety and quality of care."

But more work needs to be done, Ms. Terry said. The Coalition for Genetic Fairness has been working with Sen. Edward Kennedy (D.-Mass.) and Sen. Barack Obama (D.-Ill.) on better oversight for genetic testing in general. And the Agency for Healthcare Research and Quality recently issued a report calling for improvements to public health surveillance databases and health information technology used to monitor genetic tests. " ■