Law Strengthens FDA's Authority and Funding

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President Bush has signed into law legislation that reauthorizes the Food and Drug Administration's collection of product review fees from drug and device makers, and gives the agency new safety monitoring and enforcement powers.

The new law—which allows for collection of fees through 2012—will impact much of the agency's mission for years beyond that date.

The law "will clarify and strengthen the FDA's authority and give it new tools to take measured and appropriate steps to protect the health and safety of Americans when the agency's postmarket surveillance signals potential dangers from a drug or therapy," said Sen. Mike Enzi (R-Wyo.) who helped steer the bill through its unanimous victory in the Senate.

The almost-500-page law—known as the Food and Drug Administration Amendments Act of 2007—covers far more than just user fees; it also gives the FDA new authority to ensure that drug and device makers study their products in children, to use a burgeoning collection of electronic data in the private sector to track adverse events, to monitor the content of direct-to-consumer advertising, to track recalls of medical devices, to ensure the safety of seafood and pet food, and to weed out conflict-of-interest among outside advisory committees.

The user fees have become central to the agency's operations, providing about 25% of the FDA's annual budget; thus, they "are vitally important to the agency and its continued ability to protect and promote the public health," said FDA Commissioner Dr. Andrew von Eschenbach in a statement after the bill passed both the House and Senate.

The law would give the FDA almost $400 million in fiscal 2008 and in each of the next 4 years for review of medical devices and drugs, and at least $50 million for enhanced safety monitoring, according to Sen. Edward Kennedy (D-Mass.), who toiled with Sen. Enzi to craft a compromise with the House-passed legislation.

The agency has an "urgent need for these funds," said Sen. Kennedy in a statement. "Since 1990, the number of adverse events submitted to the FDA has increased by over 1,300%, but the agency's resources have increased only 130%."

The new law seeks to increase FDA accountability in many ways. In a much-anticipated move, Congress expanded the agency's authority to require drug and device makers to disclose clinical trial data to the public. The aim is for consumers to be able to search a clinical trials registry for basic information on the trial's purpose, where it's being conducted, and its outcomes goals, but also—if it is an FDA-approved product—on whether it succeeded or failed, and whether the intervention has been the subject of FDA safety inquiries or warnings, or any other public health advisories. The law also gives FDA the power to levy civil fines on manufacturers if they do not submit the data according to established deadlines.

The agency, working with the National Institutes of Health, will phase in the system, said Dr. Janet Woodcock, FDA Deputy Commissioner and Chief Medical Officer, in a briefing with reporters.

Some in Congress also had hoped to require a risk evaluation and mitigation strategy to be implemented for most newly approved drugs. Currently, only a handful of drugs are subject to these strictures, most notably isotretinoin and thalidomide.

Under the new law, the FDA will be given leeway to decide when such programs are necessary and what form they will take. Companies that do not comply can be fined up to $1 million. The agency also will have more power to order postmarketing clinical trials.

It is not clear yet whether FDA will have to issue rules to implement these new powers, FDA Deputy Commissioner for Policy Randall Lutter told reporters.

On the device side, in addition to user fees for product reviews, the law also directs Congress to appropriate $7-$8 million annually for collecting, developing, reviewing, and evaluating postmarket safety information.

For the first time, the FDA also will collect fees from drug or device makers who voluntarily submit direct-to-consumer television advertisements for prebroadcast review.

Finally, the new law seeks to prevent outside advisory committee members with conflicts of interest from participating in deliberations on drugs or devices. A panelist would be barred if he or she has a financial interest that would be affected. However, the FDA commissioner will have the power to grant waiver in a variety of situations. ■