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FDA Plan Would Widen User Fee Program to Improve Drug Safety, Review TV Drug Ads

By John Reichard, CQ HealthBeat Editor

A proposal unveiled Thursday by the Food and Drug Administration to reauthorize legislation relying on user fees to fund reviews of drug marketing applications would expand that program by charging companies for certain agency reviews of television drug ads.

The proposal, which would boost overall annual user fee collections by $87.4 million to a total of $393 million, also aims to beef up FDA oversight of drugs once they reach the market. The agency would use $29 million of the new money to hire 82 new agency employees for that purpose. In addition, the agency would spend $4 million on health information technology to review massive prescription drug marketing applications in an "all-electronic environment," the agency announced.

The heart of the user fee program, created under 1992 legislation (PL 102-571) that must be renewed every five years, is the review of applications to market new drugs. The lion's share of the added funding would go toward paying the rising costs of continuing that core function. The program is credited with sharply reducing drug review times, but the agency has come under harsh and widespread criticism that it is failing to properly protect consumers from the hazards of marketed drugs. The new proposal aims to address those concerns, as well as to fund new steps to streamline drug development through the agency's "Critical Path Initiative."

FDA will submit the plan to Congress later this year after obtaining public comment through a Federal Register notice to be published Friday and at a public meeting to be held Feb. 16 in Washington, D.C.

The plan will be submitted to the House Energy and Commerce Committee and the Senate Health, Education, Labor and Pension Committee to begin what may be a long and contentious process of negotiations with the Democratic-controlled Congress on how to better protect the public against drug hazards.

Energy and Commerce Committee Chairman John D. Dingell, D-Mich., issued a brief statement Thursday saying that "some elements of the FDA proposal sound promising, but I will review the details carefully and listen to affected stakeholders before taking a position."

The legislation, known as "PDUFA IV," could become a magnet for legislative attempts to broaden the availability of lower-cost generic drugs. The current version of the Prescription Drug User Fee Act expires Sept. 30 and the reauthorization measure is widely viewed on the Hill as a must-pass measure because FDA reviews of new drugs would virtually grind to a halt without the fee revenue.

The new FDA program also would allow greater agency scrutiny of television ads before companies begin airing them. Companies "would have the benefit of FDA input on whether or not the advertisements are accurate, balanced and adequately supported, enabling them to address any problems before the advertisements are shown to the public," FDA's Federal Register notice says. Critics of televised direct-to-consumer prescription drug ads say they exaggerate the benefits of drugs, leading to inappropriate and excessive prescribing while underplaying safety problems.

The agency would collect $6.3 million in fiscal 2008 to hire 27 staffers to fulfill industry requests for reviews.

FDA said the added funding would in part address recommendations by the Institute of Medicine for improving drug safety. FDA Center for Drug Evaluation and Research Director Steven Galson said he hoped to announce "within a few weeks" the details of how the agency would do so.

But the proposal does specify several safety improvement activities, including identifying the best ways to analyze the large automated databases increasingly being used to spot drug hazards. The proposal also would end the current three-year limit on how long after a drug is approved that user fees can be used to monitor its safety.

A total of $4.6 million in new user fees would be used to hire 20 employees whose duties would include advising companies on better clinical trial designs. As part of the agency's Critical Path Initiative, some user fee money would go to help fund agency collaborations with outside researchers to develop "biomarkers" that would allow FDA to more quickly determine whether drugs are safe and effective than current forms of clinical testing do.

Galson said FDA developed the proposal with the drug industry in consultation with a wide variety of outside groups, "all of whom overwhelmingly agreed" that the prescription drug user fee program should continue, he said. But a couple of consumer organizations faulted the plan. "The FDA's crucial drug regulatory functions are too important to be tainted and compromised by direct funding from the very companies whose drugs the agency reviews for safety," said Sidney Wolfe, director of the Nader-founded Public Citizen Health Research Group.

Consumers Union added in a statement late Thursday afternoon that much more funding is needed. "A proposed user-fee deal negotiated in private between the pharmaceutical industry and the FDA earmarks some funds for drug safety," it said, but added that "the administration must significantly fund comprehensive safety efforts, and Congress must pass new laws, to adequately protect the public from dangerous drugs."

"At a time when countless drugs have safety problems, it isn't enough to just rely on money paid by the pharmaceutical industry to fund needed drug safety reforms," added Bill Vaughan, senior policy analyst for the consumer organization.

The Pharmaceutical Research and Manufacturers of America lauded the proposal, saying it is designed "to make sure millions of patients continue to receive safe and effective medicines in a timely manner."

The National Health Council, an umbrella group that says its member organizations represent some 100 million chronically ill Americans, said the expanded program would be "a huge step forward" toward improving drug safety and speeding up patient access to badly needed medications.

Jeff Allen, a spokesman for Friends of Cancer Research, a coalition of cancer researchers, cancer centers and patients' groups, said Congress also must boost FDA funding through the appropriations process. "The bottom line is that we continue to give the FDA more responsibilities but not necessarily the resources to match."

Sen. Charles E. Grassley, R-Iowa, ranking member of the Senate Finance Committee, issued a statement Thursday saying stronger measures are needed than the FDA proposal.

"These dollars would represent a modest contribution to improving the post-market surveillance work of the Food and Drug Administration," he said. "I don't want to denigrate any step in that direction when a step is made with good intention, but to make sure the FDA is doing everything it should to keep American consumers safe, comprehensive reform of the agency's structure and culture is needed."

Source: CQ HealthBeat News
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