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F.D.A.'s Drug Safety System Will Get Outside Review

Troubled Agency Responds to Criticism

By GARDINER HARRIS

WASHINGTON, Nov. 5 — Amid intense criticism that it is slow to raise the alarm about unsafe medicines, the Food and Drug Administration announced Friday that it would hire the nation's top scientific review body to figure out whether the drug safety system is adequate.

In another step, after embarrassing disclosures that the views of its own drug safety officials had been suppressed, the F.D.A. said it would set up an internal appeals process. If someone inside the agency feels that superiors have made a mistake by approving a drug or, after approval, refusing to order its recall, that person will be able to make a case before a committee of experts, from inside and outside the agency, who were not involved in the decision.

"Our current drug approval system has demonstrated that we don't always understand the full magnitude of drug risks prior to approval of drug products," said Dr. Steve Galson, director of the agency's Center for Drug Evaluation and Research.

The twin moves follow the agency's handling of safety issues in two highly publicized cases.

First, after receiving studies indicating that antidepressants could cause children and teenagers to become suicidal, the agency took nearly a year to decide to require the strongest possible warning to that effect in those drugs' packaging.

The delay, which agency officials said they had needed to be sure of the data, enraged patient advocates. Criticism mounted further when The San Francisco Chronicle reported that the agency's own safety reviewer had concluded that there was a risk, but that his views had been suppressed by top F.D.A. officials.

Then, in a similar case, came the recall of Merck & Company's big-selling painkiller Vioxx, whose long-term use was found to pose cardiac risks. After the recall, word leaked that one of the agency's safety reviewers had decided well beforehand that this pill, too, was risky.

condemned the F.D.A.'s entire system of drug safety review and said the agency had acted out of "ruthless, shortsighted and irresponsible self-interest" in failing to demand the removal of Vioxx earlier.

In one of the moves announced Friday, the agency will hire the Institute of Medicine — a part of the Congressionally chartered National Academy of Sciences, the government's top scientific reviewer — to study how well the F.D.A. assesses the dangers of unexpected side effects of marketed drugs.

Responding to the announcement of the new initiatives, Senator Charles E. Grassley, Republican of Iowa, issued a statement calling them "welcome, albeit late in coming."

As chairman of the Senate Finance Committee, Mr. Grassley has spearheaded an investigation into the F.D.A. "It's obvious," he said Friday, "that the leadership of the agency must take on what look like deep-rooted problems when it comes to putting public health and safety first and public relations second."

Mary Jane Fingland, a spokeswoman for the drug industry's trade group, the Pharmaceutical Research and Manufacturers of America, said, "All medicines have risks, and it is important for patients, their physicians and pharmacists to decide whether the benefits outweigh the risks of taking the medicines."

Some conservative and industry analysts said they feared that the new steps could slow the agency's approval of drugs.

"The public health consequences of slowing down drug development and approval far outweigh the risks from drugs whose side effects turn out to be unexpectedly bad," said Sam Kazman, general counsel of the libertarian Competitive Enterprise Institute.

In a third step announced Friday, the F.D.A. said it would accelerate its search for a new director of its Office of Drug Safety. The post has been vacant since October 2003. One problem in finding someone qualified, nies, which can afford to pay far more than the $125,000 or so salary that comes with the government job.

In yet another initiative, the agency said that by the end of the year, it would publish guidelines to help drug companies manage the risks inherent in their products.

Still, Dr. Galson, the F.D.A. official, said he saw no need for a thorough overhaul of the agency's culture or systems.

"We are very proud of our independence, and we think most of the charges being leveled are just not accurate," he said. "We hope this won't result in important products for the public health of the United States being delayed in their marketing."

One physician who has long been an observer of the agency, Dr. Raymond Woosley, vice president of the University of Arizona, said he hoped that the experts from the Institute of Medicine considered an idea that he has pushed for some time: a permanent, independent review group that would play a role in pharmaceutical cases similar to the role the National Transportation Safety Board plays in plane crashes.

"Any time there is a significant event with a drug," Dr. Woosley said, "there should be an independent panel that looks to see if the right decisions were made and what should happen in the future."

Dr. Galson replied that such an independent agency would be expensive to create. "If we had several hundred million dollars lying around, we could do these independent reviews more regularly," he said.

Further, he said, drugs' risks cannot be assessed without a thorough understanding of their benefits.

Kathy Woodward, who became active as a critic of the agency after her 17-year-old daughter committed suicide while taking antidepressants, said she worried that the F.D.A.'s announcement Friday amounted to little more than a smokescreen for its failures.

"I just have a very uneasy feeling," Ms. Woodward said, "about anything the F.D.A. is doing these