

Whistleblowers Help Congress Strengthen U.S. FDA

Justin Blum Thu Feb 8, 10:13 AM ET

Feb. 8 (Bloomberg) -- Scientists who have worked at the U.S. Food and Drug Administration and criticized agency decisions are now helping Congress fashion legislation to tighten product-safety rules.

The scientists include David Ross, who said in an interview that FDA supervisors forced him to retract a recommendation that the antibiotic Ketek, made by Sanofi-Aventis SA, was probably too dangerous to be used for treating two common respiratory infections. The drug was approved in 2004 and had \$148 million in sales in 2005.

Ross is one of four current or former employees of the FDA who are working with Congress on bills intended to create more stringent drug safety rules. One change being proposed would create a new office to monitor the safety record of drugs after they're on the market. Next week, several of the critics may describe their concerns at a congressional hearing on the FDA.

"I felt like if I didn't do something and people got hurt, I wouldn't be able to stand it," said Ross, 48, who worked at the FDA for a decade before resigning in November. "I'm getting a chance to say what the problems are, and I'm getting a chance to fix them."

Legislation proposed by Senators Charles Grassley (news, bio, voting record), an Iowa Republican; Edward Kennedy (news, bio, voting record), a Massachusetts Democrat; and other lawmakers would give the FDA greater authority to restrict the use of drugs with side effects and require the registration of drug-company clinical trials.

Scientists' Clout

The proposal to create a separate group within the FDA with power to monitor the safety of drugs after they are on the market was inspired by the FDA whistleblowers, Grassley said. They told him the scientists who oversee reports about drug side effects lack the clout to alert doctors and the public about what they have identified.

"Without the benefit of whistleblowers, would I even know that the office of drug safety is under the thumb of the office of new drugs and needs to be separated?" Grassley said in an interview. He said the critics have suggested that the approval group may not be aggressive in recalling or restricting the use of drugs it allowed onto the market.

The 12,000-employee FDA regulates products that account for more than \$1.5 trillion in annual sales, or more than a 10th of the U.S. economy. Besides food and medicine safety, the agency writes and enforces rules on cosmetics and medical devices such as heart defibrillators.

Vioxx, Ketek

The FDA's oversight of drug safety has come under lawmakers' scrutiny in the past three years after studies linked antidepressants to suicide risk for children and painkillers to elevated chances of heart attacks. Merck & Co., based in Whitehouse Station, New Jersey, withdrew its top-selling pain drug Vioxx in September, 2004 after a company study showed the drug's use was tied to higher heart attack and stroke risks.

The FDA critics helping lawmakers include David Graham, an FDA medical officer who questioned the health risks of Vioxx years before its withdrawal. Ross and John Powers, former FDA medical officers, raised challenges to the agency's oversight of Ketek, sold by Paris-based Sanofi.

Another FDA employee talking to Congress is Victoria Hampshire, who in 2003 identified safety problems with a Wyeth medicine for dogs, ProHeart 6. She was forced from her veterinary medicine job to another position after Wyeth said she had a possible conflict of interest. She was later cleared of wrongdoing by the FDA. Wyeth withdrew the drug in 2004.

FDA's Response

The FDA won't comment on the pending legislation or employees' role in creating it, said spokeswoman Kathleen Quinn in an e-mail. The agency supports "employees' communicating their personal opinions," without necessarily agreeing, she said.

The drug agency last week pledged to strengthen safety monitoring. It is proposing a test program to examine side effects of new medications after 18 months of sales. Drugmakers say new legislation isn't needed.

"The U.S. drug safety surveillance system at the FDA is the best in the world," said Alan Goldhammer, deputy vice president for regulatory affairs for the Pharmaceutical Research and Manufacturers of America, the industry's trade group in Washington.

Some of the FDA employees said they have responded to requests to discuss their cases with Senate aides for Grassley and Kennedy, as well as with Christopher Dodd (news, bio, voting record), a Democrat from Connecticut, and Michael Enzi (news, bio, voting record), a Republican from Wyoming. In the House, the critics have talked with staff for Democratic Representatives Henry Waxman (news, bio, voting record) of California and Ed Markey of Massachusetts.

Safety Review

Ross said some of his suggestions were shaped by the way the FDA responded to his findings about Ketek when he was a medical team leader. He wrote in a safety review that the drug's risks appeared too great to allow approval for treatment of bronchitis and sinusitis, two common respiratory infections.

"I was called into my division director and told to 'soften my review,'" Ross said. He changed the wording to be more "neutral," he said. "When I made scientific arguments, they were ignored when there was an economic argument for the company."

On Dec. 15, a panel of FDA advisers said the drug shouldn't be routinely prescribed for the two conditions because of risks of liver damage and death. The panel suggested keeping the drug on the market only for treating pneumonia, a more severe illness. The FDA hasn't acted on the recommendation.

Sanofi's chief medical officer, Doug Greene, said in a statement issued after the FDA panel meeting that the company would discuss the matter with the FDA. He said Sanofi considers patient safety its "highest priority."

Reviews Online

In a recent meeting with staff for Grassley and Dodd, Ross said he suggested that all FDA staff reviews of medications be posted on the agency's Web site. Powers said congressional aides have sent him draft legislation for comment.

"Some FDA managers refuse to even admit there's a problem," said Powers, who quit in October as the lead medical officer for antimicrobial drug development and resistance initiatives. "Its kind of like alcoholism. You have to admit you have a problem before you can do something about it."