Hearing Examines Ways to Bolster Drug Safety

Congress considering boosting FDA's authority; agency would have more clout over product labeling.

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WASHINGTON — Congress is considering giving the Food and Drug Administration more authority over the pharmaceutical companies it deals with, but some legislators are warning against doing too much too fast.

"Changes to drug safety … must be carefully considered to make sure they don't unduly impact patient access," Sen. Mike Enzi (R-Wyo.), chair of the Senate Health, Education, Labor, and Pensions Committee, said at a hearing on FDA oversight. "Congress needs to engage in strong oversight to maintain public confidence in the FDA."

Sandra Kweder, M.D., deputy director of the Office of New Drugs at the FDA's Center for Drug Evaluation and Research, told the Senate committee that in order to ensure drug safety, it would be helpful if the FDA had more clout. She noted that it took a lot of back-and-forth haggling just to get some earlier warnings added to the label.

"The most important lapse [with the safety concerns surrounding Vioxx] was the delay it took to get the information into the labeling; it took over a year," she said. "I think stronger ability to require changes in labeling would be very helpful."

The committee's ranking member, Sen. Edward Kennedy (D-Mass.), also spoke in favor of giving the agency greater labeling authority. "The FDA needs clear authority to require relabeling of a drug after approval once a risk is found," he said. "Negotiations with the drug company should never delay [that]."

Some observers said that although giving the agency more authority over label changes is a good idea, it only goes so far. "We all know product labeling does not change provider behavior very much," said Arthur Levin, director of the Center for Medical Consumers in New York and the consumer representative on the FDA's Drug Safety and Risk Management advisory committee. Even if FDA does get more labeling authority, "we shouldn't count on it protecting the public from harm," Mr. Levin said at a teleconference announcing the release of a new survey on consumer attitudes about the FDA.

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The survey of 1,000 adults nationwide was performed by pollster Celinda Lake and sponsored by a coalition of consumer groups. The results showed that only 14% of respondents had a great deal of confidence in the agency's ability to ensure the safety of prescription drugs. And 48% of respondents said they believed the FDA was too influenced by the industries over which it has jurisdiction.

Another subject discussed at the Senate hearing was the secrecy of clinical trial data. "I'd like to emphasize the importance of open access to data from clinical trials, including negative trials and unpublished research," David Fassler, M.D., a child and adolescent psychiatrist in Burlington, Vt., who testified on behalf of the American Academy of Child and Adolescent Psychiatry and the American Psychiatric Association.

In 2004, when Dr. Fassler testified on the question of whether there was a link between selective serotonin reuptake inhibitors (SSRIs) and suicide, "there were only four studies in the published literature on [the use of] SSRIs in adolescents. But I later learned that there were 11 unpublished studies whose results had been submitted to FDA. Parents clearly need access to this kind of evidence." ■