HEALTH

House Panel Grills FDA, Drug Firms

Hearing Centers on Method For Releasing Negative Data On Use of Antidepressants

By ANNA WILDE MATHEWS
Staff Reporter of THE WALL STREET JOURNAL
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WASHINGTON -- A congressional panel harshly questioned officials from the Food and Drug Administration and major drug companies about how they disclosed negative findings about antidepressants, criticizing the agency and the industry for slow and inadequate responses.

House Energy and Commerce Committee Chairman Joe Barton of Texas took aim at the FDA for "stonewalling, slow-rolling and plain incompetency" in failing to fully answer his requests for information about the issue, citing an e-mail in which an agency official told colleagues not to give congressional investigators materials including "draft documents, notes, memos to self or file, or incoming communications from non-FDA individuals."

The hearing by the committee's investigations subcommittee was the latest forum for questions about the safety and effectiveness of antidepressant drugs for young people, a debate that has focused on the drugs' potential link to suicidal tendencies. The FDA has come under criticism for the way it handled internal debates over the issue.

The matter is at the heart of a broader discussion about disclosure in the drug industry following revelations that negative clinical trial results about antidepressant weren't always published. Lawmakers quizzed drug makers about a number of specific studies that were made public in only limited or belated ways.

Yesterday, as expected, the American Medical Association and drug makers discussed their plans for databases that could hold results of unpublished

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studies. Democratic lawmakers have also announced plans to introduce bills for mandatory federal clinical-trial registries.

Testimony in the hearing also revealed new details of the FDA's interactions with some of the companies over disclosing the results of pediatric studies. Two drug makers -- Bristol-Myers Squibb Co., which makes Serzone, and Wyeth, which makes Effexor -- said yesterday that they sought to place language on their drugs' labels indicating that clinical trials in young people hadn't shown that the drugs performed significantly better than placebo pills. Both companies said the FDA had declined to allow the label changes.

"We had a point of view and the FDA had a different point of view," said Joseph Camardo, a Wyeth senior vice president, who said the company also wanted to add a caution about hostility and suicidal thoughts. The committee also released a document confirming a previously reported incident in which the FDA asked Wyeth to remove a label precaution it added later about Effexor's possible link to hostility and suicidal tendencies in young people. In the letter the agency said the sentence could be "confusing and potentially misleading" when combined with a new FDA-recommended label warning urging doctors to closely watch adult and pediatric patients. The agency had recommended that warning for the labels of all major antidepressants.

The FDA was also questioned about whether it pressed as hard as possible for disclosure of the pediatric trial efficacy results, several of which were unveiled last month after the agency asked companies' permission. "Did it occur to anyone to do it before?" asked Rep. Diana DeGette (D., Colo.).

Responding to questions, FDA Deputy Commissioner Janet Woodcock said the agency "will make every effort to cooperate with the committee." She generally declined to discuss specific details about individual drug labeling and disclosure decisions, which are made within the FDA's drug center. But she said the agency must follow laws that sharply restrict its ability to make public corporate data, particularly about unapproved drug indications. "We want balanced information that reflects what is known scientifically about the drug" on the label, she said. She also said the agency believes "the jury is still out" about the effectiveness of most of the antidepressants in treating depressed young people.

Only one antidepressant, Prozac, made by Eli Lilly & Co. and available generically, is approved by the FDA to treat depressed young people, while the others haven't shown enough effectiveness to win the agency's backing for a label indication. An FDA staffer has told Senate Finance Committee investigators that in an upcoming advisory-committee meeting the agency may discuss data that could raise the question of whether Prozac, too, carries at least some risks for young people, according to a person familiar with the matter.

Write to Anna Wilde Mathews at anna.mathews@wsj.com

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