

Bloomberg.com



Lilly May Face More Zyprexa Lawsuits After FDA Letter (Update2)

By Rob Waters and Margaret Cronin Fisk



[+ Enlarge/Details](#)

June 29 (Bloomberg) -- Eli Lilly & Co. may attract more lawsuits alleging it failed to warn users that a psychiatric drug was linked to diabetes after the pharmaceutical company received a letter from U.S. regulators.

The U.S. Food and Drug Administration told Lilly in March it would delay the approval of Symbyax for hard-to-treat depression because the agency wanted more information about the risk of diabetes in the medicine's prescribing label. Symbyax combines Lilly's antipsychotic pill Zyprexa and the antidepressant Prozac.

The FDA's request, in a letter to Lilly obtained by Bloomberg, may bolster plaintiffs' suits against the Indianapolis company over side effects tied to Zyprexa, lawyers said. Lilly has paid more than \$1.2 billion to settle 29,000 claims that patients weren't adequately warned that Zyprexa can cause diabetes, weight gain and pancreas infections.

"When the FDA says something damning about the warnings of a drug, it's admissible as evidence on the reasonableness of the manufacturer's decisions," said David Logan, dean of the Roger Williams University School of Law in Bristol, Rhode Island, in an interview. "It would likely carry some weight with juries."

Logan isn't involved in Zyprexa litigation and hasn't been an expert witness in product-defect lawsuits.

In addition to the individual claims, at least eight states have sued the company on behalf of their Medicaid health programs for the indigent, alleging Lilly concealed risks and marketed the drug for unapproved uses.

Studies have shown that Zyprexa and other, similar medications known as atypical antipsychotics are associated with weight gain and an increased risk of diabetes. These studies prompted the FDA to require Lilly and other drugmakers to warn doctors of the risks in September 2003 and again in March 2004.

Replacing Zyprexa Sales

Lilly asked the FDA for permission to market Symbyax for patients who have hard-to-treat depression. It is already approved for a less-common bipolar form of the illness. The addition may help Lilly make up for declining revenue from Zyprexa, its best-selling product.

Zyprexa sales fell 0.4 percent last year to \$4.7 billion, according to IMS Health Inc., the Fairfield, Connecticut-based prescription data company. The drug, approved for schizophrenia in adults, is also used to treat children with mental disorders and elderly patients with dementia, although it isn't approved for those uses. Zyprexa competes with similar medicines from Johnson & Johnson, AstraZeneca Plc and Bristol-Myers Squibb Co.

FDA's Letter

Shares of Lilly fell 30 cents to \$55.88 at 4:01 p.m. in New York Stock Exchange composite trading. In the past 12 months, the shares gained 2.5 percent, second-worst in the 14-member Standard & Poor's 500 Pharmaceutical Index, which gained 17 percent in the same period.

The FDA made its request for more information on patients' weight gain and diabetes in what is called an approvable letter, which the agency uses to tell a company what more is needed to gain marketing clearance. The letter hasn't been publicly released.

"We are concerned that the proposed labeling is deficient with regard to information about weight gain" and high levels of sugar and fat in the blood of patients who took the drug, the FDA said in the letter, referring to proposed prescribing information on Symbyax. "We do not feel that current labeling for either Symbyax or Zyprexa provides sufficient information on these risks."

Susan Cruzan, an FDA spokeswoman, said the agency couldn't comment on the letter because it is a confidential communication.

Diabetes Link

Lilly's proposed prescribing information for Symbyax failed to disclose that almost half of patients who had high or borderline levels of blood sugar when they started taking the drug ended up with levels high enough to be considered diabetic, the FDA said in its letter. That was more than nine times the number of patients on placebos, or inactive dummy pills.

"We were troubled that this important information was not included in your proposed label," the agency said in the letter.

The information Lilly proposed to include on risks was "just a starting point," and the company was prepared to provide more information as requested by the FDA, Lilly spokeswoman Carol Puls said in an interview in which she discussed the letter's contents. The agency hasn't asked Lilly to make additional changes to Zyprexa's prescribing information, Puls said.

The letter, signed by Thomas Laughren, director of the FDA's division of psychiatry products, was cited in a June 11 decision by U.S. District Judge Jack Weinstein in Brooklyn allowing three lawsuits against Lilly to go to trial. The judge quoted the FDA's concern that doctors would have trouble making "reasonable treatment decisions until they have such information" on risks.

Statute of Limitations

After the ruling, Lilly notified Weinstein in a June 13 letter that the cases had been settled, according to court documents. The lawsuits were resolved before the decision, Lilly said today.

Weinstein, who is overseeing all federal Zyprexa cases, didn't rule on whether the letter affected the statute of limitations for filing new suits. Logan and Blair Hahn, who has represented several thousand Zyprexa patients, said the letter may still have that effect.

"We have all been assuming that March of 2004 was the date the statute of limitations" began running, Hahn said. That's the date Lilly issued a "Dear Doctor" letter expanding its warning on the risk of diabetes.

"Judge Weinstein seems to be suggesting that the statute of limitations has not yet begun to run" because the company has yet to provide full information on the risks, Hahn said. He will now reconsider cases he had turned down from people who started taking the drug after March 2004, he said.

500 Lawsuits

Lilly's Puls said in an e-mail that the company wouldn't comment on whether the letter might strengthen the legal position of plaintiffs suing the company. She said Weinstein made no ruling extending the statute of limitations for filing a suit.

Howard Nations, an attorney representing about 185 Zyprexa users with pending cases, said he didn't expect a new round of lawsuits because Judge Weinstein "wants the cases disposed of." He said he

does think the FDA letter will bolster claims in remaining suits by showing that Lilly didn't properly warn people of the risks of using Zyprexa.

About 500 personal injury lawsuits are pending in Weinstein's court. The first will go to trial in October, he said last week. Weinstein yesterday allowed a separate suit filed by private health insurers to go forward. The complaint, filed as a class action, claims that Lilly violated racketeering laws in its marketing of Zyprexa.

To contact the reporters on this story: Rob Waters in San Francisco at rwaters5@bloomberg.net ; Margaret Cronin Fisk in Southfield, Michigan, at mcfisk@bloomberg.net .

Last Updated: June 29, 2007 16:09 EDT



©2007 BLOOMBERG L.P. ALL RIGHTS RESERVED. [Terms of Service](#) | [Privacy Policy](#) | [Trademarks](#)