MSNBC.com

US FDA reviewer says 5 drugs need closer scrutiny

By Lisa Richwine and Ransdell Pierson
Reuters
Updated: 5:32 p.m. ET Nov. 18, 2004

WASHINGTON/NEW YORK - A U.S. Food and Drug Administration reviewer who has accused the agency of being lax in monitoring drug safety on Thursday said five medicines on the market need closer scrutiny.

Shares of several makers of the drugs, including British rivals GlaxoSmithKline Plc and AstraZeneca Plc , fell sharply after the testimony.

Dr. David Graham, speaking at a Senate hearing, singled out Abbott Laboratories Inc.'s weight-loss drug Meridia, AstraZeneca's cholesterol fighter Crestor, Pfizer Inc.'s arthritis treatment Bextra, Roche's acne drug Accutane and GlaxoSmithKline's asthma drug Serevent.

"There are at least five drugs on the market today that I think need to be looked at quite seriously to see if they belong there," said Graham, associate director for science in the FDA's Office of Drug Safety.

Graham in August presented his FDA-sponsored study suggesting Merck & Co's arthritis drug Vioxx caused heart attacks and stroke, the month before Merck recalled its $2.5 billion-a-year drug. Graham has alleged senior FDA officials tried to suppress his findings.

"David Graham was the FDA researcher who had questioned Vioxx's safety before it was recalled, so a list of drugs he's also concerned about is going to be taken quite seriously," said David Moskowitz, an analyst at Friedman, Billings, Ramsey & Co.

A top official at the FDA's Office of New Drugs, however, disagreed with Graham's list.

"I do not have reason to believe that set of five drugs is specifically more concerning," Dr. Sandra Kweder, deputy director of the Office of New Drugs, told the Senate Finance Committee hearing on Thursday.

Henry Dummett, an analyst at World Markets Research Center, said he was concerned about "a degree of paranoia" about drug safety in the wake of the Vioxx recall.

AstraZeneca last year launched Crestor as a challenger to Pfizer's Lipitor. The new drug had global third-quarter revenue of $260 million. Graham said a serious look was needed at the chances of Crestor causing kidney failure and a potentially fatal muscle breakdown.

"The FDA to date has not given us any indication of a major concern regarding Crestor," said AztraZeneca spokeswoman Rachel Bloom-Baglin.

AstraZeneca closed down 8.6 percent to $40.34 on the New York Stock Exchange.

Serevent is used by itself and also as one of two ingredients in GlaxoSmithKline's asthma treatment Advair, the company's biggest product with sales of $4 billion a year.

Graham said he was worried about reports Serevent might increase the chances of dying. Serevent carries a warning of rare cases of asthma-related fatalities in studies.

"Any issues concerning mortality associated with Serevent have been fully considered by the FDA," Glaxo said.

Glaxo shares fell 3.2 percent at $43.59, also on the New York Stock Exchange.

Pfizer's Bextra is in the same class of arthritis drugs as Vioxx, which was recalled Sept. 30 after a company study showed it doubled heart attack and stroke risk.

The FDA is planning to look at the entire family of Vioxx-type drugs at an advisory committee meeting next year, including Pfizer's older treatment Celebrex.

"I would be looking at Bextra very, very carefully," Graham said at the hearing, which was called to examine the actions of the FDA and Merck regarding Vioxx.

Pfizer last week said it is considering a "black box" warning on Bextra's package insert label that the drug can cause a rare but sometimes fatal skin disorder called Stevens-Johnson syndrome. The pill, launched in 2001, had sales of $687 million last year.

"Bextra has been found safe and effective when used as indicated," Pfizer spokeswoman Susan Bro said. Pfizer last month acknowledged, however, that Bextra has been shown to raise risk of heart attacks and stroke in patients undergoing heart bypass surgery.

Roche's Accutane, also sold generically under the name isotretinoin, has been on the market for 22 years and is reserved for the most severe forms of acne that are not responsive to other treatments. It can cause birth defects.

"Over the years a strong risk management program has evolved with the drug to make sure it is used appropriately," said Roche spokeswoman Carolyn Glynn. She said the drug is expected to have sales of about $84 million this year.

Graham said Abbott's Meridia diet drug only works if used long-term, but many people stop taking it early on because of side effects. "Is there a need for this product in the first place?" he asked.

Abbott spokesman Tim Lindberg defended Meridia as a "safe" treatment for obesity. (Additional reporting by Toni Clarke and Bill Berkrot in New York, editing by Chizu Nomiyama; Reuters Messaging: lisa.richwine.reuters.com@reuters.net; +1 202 310-5691))

© Reuters 2004. All rights reserved. Republication or redistribution of Reuters content, including by caching, framing or similar means, is expressly prohibited without the prior written consent of Reuters. Reuters and the Reuters sphere logo are registered trademarks and trademarks of the Reuters group of companies around the world.

URL: http://msnbc.msn.com/id/6521912/