

Concern About Drug Safety Doesn't Stop With Vioxx

USA TODAY - Rita Rubin

11/22/04 - Doctors have been taking calls from anxious patients ever since a Senate hearing on Vioxx last week at which an FDA scientist expressed concerns about the safety of five other drugs on the market.

That David Graham of the Food and Drug Administration's Office of Drug Safety named names was surprising. But to anyone who has kept up with the scientific literature and the drugs' evolving labels, the names themselves were not.

Steven Galson, an FDA administrator, attempted to temper Graham's testimony by saying the agency must consider benefits as well as risks, "so that safe and effective drugs remain available to patients who need them."

Some of what is known about the five drugs so far:

Accutane. Accutane can cause major fetal defects, and Roche, its maker, has warned against use during pregnancy since it came on the market in 1982. Yet, according to the March of Dimes, thousands of pregnant women have taken it.

In 2001, the FDA approved a voluntary system developed by Roche to prevent pregnant women from taking Accutane. But an FDA review found the proportion of Accutane users who were pregnant might actually have gone up in the year since the system went into effect.

In February, an FDA advisory panel recommended a more-restrictive program that would set up a registry of all Accutane prescribers, all pharmacists who dispense it and all users. It has not yet been implemented.

Bextra. As with Accutane, Graham did not call for Bextra in the same class of drugs as Vioxx to come off the market. But, he said, too little is known about Bextra's effect on heart attack or stroke risk. Last month, Pfizer sent a letter to health-care professionals mentioning results of two Bextra trials in heart-bypass-surgery patients. In both, the Bextra groups had more heart attacks and strokes than the placebo groups.

Crestor. This cholesterol drug has drawn regulators' attention in Europe and Canada.

At the Senate hearing, Graham said Crestor is the only statin drug that causes kidney failure. And, he said, it carries a higher risk of rhabdomyolysis than any other statin. Rhabdomyolysis is a potentially fatal muscle complication that benched another statin, Baycol, in 2001.

In June, Crestor maker AstraZeneca released a revised package insert for use in the European Union. It highlighted the rhabdomyolysis issue. Later that month, the Canadian government issued an advisory warning of a possible link between Crestor and rhabdomyolysis, especially at higher doses

Two months after the FDA approved Crestor in August 2003, consumer watchdog Public Citizen warned consumers not to use it because of kidney toxicity. The group has asked the FDA to ban Crestor.

Meridia. Graham said that few patients stay on the weight-loss drug very long because extended use can lead to increased blood pressure and stroke. Before Meridia was approved in 1997, an FDA advisory panel voted 5-4 that the drug's benefits did not outweigh its risks. Public Citizen has twice petitioned the FDA to pull it off the market.

Serevent. The Glaxo asthma drug, approved in 1994, dilates breathing passages. In 2003, its label began carrying a "black box" warning, the strongest type of warning, about the results of a large U.S. study that showed a small but significant increase in asthma-related deaths in patients who took Serevent. Advair, another Glaxo asthma treatment, which contains Serevent and a steroid, carries the same warning.

Richard Honsinger, a Los Alamos, N.M., asthma and allergy specialist, says he fielded some calls from worried patients after Graham's pronouncement. He says Serevent only relieves symptoms and should be taken along with a steroid to prevent permanent scarring in the lungs from inflammation.

[Home](#)