Plaintiffs build case against diabetes drug

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In the wake of a new study linking the Type II diabetes drug Avandia to a 43 percent increase in the risk of a heart attack, the plaintiffs' bar is building its failure-to-warn case against GlaxoSmithKline, the drug's manufacturer.

Although no personal injury suits had been filed at press time, a shareholder class action was filed on behalf of investors, claiming that GlaxoSmithKline issued multiple "false and misleading" statements about the drug.

Meanwhile, personal injury lawyers have been fielding a steady stream of calls since the study came out. Both Thomas Kline of Kline & Specter in Philadelphia and Karen Barth Menzies of Baum Hedlund in Los Angeles are currently evaluating cases.

The potential for litigation is vast, because more than a million people have taken the drug in the U.S. alone - and 6 million worldwide.

Like Vioxx, the major claims by Avandia plaintiffs will be failure-to-warn and aggressive marketing despite risks the drug maker knew or should have known existed.

"Similar to Vioxx, Avandia is one of those drugs that has been [heavily] promoted with direct-to-consumer advertising," said Kline, who was a member of the plaintiffs' steering committee for Vioxx.

But it's also true that both drugs have been prescribed to vulnerable populations that would already have an increased risk of heart attacks. That means there's no guarantee that these cases will be winners for the plaintiffs, because juries will be forced to weigh whether the disease or the drug caused the heart attack.

"When we get down to specific cases, the individual risk factors will be present and strong and probably overwhelming," said Philadelphia pharmaceutical defense attorney Nathan Schachtman, a partner with McCarter & English.

A hearing before the House Oversight and Government Reform Committee on June 6 - scheduled immediately after the study results surfaced - focused on the FDA's role in evaluating the safety of Avandia once it hit the market.

Plaintiffs' lawyers said the unprecedented race to hold a congressional hearing was a political move to push pending drug safety legislation to the front burner.

Members of Congress were "trying to use Avandia as an illustration to justify legislation to reform the FDA," said Menzies, who attended the hearing.

GlaxoSmithKline did not return a call requesting comment.

The evidence mounts

Dr. Steven Nissen, a well-known cardiologist from the Cleveland Clinic, conducted a meta-analysis, evaluating the results of 42 previous studies of Avandia.

The study - which was published in the New England Journal of Medicine on May 21 - concluded that Avandia increases a patient's risk of a heart attack by 43 percent and the risk of death from cardiovascular causes by 64 percent.

During his testimony at the Senate hearing, FDA Commissioner Andrew von Eschenbach announced publicly the agency's request that GlaxoSmithKline add a "black box" warning to the label of Avandia.

However, that warning - the most serious type the FDA issues - is set to address an increased risk of heart failure, not heart attacks.

At the hearing, GlaxoSmithKline and the FDA both defended their actions with respect to Avandia. The company claimed Avandia was just as safe as other diabetes drugs on the market, and the FDA claimed it warned of risks as they came to light.

After the Nissen study came out, Glaxo published interim results of its own study, indicating no increased risk of heart attack.

But Menzies said testimony at the hearing made it clear that GlaxoSmithKline was on notice of a potential elevated risk of heart attack from the drug as early as 1999.

Diabetes expert Dr. John Buse testified that when he raised a concern about an increased risk of heart attacks from Avandia in 1999, the drug maker subjected him to intimidation tactics and characterized him as a liar.

"When I heard that, my eyebrows went up," said Menzies. "From a legal perspective, I thought, 'Wow, that's notice as early as 1999 when the drug hadn't even been on the market a year.' If they have something that puts them on notice there is a risk, they have an obligation to warn."

Other evidence includes a 2001 letter from the FDA warning GlaxoSmithKline not to minimize the risk of cardiovascular disease associated with Avandia in its marketing materials.

Vance Andrus, a partner with Andrus, Boudreaux, Lemoine & Tonore who practices in Denver, predicted that there is more evidence to come.

"History has shown us that when information like this breaks open, it's often the tip of the iceberg," said Andrus, who is chairing Mealey's Avandia Litigation Conference in Chicago in July.

What lies ahead

Plaintiffs' lawyers who have handled other drug litigation say many aspects of Avandia cases will be similar to Vioxx claims.

"The Avandia plaintiff, like the Vioxx plaintiff, will be a classic eggshell plaintiff," said Kline, who is speaking at the upcoming Avandia litigation conference. "People with diabetes are at greater risk for heart attacks and strokes, like the older population that generally took Vioxx. The last thing they should be given is a drug that increases that risk."

Andrus agreed.

"Diabetic persons are very prone to heart disease, so you're increasing risk in the most at-risk population possible," he said.

One question that will arise in the litigation is whether the heart attack was caused by the drug or the disease.

When deciding whether to take a case, plaintiffs' attorneys will have to "rule out other risk factors," said Menzies, who is also speaking at the Avandia conference. "We'll be looking at whether a person's condition worsened at the time he or she started taking the drug."

Meanwhile, the defense side will start by attacking the new study.

Schachtman noted that of 48 trials that could have been studied, Nissen excluded the six that didn't report heart attacks or death from cardiovascular causes.

"The meta-analysis is no better than all the little studies polled together and the selection of the studies is highly suspect," he said.

In defending any over-promotion allegations, Schachtman said the company will have to bring to light the cost-benefit analysis for a patient using Avandia - something that sets it apart from a pain medication like Vioxx.

"If you don't treat Type II diabetes, you're going to lose your patient in a really horrible way," he said. "A jury will understand that this is not the sort of drug that gets promoted to make people feel good. It's to save lives."

And there are still some open questions for the plaintiffs.

"If someone has already come off the drug, how much time did he have to be on it before his risk was increased?" asked Saddlebrook, N.J., plaintiffs' attorney Barry Knopf, a partner with Cohn Lifland Pearlman Herrmann & Knopf.