

Drug Maker, FDA Taken to Task over Avandia Concerns

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GlaxoSmithKline, maker of the popular diabetes drug Avandia, came under fire on Capital Hill yesterday, as one prominent researcher testified that he was threatened with legal action when he raised concerns about the drug's safety as far back as 1999. At the same hearing, a member Congress berated the company's CEO for what he called an "absurd" warning regarding the drug's dangers to patients with heart failure buried within the product's label.

Stephen Lynch, (D-Mass), who sits on the House Oversight Committee, questioned why a statement cautioning physicians not to prescribe Avandia to patients with a history of congestive heart failure was not mentioned until page 15 of the products label.

"You're not seriously suggesting that it is a warning?" Lynch asked. "This is really absurd." Lynch also expressed concern that the wording of the warning was ambiguous.

During the hearing, the FDA announced that it would now require a "black box" warning about the risks the drug posed to patients with pre-existing cardiac problems to be placed on the front of the drug's packaging. The agency said it was taking this action because many doctors were not familiar with the warning contained within Avandia's label.

Although the controversy surrounding Avandia's warning label created much drama at yesterday's hearing, it was not the main focus of the proceeding. Instead, the hearing was called to examine the FDA's and GlaxoSmithKline's apparent failure to warn patients of other heart problems associated with the drug. These problems came to light last month after an analysis done by the Cleveland Clinic found that patients taking Avandia had a 43-percent higher chance of having a heart attack.

The committee also heard testimony from Dr. John Buse, a diabetes expert who raised questions about Avandia's cardiac risks in 1999. Dr. Buse told the committee that he felt pressured by the drug's maker, SmithKlineBeecham (now part of GlaxoSmithKline) to sign a clarifying statement drafted by the company that downplayed his concerns.

Congressman Henry Waxman (D-Calif), chairman of the committee, expressed chagrin that the FDA failed to act on the warnings of Buse and other researchers. Waxman questioned why the FDA had never required the drugs maker to conduct a post-market study of Avandia's possible heart risks, as a FDA reviewer had suggested when the drug was first approved.

The FDA has said that GlaxoSmithKline had alerted the agency to some safety concerns in 2005, but that both the agency and the manufacturer felt that more investigation was needed before conclusions could be made about Avandia's possible safety issues.

Avandia, one of the most popular drugs for Type II Diabetes, is taken by millions of patients, and accounts for \$3 billion in sales worldwide. However, some reports suggest that prescriptions for Avandia have dropped as much as 25-percent since controversy

over its safety erupted. Shares of the company's stock have also fallen nearly 11-percent since the Cleveland Clinic study was released last month.