

## Dingell, Stupak Question FDA & Glaxo for Failing to Warn Diabetics of Dangers of Avandia

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### NEWS RELEASE

Committee on Energy and Commerce

Rep. John D. Dingell, Chairman

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### Dingell, Stupak Question FDA & Glaxo for Failing to Warn Diabetics of Dangers of Avandia

Washington, D.C. - Rep. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce, and Rep. Bart Stupak (D-MI), Chairman of the Subcommittee on Oversight and Investigations, today pledged to investigate the failure of GlaxoSmithKline and the Food and Drug Administration (FDA) to warn diabetics of the increased risk of severe adverse cardiac issues attributable to the diabetes drug Avandia.

The lawmakers are responding to a study released today by the New England Journal of Medicine. The study, which was conducted by Dr. Steven Nissen, head of Cardiology at the Cleveland Clinic, found that diabetics taking Avandia (rosiglitazone) were more than 40 percent more susceptible to heart attack, stroke and death than those taking other treatments or placebo.

"We learned from an FDA briefing that the Agency has known about this problem for at least eight months and perhaps even longer," said Dingell. "What we don't know is why diabetics and their doctors haven't been notified of the substantial risk to the heart from a drug prescribed to protect the cardiovascular system."

Nissen studied data from Glaxo-sponsored trials that was reported both individually and in pooled form. The New England Journal of Medicine article also noted that another drug from the same class as rosiglitazone, Actos (pioglitazone) has been shown to be protective of the heart.

"It is incredible that the Agency charged with protecting the public health has such a poor record when it comes to post market drug safety," said Dingell. "Regrettably it is incidents like this that demand legislative changes in the way FDA deals with drug safety. The Committee will address these dangerous shortcomings while writing legislation to reauthorize PDUFA."

Stupak weighed in on the failure of the FDA to take action before the release of the Nissen study, "FDA's apparently callous disregard for the safety of diabetics taking Avandia is very reminiscent of the Agency's failure to move on Vioxx when substantial safety signals first became known. Like Vioxx, Avandia may have unnecessarily risked the lives of tens of thousands of Americans."

Stupak noted that the FDA has been less than cooperative with the Oversight efforts on drug and food safety issues. He said, "The FDA is on notice that we have reached the end of our rope on their stonewalling of investigations into their failures to keep Americans safe from dangerous drugs and poisonous foods. We are going to find out who in FDA knew about the dangers of Avandia, what they knew, and when they knew it. If the Commissioner's Office and the Center for Drugs think that we will tolerate delays and misinformation regarding Avandia like they have attempted in the Ketek matter and other Committee inquires, they are sorely mistaken."

Dingell and Stupak, along with Reps. Henry Waxman (D-CA), Chairman of the House Oversight and Government Reform Committee, and Ranking Minority Members Joe Barton (R-TX), Ed Whitfield (R-KY) and Tom Davis (R-VA), recently wrote to FDA Administrator Andrew von Eschenbach about Avandia. The letters dated April 30 and May 4, 2007 are attached.

See April 30, 2007 letter

See May 4, 2007 letter

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Prepared by the Committee on Energy and Commerce

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