United States Senate
Committee on Finance

Sen. Chuck Grassley · Iowa
Ranking Member

http://finance.senate.gov
Press_Office@finance-rep.senate.gov

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Grassley seeks transparency in FDA review of heart health risks with diabetes drug

WASHINGTON --- Sen. Chuck Grassley has asked the Food and Drug Administration to respond to accounts that an agency-convened drug safety oversight board voted earlier this month to keep Avandia on the market by a one-vote margin amid agency considerations of a second warning for the drug label about heart attack risks.

Grassley said sources indicate the board vote occurred on October 2, so he's also asking the FDA about the terms and conditions governing public notification with this sort of information.

The FDA first issued a heightened warning about Avandia and heart failure risk in August, following a May study that appeared in the New England Journal of Medicine regarding the drug's cardiovascular risks.

"The Avandia case continues to present new rounds of questions about the way the FDA monitors and assesses drug risks and decides whether to let the public know about emerging risks," Grassley said.

The text of Grassley's letter follows here.

October 26, 2007

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner von Eschenbach:

Since May of this year, I have been looking into a matter involving the Food and Drug Administration's (FDA) handling of Avandia, a pharmaceutical manufactured by

GlaxoSmithKline (GSK) to treat type II diabetes. At that time, the New England Journal of Medicine published a study that reported a 43% increase in the risk of myocardial infarctions/heart attacks in people taking Avandia and potentially a 64% increase in the risk of cardiovascular deaths.

In August, the FDA announced that GSK agreed to add a "boxed" warning on the Avandia label regarding heart failure risks. According to an article earlier this week by the Wall Street Journal, the FDA is discussing the possibility of a second "boxed" warning on the Avandia label-this time for heart attacks.[1] My Committee on Finance (Committee) investigators learned that the FDA recently convened its Drug Safety Oversight Board (DSOB). It was reported to the Committee by sources outside of the FDA that, among other things, the DSOB was asked to vote on the question of whether or not Avandia should be removed from the market. These same sources stated that the DSOB voted 8 to 7 to keep Avandia on the market. Among those who voted in favor of Avandia's removal was the Department of Veterans Affairs.

It is my understanding that the DSOB vote took place 24 days ago on October 2, 2007. To the best of my knowledge, I have yet to see any public notification of this vote. Accordingly, I would appreciate information from the FDA regarding the internal policies and procedures governing the DSOB and the terms and conditions governing the release of information from the DSOB to the public.

Thank you for your attention to this important matter.

Sincerely,
Charles E. Grassley
Ranking Member

[1] Wall Street Journal "Tougher Avandia Warning is Urged" October 24, 2007.