United States Senate
Committee on Finance
Sen. Chuck Grassley · Iowa
Ranking Member
http://finance.senate.gov
Press_Office@finance-rep.senate.gov

Floor Statement of U.S. Senator Chuck Grassley of Iowa
Safety of Avandia
Thursday, May 24, 2007

Mr. President. Over the last few days there have been countless articles about the popular diabetes drug Avandia. For me, some of the most important questions that need to be answered here are what did FDA know, when did it know it, and what did it do with the information.

Since The New England Journal of Medicine first reported on a new study by Cleveland Clinic Cardiologist Dr. Steven Nissen, my investigative staff has continued to gather information about both FDA and the drug maker.

We're hearing a lot about what's called the "RECORD" study, which was requested by the Europeans. There was talk at the FDA, before this week's stories started appearing, that the agency wanted to wait for that study to be completed before it made a decision about whether or not to say anything about Avandia and the possible increased risk in heart attacks. Believe it or not, FDA officials have confirmed for my investigators this week that the "RECORD" study is not expected to be completed for two more years, until the summer of 2009. That's a long time from now when you have millions of American's taking this drug.

Second, there is something I'd like to clarify. We've been reading this week that the FDA was not in a position to tell the American people about its concerns with Avandia because it needed "conclusive" information. That doesn't make sense to me. The preliminary findings of the FDA's ongoing "meta-analysis" of the Avandia clinical trials have been consistent with Dr. Nissen's findings of an increased heart attack risk, as well as the drug maker's findings. It goes like this: the drug maker sees a 31 percent increased risk of a heart attack; the FDA sees a 40 percent increased risk for heart attacks; and Dr. Nissen sees a 43 percent increased risk for heart attacks. Those numbers seem like a high enough threshold to me for the FDA to warn the American people of the possibility of a problem.

Third, several months ago, the Division of Drug Risk Evaluation, which sits within the Office of Surveillance and Epidemiology, recommended a "boxed" warning for Avandia. Why? Because it was believed that Avandia increased the risk of heart attacks. To date FDA has not acted on upon this recommendation.

In a statement I released on Tuesday, I also pointed out that about a year ago some FDA scientists recommended a black box warning for congestive heart failure. There is still no black box warning for congestive heart failure, and I understand that happened because the office that put Avandia on the market in the first place wanted to look into it further. America is still waiting for a decision.

It was also reported to me that the incidence of heart attacks with Avandia could be about 60,000 to100,000 from 1999 to 2006. That is a lot. Just doing the math and using conservative numbers, that means about 20 or more unnecessary heart attacks a day.

At a minimum, I think that the office responsible for post marketing safety needs to have the ability to warn Americans when it thinks it needs to do so. If not, we have what we have here today, delays in telling the American people about a possible serious safety problem. It's not right, and I am going to keep working to change things once and for all. The FDA legislation passed by the Senate two weeks ago dropped the ball on this important reform. The Avandia case sets it up for the House of Representatives to give real clout to the FDA office that monitors and assesses drugs after they're on the market and taken by millions of people. If the Office of New Drugs continues to call all the shots, like it does today, then it's more status quo and less public safety from the FDA. Both the evidence and the experts underscore the need for real reform here.

One opportunity to improve upon post-marketing drug safety stems from the Access to Medicare Data Act that I filed today with Senator Baucus. This bill is based on S.3897, the Medicare Data Access and Research Act, which Senator Baucus and I introduced in the 109th Congress. The purpose of the bill is to provide federal health agencies and outside researchers more sources of data for examining adverse events so that serious safety questions are identified promptly and timely action can be taken to protect American consumers.