

United States Senate
Committee on Finance
Washington, D.C. 20510

For Immediate Release
Wednesday, June 6, 2007

Senators ask for details of effort to muzzle a doctor's concern about Avandia risks

WASHINGTON — In response to testimony given today to a House committee reviewing the safety of the diabetes drug Avandia, Sens. Chuck Grassley and Max Baucus today asked GlaxoSmithKline and the University of North Carolina to account for intimidation of a medical researcher who suggested the drug may carry risks beyond those contained in the FDA label on the drug.

“Today’s testimony reveals a repeat in the pattern we’ve seen unfold during the last three years, starting with Vioxx, where extraordinary efforts are taken to protect drug sales at the expense of public safety. It’s the FDA’s job to overcome these efforts and make certain that science and safety prevail,” Grassley said. “I’ve become convinced that the FDA’s current structure doesn’t give the post-market surveillance of drugs the voice and power that’s necessary to protect the public, and I’m committed to do everything possible to strengthen the FDA’s monitoring of drugs once they are the market.”

“If pharmaceutical executives tried to silence a researcher who found safety issues with Avandia, then we’ve found a whole new level of culpability here. If credible research exposes the risk of death for patients taking a drug, then any drug company attempt to squelch that information would be morally reprehensible,” said Chairman Baucus. “The Finance Committee has a responsibility to root out the facts and take whatever action is appropriate to protect Medicare and Medicaid beneficiaries.”

Baucus is Chairman and Grassley is Ranking Member of the Senate Committee on Finance. The text of their letters to the drug maker and the university follows here.

June 6, 2007

Mr. Christopher Viehbacher
President
U.S. Pharmaceuticals
GlaxoSmithKline
5 Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Mr. Viehbacher:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs and, accordingly, a responsibility to the more than 80 million Americans who receive health care coverage under those programs to ensure that beneficiaries receive drugs that are both safe and effective.

At a congressional hearing today on the Food and Drug Administration's role in assessing the safety of the diabetes drug Avandia, Dr. John Buse, a professor of medicine at the University of North Carolina School of Medicine, stated that a high-ranking person at SmithKline Beecham (SB), which is now part of GlaxoSmithKline, made phone calls to his department chairman soon after presentations he gave in 1999 on the possible cardiovascular risks of Avandia. Dr. Buse testified that his department chairman informed him, as a consequence of his presentations, that SB suggested that it could hold Dr. Buse liable for the company's resulting \$4 billion decrease in market capitalization. According to Dr. Buse, the department chairman added that some at SB characterized Dr. Buse as a "liar" and "for sale." Dr. Buse stated that he later "signed a clarifying statement drafted by SB" to be used with the "investment community."

In response to the company's accusations, Dr. Buse wrote a letter to SmithKline Beecham, stating, in pertinent part:

I may disagree with SB's interpretation of data. I am not for sale. I am anxious to help in any way that I can to establish rosiglitazone as a safe and effective antidiabetic agent with certain stipulations. I cannot change my opinions in the absence of new data or understanding, in large part because I am not for sale. I look forward to working with SB in the future, but will understand and not take offence if I do not. Please call off the dogs. I cannot remain civilized much longer under this kind of heat.

Dr. Buse's testimony is of serious concern to us because we believe that scientists should be able to raise issues related to public health and safety in a free and uncensored manner. In fact, they may have an ethical duty to do so. In a letter to you on May 21, 2007, we raised concerns about allegations that "GSK employees silenced one or more medical professionals who attempted to speak out about the potential for cardiovascular problems with Avandia." That same day, GSK issued a press release that said that any suggestion that GSK has "attempted to silence independent investigation of data is absolutely false." We believe that the press release is not responsive to the allegations we raised in our letter. We would appreciate a direct response to our concerns, including any other similar situations of which the Committee should be aware.

Dr. Buse's testimony called to our minds troubling memories of how Merck & Co. sought to silence Dr. Gurkupal Singh of Stanford University when he raised concerns about Vioxx. In Dr. Singh's written testimony to the Committee on November 10, 2004, he noted "a persistent pattern of intimidation" by Merck which he characterized as "unethical." As Dr. Singh wrote, "An open scientific debate was important - it is only through open debate and discussion that we advance science." We certainly agree.

We look forward to hearing from you regarding the concerns and questions set forth in this and our May 21, 2007 letters by no later than June 11, 2007.

Sincerely,

Max Baucus
United States Senator
Chairman of the Committee on Finance

Chuck Grassley
United States Senator
Ranking Member of the Committee on Finance

June 6, 2007

James Moeser, PhD
Chancellor
University of North Carolina at Chapel Hill
103 South Building
Campus Box 9100
Chapel Hill, NC 27599-9100

Dear Chancellor Moeser:

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As Chairman and Ranking Member of the Committee, we have a duty to protect the Medicare and Medicaid programs, including safeguarding taxpayer dollars appropriated by Congress. Recently, we initiated an inquiry into the handling of safety concerns related to Avandia. We are very concerned about allegations that GlaxoSmithKline sought to stifle scientific debate about the drug. Dr. Buse's testimony today justifies our concern.

Accordingly, we request that you provide us with copies of all pertinent documents concerning Avandia, including, but not limited to, contracts, agreements and/or other legal instruments between GlaxoSmithKline and the University of North Carolina and/or its researchers, employees, staff or officials. We also request copies of all documentation of contacts and communications between researchers, employees, staff and officials at your university and representatives of GlaxoSmithKline regarding Avandia.

We appreciate your cooperation. We look forward to your response by no later than June 29, 2007.

Sincerely,

Max Baucus
United States Senator
Chairman of the Committee on Finance

Chuck Grassley
United States Senator
Ranking Member of the Committee on Finance