

Avandia Safety Scandal Won't Go Away, As Senators Seek to Question Former Glaxo Exec

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The addition of a new Avandia black box warning about heart attack risk has done little to quell criticism over the way GlaxoSmithKline, the drug's manufacturer, and the Food & Drug Administration (FDA) handled concerns over Avandia safety. Earlier this week, a Senate Committee report found that Glaxo had engaged in a concerted effort to intimidate a leading diabetes doctor in order to force him to stay silent about his Avandia concerns. Now, two prominent senators are seeking to question a former Glaxo executive who was allegedly involved in that intimidation campaign.

Avandia was linked to a higher risk of heart attack by a study published by the Cleveland Clinic in May. That study, an analysis of 42 different clinical trials, showed that patients taking Avandia had a 43-percent higher risk of having a heart attack. Following that publication, both the Food & Drug Administration (FDA) and Glaxo were criticized for not taking the heart attack risk more seriously. Testimony at a congressional hearing in June revealed that the company and the FDA had known about the heart attack risk as far back as September 2005. That congressional investigation also uncovered allegations that in 2005, an unnamed FDA scientist who had advocated for a strong black box warning on Avandia about its risk for congestive heart failure had been removed from an Avandia safety review.

On Monday, a Senate Finance Committee report alleged that Glaxo tried to silence Dr. John Buse, a diabetes expert and professor of medicine at the University of North Carolina in Chapel Hill. In 1999, Dr. Buse began expressing concerns about the cardiovascular risks of Avandia. Earlier this summer, the Senate committee heard testimony from Dr. Buse, who said 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. During his testimony, Dr. Buse described name-calling and what he said was the veiled threat of a lawsuit by a high-ranking drug company executive after he had criticized Avandia at a medical meeting. Dr. Buse also testified that Glaxo complained about him to his supervisors at the University of North Carolina. This week's Senate committee report implicated Glaxo Chief Executive Jean-Pierre Garnier and former research chief Dr. Tachi Yamada in the intimidation campaign against Dr. Buse.

Now, Senators Max Baucus (D-Mont.) and Charles Grassley (R-Iowa) want to speak with Dr. Yamada, who left Glaxo recently to join the Bill and Melinda Gates Foundation. In a letter to Dr. Yamada dated November 16, the Senators requested a meeting with him because of the "significant role" Yamada allegedly played in Glaxo's campaign against Dr. Buse.

Earlier this week a Glaxo spokesperson told the Wall Street Journal that the company was only trying to correct "inaccuracies" when it contacted Dr. Buse. "People at the time were very passionate about this new medicine and could perhaps have handled the interactions with Dr. Buse better," the Glaxo spokesperson said. "We did apologize to Dr. Buse for the tone of some of the conversations."

A representative for Dr. Yamada told Reuters news agency that he would be willing to meet with congressional staff.