

Avandia Risks Pointed out by FDA Scientist Results in Removal From 2005 Safety Review Board

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A senior Food & Drug Administration (FDA) scientist was kicked off an Avandia review in 2005 after raising concerns about the drug's safety. Now, two senators have sent a letter to the FDA demanding to know the reason.

The name of the scientist, who was once the FDA's primary reviewer for Avandia, has not been revealed. The scientist has told congressional investigators that in 2005, he or she advocated for a strong "black box" warning on Avandia about a risk for congestive heart failure. Shortly afterwards, this person was told to stop participation in the Avandia review.

Senator Max Baucus (D-Montana) and Charles Grassley (R-Iowa) sent a strongly worded letter to the FDA regarding the scientist's dismissal. "This allegation is especially significant and raises our level of concern about FDA interference in safety decisions regarding Avandia," the letter said. A spokesperson for the agency said that the FDA had received the senators' letter, and was working on a response.

The scientist's allegations are only the latest disturbing revelation in the sordid story of Avandia. The drug has been under intense scrutiny since May when an analysis of 42 clinical trials published by the Cleveland Clinic showed that patients taking the drug had a 43-percent higher risk of having a heart attack. Recently, the drug's maker, GlaxoSmithKline, and the FDA have come under fire for an apparent failure to warn the public about the cardiac risks associated with Avandia. Testimony at a congressional hearing last month revealed that the company and the FDA had known about the heart attack risk as far back as September 2005.

The Avandia controversy has hit GlaxoSmithKline hard. In 2006, Avandia generated \$3.3 billion in sales, making it the company's second highest selling drug. Since the revelations of possible heart risks were made public, however, prescriptions of Avandia have plunged, and global sales of the drug have dropped more than 23-percent. At least one lawsuit has been filed by the family of a man who suffered a fatal heart attack while taking Avandia, and others will surely follow. GlaxoSmithKline is also a defendant in a class action suit brought by some of its shareholders. That suit alleges that the company deliberately withheld information about Avandia's safety problems from investors.

While both Glaxo and the FDA insist that other studies contradict the Cleveland Clinic analysis, the agency did finally order a black box warning about heart failure risks associated with Avandia in June. On Monday, the agency will hold a meeting of an outside panel to investigate Avandia's safety issues