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BAUCUS, GRASSLEY FIND COMPANY FAILED TO PROMPTLY ALERT FDA ABOUT DRUG RISKS

Finance Leaders Send Findings to FDA Regarding Safety of Diabetes Drug Avandia

Washington, DC - Senate Finance Committee Chairman Max Baucus (D-Mont.) and Ranking Member Chuck Grassley (R-Iowa) provided recent findings from their ongoing inquiry into diabetes drug Avandia to the Food and Drug Administration (FDA) on Monday. The Finance Committee inquiry uncovered documents suggesting that GlaxoSmithKline, the manufacturer of Avandia, failed to publish studies that found serious health risks associated with Avandia in a timely manner and actively promoted the drug despite the known safety concerns.

"Information is the most important tool the FDA has to protect American consumers, and the documents we uncovered in our investigation will help arm the FDA with the best information possible as it evaluates Avandia's safety," Baucus said. **"Patients and doctors have a right to know the risks of the medicines they use and prescribe, and drug companies have a responsibility to release data regarding safety concerns about their products. We will continue working with the FDA on Avandia to ensure patients and doctors have the information they need to make safe, informed decisions about their medications."**

"What's happened with this drug further makes the case about the need to strengthen the office within the FDA that monitors drug safety after a drug is on the market and being sold to patients. The inequality between the FDA's post-market office and the FDA office that decides whether to approve a drug for market in the first place has led to FDA physicians and scientists who are committed to the post-market monitoring of drugs being suppressed or even ignored. I'll continue my effort to achieve this reform. A lack of accountability damages public confidence and hope in new drugs. Trust can be rebuilt through the work of a more independent FDA," Grassley said.

Among the documents the Finance Committee uncovered are internal emails showing that GlaxoSmithKline attempted to downplay scientific findings about the safety of Avandia as far back as 2000. Additionally, the committee found Avandia was part of the drug manufacturer's ghostwriting campaign – a practice by which drug companies initiate authorship of articles, often through a medical education or communications company, that are then marketed to medical journals for publication under the names of doctors without public disclosure that the drug company sought the article in the first place.

Baucus and Grassley sent the letter and associated documents to the FDA this week as the Agency began its advisory board meeting to examine the health risks associated with Avandia, if any, and determine the next steps to ensure patient safety. The recent findings are part of Baucus and Grassley's ongoing inquiry into the safety of Avandia. The Finance leaders released a detailed report on the diabetes drug in February 2010, available on the committee website at: **http://finance.senate.gov/newsroom/chairman/release/?id=bc56b552-efc5-4706-968d-f7032d5cd2e4**.

The letter the Finance leaders sent to the FDA Monday and the associated documents are available on the Finance Committee website at: **http://finance.senate.gov/newsroom/chairman/download/?id=a5c07780-6351-4905-8c63-52e4a7a7a66b**.

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