# Glaxo defends handling of Avandia heart risks

24 February 2010, By MATTHEW PERRONE , AP Business Writer

(AP) -- GlaxoSmithKline said Wednesday a Senate report criticizing its handling of heart risks with its diabetes drug Avandia "mischaracterizes and distorts" the company's record.

In a memo posted online, the British drugmaker takes aim at the highly critical Senate Finance Committee report that has reignited debate around its troubled diabetes treatment.

The Food and Drug Administration added a warning about potential heart attacks to Avandia in 2007, but the scope of that risk is still not fully understood.

The Senate report, issued over the weekend, charged that Glaxo downplayed the drug's safety risks and withheld important data from the FDA.

"That suggestion is fundamentally flawed and contradicted by the record of extensive, ongoing interactions between GSK and the FDA," states the company.

According to the 30-page Glaxo document, the company voluntarily submitted data on Avandia's heart effects in 2005, and has steadily updated the government since then.

The company also blasts Senate investigators for excluding results of several recent studies that appear to support Avandia's safety.

One trial, called RECORD, followed patients for five years and found no difference in heart-related hospitalization or death between those taking Avandia versus other treatments.

"The absence in the staff report of any reference to the final results of these studies ... leaves the record incomplete," Glaxo states.

Avandia was Glaxo's third best-selling drug in 2006 with revenue of $2.2 billion. But the safety concerns disclosed the following year slashed revenue to $1.2 billion by 2008.

The debate over Avandia was sparked by a May 2007 analysis that showed a 43 percent higher risk of heart attack for patients taking Avandia compared to other diabetes drugs or no diabetes medication.

Because the analysis involved results from dozens of different studies, experts have continued to debate its accuracy.

In 2007, the FDA's panel of outside experts voted 22-1 to keep Avandia on the market.

The FDA has scheduled another meeting for July to have the panel re-examine the issue.