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## **GSK rejects conclusions of Senate Committee on Finance Staff Report on *Avandia***

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The Staff Report of the Senate Committee on Finance draws conclusions on the safety of *Avandia* (rosiglitazone) that are based on analyses that are not consistent with the rigorous scientific evidence supporting the safety of the drug. In addition, the report cherry-picks information from documents, which mischaracterizes GlaxoSmithKline's comprehensive efforts to research *Avandia* and communicate those findings to regulators, physicians and patients. In fact, the safety and effectiveness of *Avandia* is well characterized in the label approved by the FDA.

Contrary to the assertions in the report, and consistent with the FDA-approved labelling, the scientific evidence simply does not establish that *Avandia* increases cardiovascular ischemic risk or causes myocardial ischemic events. In 2007, the FDA considered all the available scientific evidence on *Avandia*, including Dr. David Graham's assertions of elevated heart attack risk and demands that the product be withdrawn. Based on the scientific evidence and a recommendation by an independent advisory committee of experts convened by the FDA, the agency has ruled that *Avandia* remain available to patients for the treatment of Type 2 diabetes.

In the years since the FDA addressed these questions about the cardiovascular safety of *rosiglitazone*, seven large, prospective, randomized, clinical trials have reported results. None of these randomized clinical trials, which remain the gold standard for evaluating scientific and medical questions, show a statistically significant association between *rosiglitazone* and myocardial infarction (heart attack) or other ischemic cardiovascular events. For instance, RECORD demonstrated that *rosiglitazone* was not associated with an overall increase in cardiovascular hospitalization or death compared to those treated with metformin and sulfonylureas. Additionally, independent investigators, Mannucci et al., have conducted the largest, most comprehensive meta-analysis of *rosiglitazone* clinical trials to date (164 clinical trials) and found no association between *rosiglitazone* and myocardial infarction.

Patient safety is a priority at GSK and the company's efforts to understand the cardiovascular safety profile of *Avandia* began before submission of the initial marketing authorization application for *Avandia* and continue to this day. GSK has rigorously followed an extensive and long-term program of scientific study, which is the most comprehensive program of scientific analysis for any oral anti-diabetes medicine available to patients today, with clinical trial experience in well over 52,000 patients.

GSK has consistently shared this data with regulators around the world, and worked with them to ensure that the *Avandia* product labeling is updated to add cardiovascular and other safety information as new data become available so that physicians can make the best treatment choices for their patients.

The assessment of the safety of *Avandia* is continuing now with a clinical trial called TIDE which was mandated by the FDA. The protocol for conducting the study was developed with and approved by FDA. The TIDE protocol has also been approved by an independent review board and appropriate safety boards that are responsible for monitoring and assessing the safety of the trial in Type 2 diabetes patients.

GSK welcomes and supports open and independent scientific debate about its products. To that end, we have posted the results of our clinical trials as well as meta-analyses and observational studies on our website for all to see. GSK does not condone any effort to silence scientific debate. When GSK believes that statements made by others don't accurately present information on its products or its actions, GSK corrects inaccuracies and misstatements.

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