

Older Avandia Patients Have Higher Rates of Heart Attacks, Death

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Avandia puts older patients at a significantly higher risk of heart attack and death, says a new study. The research, conducted by the Institute for Clinical Evaluative Sciences in Toronto, Canada, is just the latest scientific evidence to highlight Avandia's safety issues. Only last month, a black box warning detailing Avandia's heart attack risks was added to the label of the controversial diabetes drug, but that move has done little to quiet critics who believe Avandia should be pulled from the market.

Avandia has been a subject of debate since May 21, 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. This latest Avandia study, published in the "Journal of the American Medical Association" analyzed drug use and health outcomes for 159,000 people age 65 and older treated for Type 2 diabetes in Ontario, Canada. Of those patients, 2,268 people were being treated with Avandia. The analysis found that for every 100 people taking Avandia over a four-year period there would be five additional deaths, four additional heart attacks and three additional episodes of heart failure.

Dr. Steven Nissen, who headed the Cleveland Clinic Avandia study, told The New York Times that the Canadian research mirrored his findings, and said that they should prompt the Food & Drug Administration (FDA) to take another look at Avandia. "As you accumulate more and more evidence that Avandia has this problem, and it involves a very serious consequence, namely heart attack and death, it puts a lot of pressure on the FDA to do more," Dr. Nissen said.

But at this time, the FDA does not seem inclined to act on the findings of the latest Avandia study. In a statement released yesterday, the agency said that the Canadian research would not change its recommendations on Avandia. "The information FDA provided for the most recent labeling change remains accurate — the data are inconclusive and we have added a boxed warning to the labeling to ensure that health care professionals and patients are aware of this potential risk and can take this into account as they make individual prescribing decisions," the statement read.

The FDA's stance will not surprise many Avandia critics, who feel the agency has been less than aggressive in dealing with the drug's safety problems. Over the summer, GlaxoSmithKline, the maker of Avandia, and the FDA came under fire for an apparent failure to warn the public about the cardiac risks associated with Avandia. 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 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.

Even after Avandia's heart attack risk became clearer, the FDA spent months negotiating with Glaxo over the wording of a black box warning. The FDA's decision last month to finally add a black box label to Avandia did little to quiet critics, who

charged the wording was too weak. That black warning states that “the available data on the risk of myocardial ischemia are inconclusive.”