

## FDA issues safety alert on diabetes drug

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The widely prescribed diabetes drug Avandia is linked to a greater risk of heart attack and possibly death, a new scientific analysis revealed, and the U.S. government issued a safety alert Monday.

The Food and Drug Administration urged diabetics taking the pill to talk to their doctors, but stopped short of forcing a sharper warning label on the drug sold by GlaxoSmithKline PLC of London.

More than 6 million people worldwide have taken the drug since it came on the market eight years ago. Pooled results of dozens of studies revealed a 43 percent higher risk of heart attack, according to the review published by the New England Journal of Medicine.

Experts said the overall risk was small and cautioned people not to stop taking the drug on their own but to talk to their doctors.

The company downplayed the report of heart risks, saying the analysis by Dr. Steven Nissen and statistician Kathy Wolski at the Cleveland Clinic is not definitive scientific proof. In a conference call Monday, Dr. Lawson McCartney who leads Glaxo's diabetes drug development, said the company is not seeing "anything like" the problems reported in the medical journal.

"We remain very confident in the safety and of course in the efficacy of Avandia as an important diabetic medicine," McCartney said.

The government will take no immediate action on a label change or other measures regarding the drug, said Dr. Robert J. Meyer of the FDA's Center for Drug Evaluation and Research.

Some data suggests "that there is a potentially significant increase in the risk" but there also is risk if patients switch drugs or do not keep their blood-sugar under control, an FDA statement says.

FDA officials acknowledged that Glaxo submitted information last August indicating some increased risk from the drug but that other studies were contradictory. However, several members of Congress expressed alarm and said they would hold hearings on the safety issues.

Avandia is used to treat Type 2 diabetes, the most common form of the disease, which is linked to obesity and afflicts 18 million Americans and 200 million people worldwide. This form of diabetes occurs when the body does not make enough insulin or cannot effectively use what it manages to produce.

Avandia helps sensitize the body to insulin and was considered a breakthrough medication for blood-sugar control.

Worried patients should not quit Avandia on their own and should discuss concerns with their doctors, wrote Drs. Bruce Psaty and Curt Furberg in an editorial in the New England Journal. Psaty is with the University of Washington in Seattle and Furberg is with Wake Forest University.

However, to the extent that the new analysis shows valid risks, the drug "represents a major failure of the drug-use and drug-approval processes in the United States," they said.

When the drug was approved, "evidence was at best mixed" on its benefit, wrote the two doctors. Both have been frequent critics of the FDA's failure to spot dangers in the drug approval process and its conduct in the case involving Vioxx. The popular arthritis medicine sold by Merck & Co. was taken off the market in 2004 when heart problems came to light after it had been taken by millions of people

Several experts said Avandia was another example of the FDA failing to detect a safety problem early enough.

The report on the diabetes drug's risks follow Glaxo's \$2.5 million settlement of a lawsuit filed by former New York Attorney General Eliot Spitzer over the release of data on the safety and effectiveness of its drugs. Spitzer, now New York governor, accused Glaxo of fraudulently withholding some results of studies that had examined the safety of prescribing the antidepressant Paxil to children.