

Avandia Liver Failure Reports Prompt Call for Ban

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Avandia has been linked to more than a dozen cases of liver failure, most of which proved fatal. Reports of liver failure and deaths linked to Avandia have prompted the consumer group Public Citizen to file a petition with the Food & Drug Administration (FDA) asking that the diabetes drug be removed from the market.

Public Citizen said yesterday it had identified 14 cases of Avandia-induced liver failure in the FDA's Adverse Event Reporting System. Of the 14 cases of liver failure, 12 resulted in deaths.

The liver failure associated with Avandia, taken together with the drug's risk of other side effects, including heart failure, fractures and vision loss, was too great to allow the drug to continue to be sold in U.S., the group's petition said.

"The scientific evidence against Avandia is overwhelming," Dr. Sidney Wolfe, director of Public Citizen's Health Research Group, said in news release. "The timing of these findings should give the FDA the momentum it needs to act swiftly to prevent further needless deaths and health damage by banning this drug."

Public Citizen said that Avandia should be banned because safer, more effective drugs for type 2 diabetes already exist.

Public Citizen is just the latest group to criticize Avandia. Earlier this month, the American Diabetes Association/European Association for the Study of Diabetes working group dropped Avandia from its treatment guidelines.

Avandia has been a subject of controversy since May 2007, 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. In June 2007, Congress held hearings to discuss the FDA's handling of its safety issues. At those hearings, it was revealed that in 2005 GlaxoSmithKline had informed the FDA of a study it had conducted that produced similar results. However, both the agency and the manufacturer felt that more investigation was needed before conclusions could be made about Avandia's possible safety issues. Thus, the public was not made aware of the Avandia heart attack risk until the publication of the Cleveland Clinic article.

Since the May 2007 study was published, the number of people taking Avandia worldwide dropped from 13.2 million in 2006 to 4.6 million for the last full year. But according to Public Citizen, around 10,000 Avandia prescriptions are still being filled every day.

Earlier this summer, an FDA advisory panel recommended that new diabetes drugs be subject to more stringent safety testing. In particular, the panel recommended pre-market studies designed to make sure new medications don't raise risks of heart problems.