

Avandia Reviewer Calls for Changes in FDA Drug Approval Process

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The Avandia debacle has prompted a safety official from the Food & Drug Administration (FDA) to call for changes in the way diabetes medications are approved for use in the United States. The FDA official, who reviewed the original approval application for Avandia, told the Journal of Diabetes Care that the safety and effectiveness of experimental diabetes medications should be tested against existing drugs before they are approved. If such a testing protocol were to be adopted by the FDA, it would mark a significant departure from the way most medications are granted approval in the United States.

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. Since the Cleveland Clinic study was published, a great deal of controversy has swirled around Avandia. In June, Congress held hearings to discuss Avandia and the FDA's handling of its safety issues. At those hearings, it was revealed that GlaxoSmithKline, Avandia's manufacturer, 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. Since those revelations were made public, the FDA has been under a great deal of pressure to take action on Avandia.

In July, the FDA convened a panel to discuss the issues surrounding Avandia's heart attack risk. The panel voted 20-3 that the drug did in fact raise the chance of heart attacks, yet the panel still voted 22-1 to allow it to remain on the market. They recommended that Avandia be given a warning label about the cardiac problems. The FDA did finally add that black box warning to the Avandia label this month.

Now, Dr. Robert Misbin, an FDA safety reviewer who worked on the original Avandia approval, has called for changes in the way such drugs are handled by the FDA. Currently, an experimental drug is tested against a placebo. But Dr. Misbin now feels that diabetes drugs like Avandia, should be tested against other drugs currently on the market. In his interview with the Journal of Diabetic Care, Dr. Misbin likened comparing a drug's effectiveness to a placebo to evaluating it in a vacuum. Dr. Misbin argued that putting an experimental medication up against a tried and true existing drug would give medical reviewers a better idea of the new medication's efficacy and safety.

Dr. Misbin focused his comments on diabetes drugs, because he was part of the Avandia approval process, and because the subsequent safety issues surrounding Avandia highlighted weaknesses in the FDA approval system. Misbin also said because there are so many safe and effective diabetes medications on the market now, experimental diabetes drugs should have to pass more hurdles to be approved by the FDA.