
May 25, 2007

Senator Says F.D.A. Was Lax on Label For Avandia

Federal regulators did not act on a recommendation from their safety reviewers several months ago that GlaxoSmithKline's diabetes drug Avandia should carry the strongest possible caution about heart attacks, Senator Charles Grassley said Thursday in a statement.

Mr. Grassley, Republican of Iowa, said in a statement that some Food and Drug Administration staff members had concluded that prescribing information for the medicine should include a warning framed by a black box, the most serious type of alert.

Lawmakers have raised questions about the F.D.A.'s handling of Avandia since May 21, when an analysis released by The New England Journal of Medicine found patients on Avandia were 43 percent more likely to have a heart attack. Mr. Grassley has repeatedly criticized the agency for ignoring safety reviewers' advice about other products, including Merck's Vioxx painkiller, which was linked to increased heart risk.

"Over the last few days there have been countless articles about the popular diabetes drug Avandia," Mr. Grassley said in the statement. "For me, some of the most important questions that need to be answered here are what did F.D.A. know, when did it know it, and what did it do with the information."

The F.D.A. is still reviewing data on Avandia's heart attack risks and says it has not reached conclusions. Glaxo said more reliable, longer-term studies found no greater risks than for other diabetes drugs. Avandia, approved in the United States in 1999, was the world's top-selling diabetes pill and had \$3 billion in sales last year.

The recommendation for Avandia was made by the division of drug risk evaluation within the agency's Office of Surveillance and Epidemiology, which monitors safety, Mr. Grassley said. His statement did not say why the agency took no action on the advice.

The F.D.A. would not comment on Grassley's statement about the heart attack warning because of "ongoing regulatory matters," an agency spokeswoman, Julie Zawisza, said in an e-mail message.