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Press_Office@finance-rep.senate.gov

MEMORANDUM

TO: Reporters and Editors
FR: Jill Kozeny, 202/224-1308
for U.S. Sen. Chuck Grassley of Iowa
RE: FDA Black Box Warning for Avandia
DA: Wednesday, Nov. 14, 2007

Sen. Chuck Grassley issued the comment below about the decision announced today by the Food and Drug Administration to add a new warning to the existing black box on the diabetes drug Avandia. The new warning concerns the drug's risk for heart attacks. The FDA first applied a black box to Avandia in August concerning the drug's risk for heart failure. The agency said publicly that a black box was needed in June, following an analysis that appeared in May in the *New England Journal of Medicine* regarding the drug's cardiovascular risks. Sen. Grassley has questioned the FDA's handling of information about emerging safety questions with Avandia and sought greater transparency with new information for patients and their doctors.

Sen. Grassley's comment:

"The good news is, the Food and Drug Administration is taking action to better inform the public about a major safety issue with this popular diabetes drug. The bad news is, 2014 is a long time to wait for a more definitive review of the drug's risks and benefits.

"Overall, this case is a clear example of the problem within the FDA, where the views of the office that reviews drugs after they're on the market must play second fiddle to the position of the FDA office that approved a drug for the market in the first place. The system is off balance, and that's not good for public safety."