U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
http://finance.senate.gov

M E M O R A N D U M

TO: Reporters and Editors
FR: Jill Kozeny, 202/224-1308
RE: Celebrex, drug safety
DA: Friday, Dec. 17, 2004

Sen. Chuck Grassley issued the comment below in response to the announcement made today that the painkiller Celebrex increased the risk of heart attacks in a new study.

As Chairman of the Senate Committee on Finance, Sen. Grassley has looked into the reluctance of the Food and Drug Administration to provide information to the public about the increased risk for suicide with young people taking antidepressants. His committee has examined how the Food and Drug Administration handled information about cardiovascular risks with Vioxx, as well as the way that the Food and Drug Administration manages its own scientists and interacts with pharmaceutical drug makers.

Sen. Grassley has called on the Food and Drug Administration to do business in a way that's more open and transparent and to demonstrate a far stronger commitment to the scientific process and leadership in the area of drug safety. He has said that the agency needs to show that "its relationships with drug companies is arms length rather than arms locked." Sen. Grassley has announced plans to offer two pieces of legislation in the new Congress. The first would empower the FDA's Office of Drug Safety and distance its work from the Office of New Drugs. The second would empower the public and the scientific community by creating a public registry for all clinical trials conducted on prescription drugs. Earlier this month, Sen. Grassley asked the Inspector General for the Department of Health and Human Services to investigate the way the National Institutes of Health handled information about the safety of an AIDS drug.

Here is the comment Sen. Grassley issued today:

"Right now we have a situation where the public is left wondering when the next shoe might drop when it comes to drug safety. Today, Pfizer released information about an increased risk of heart attack for its drug Celebrex, and Eli Lilly issued a new warning about liver problems with the drug Strattera. The last year revealed serious problems involving children and antidepressants, painkillers like Vioxx, Bextra and Celebrex, the flu vaccine, and the AIDS drug nevirapine. At this point, no one can say with confidence whether the worst drug safety problems are behind us or ahead of us. Given these problems, it seems the time has come for a

comprehensive review of drug safety and of how federal government agencies oversee drug research and approve, license and regulate drugs. An independent commission of experts – along the lines of the 9-11 commission – could provide valuable recommendations for both the executive and legislative branches about changes that could enhance drug safety in the United States.

"The status quo can't stand. The Food and Drug Administration, for example, has earned a good reputation with decades of good work. But serious mistakes have taken place and lives may have been risked and lost. By having scientific experts scrutinize what's happened and make well-informed recommendations, both the executive branch and Congress could make reforms and strengthen public confidence in prescription drugs and the agencies that regulate those drugs."