United States Senate
Committee on Finance

Sen. Chuck Grassley · Iowa
Ranking Member

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M E M O R A N D U M

TO: Reporters and Editors
FR: Jill Kozeny, 202/224-1308
for Sen. Chuck Grassley
RE: Conflicts of interest among FDA panel members
who will be serving on the Avandia advisory committee of the FDA
DA: Friday, July 13, 2007

Sen. Chuck Grassley issued the comment below about the Food and Drug Administration posting information on its website today regarding conflicts of interest among FDA panel members who will be serving on the Avandia advisory committee of the FDA.

Sen. Grassley's comment:

"It's good to see the FDA post information about conflicts in a timely way. Transparency is key to greater accountability. Accountability would also be enhanced if the FDA office that's responsible for drug safety had a meaningful role in this advisory board meeting. Instead, reports indicate the meeting is being put together by the FDA office of new drugs. It was the FDA office of new drugs that defended Avandia when concerns were first raised about the drug and also prompted the reprimand of Dr. Johann-Liang when she signed off on a black-box warning for Avandia. It seems so obvious that post-market safety decisions should be handled by the FDA's office in charge of drug safety. This office needs clout and independence to call the shots and look out for public safety."

Background Information:

Strengthening the FDA Office of Drug Surveillance and Epidemiology has been a central focus of Sen. Grassley's efforts to fix problems at the FDA.

In January, he and Sen. Christopher Dodd introduced for the second time two bills to revamp and prioritize the post-market surveillance process within the FDA and to greatly expand public access to information about all clinical trials through a registry and results database. Their bills are S.468, the Food and Drug Administration Safety Act of 2007, and S.467, the Fair Access to Clinical Trials Act of 2007. In May, Sen. Grassley offered an amendment to the Food and Drug Administration Revitalization Act of 2007 that would have made the FDA office that

studies drugs after they're on the market an equal partner with the FDA office that initially approves drugs for all post-approval decisions related to the safety of drugs that are on the market. The amendment was defeated by only one vote.

Sen. Grassley has conducted active oversight of the FDA for the last three years and has put pressure on the drug safety agency to act with more independence and transparency in order to restore public confidence and strengthen public safety especially when it comes to drugs already on the market. Sen. Grassley has called the FDA's relationship with the drug industry "too cozy" and revealed how agency leaders have acted to suppress scientific dissent regarding agency actions and drug-safety recommendations.