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MEMORANDUM

TO: Reporters and Editors
FR: Jill Kozeny, 202/224-1308
for U.S. Sen. Chuck Grassley of Iowa
RE: Questions about statements regarding drug trial
DA: Wednesday, February 6, 2008

Sen. Chuck Grassley is asking drug maker GlaxoSmithKline for documents regarding the antidepressant medication Paxil. Sen. Grassley is making his request based on a review of documents recently made public and reported today in the magazine *New Scientist*. The newly public documents include a report about risks of suicidal behavior associated with Paxil. Nine pages of that report are missing in the publicly available material. In May 2006, GlaxoSmithKline distributed a "Dear Healthcare Professional" letter informing doctors of "a higher frequency of suicidal behavior" associated with Paxil compared to placebo. The *New Scientist* report today indicates that GlaxoSmithKline allegedly knew about such an increased risk in 1989.

Sen. Grassley's comment:

"With new questions about when GlaxoSmithKline knew about risks for suicidal behavior compared to when it let the public know about those risks, it seems like it'd be in the drug maker's best interest to provide every bit of information about this issue. At this point, any sense that more information is being withheld only leads to more suspicion about what went on and what still might be going on. The public has a right to know what there is to know about this and other drugs."

Background information:

Sen. Grassley has conducted active oversight of the Food and Drug Administration since 2004 and has put pressure on the drug safety agency to act with more independence and transparency in order to build public confidence and strengthen public safety. Sen. Grassley has called the FDA's relationship with the drug industry "too cozy." Grassley has also conducted oversight of the pharmaceutical industry to ensure that Medicare and Medicaid dollars are spent appropriately on safe and effective drugs. His investigations have revealed attempts by drug companies to suppress negative data and intimidate scientists who voice concerns about their

drugs.

The publicly available portions of the report on Paxil that is missing nine pages is posted at <http://finance.senate.gov> along with this press release.

Sen. Grassley's letter:

February 6, 2008

Mr. Christopher Viehbacher
President
U.S. Pharmaceuticals
GlaxoSmithKline
5 Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Mr. Viehbacher:

As the Ranking Member of the United States Senate Committee on Finance (Committee), I have an obligation to the more than 80 million Americans who receive health care coverage under Medicare and Medicaid to ensure that taxpayer and beneficiary dollars are appropriately spent on safe and effective drugs and devices. This includes the responsibility to conduct oversight of the medical and pharmaceutical industries that provide products and services to Medicare and Medicaid beneficiaries.

As reported today in New Scientist, several documents were unsealed on January 18, 2008, in the case of O'Neal v. SmithKline Beecham d/b/a GlaxoSmithKline. Several of these documents and transcripts suggest that GSK knew as far back as 1989 that Paxil is associated with an increased risk of suicide. However, the American public was never adequately informed of this risk until May 2006 in a "Dear Healthcare Professional" letter that reported a "higher frequency of suicidal behavior" associated with Paxil as compared to placebo.

Specifically, Dr. Joseph Glenmullen, a Clinical Instructor in Psychiatry at Harvard Medical School, prepared an expert report based on a review of internal GSK documents. Dr. Glenmullen's report suggests that GSK ensured that suicides and suicidal attempts were systematically included in the placebo arm of GSK's study, which had the effect of making it more difficult to detect suicide risks associated with Paxil. This information was then submitted to the FDA.

Dr. Glenmullen concluded in his report:

Analyses of GlaxoSmithKline's data demonstrate a causal link between the antidepressant and suicidal behavior. This has been true since 1989 although the "bad" Paxil numbers obscured the risk for a decade-and-a-half.

It is my understanding that 9 pages of Dr. Glenmullen's report are not available publicly. Accordingly, please respond to the following questions and request for information. Please repeat each enumerated question and follow it with your response.

1. When did GSK first learn that Paxil was associated with an increased suicide risk?
2. When did GSK first report to FDA that Paxil was associated with an increased suicide risk?
3. When did GSK first notify patients and doctors that Paxil was associated with an increased suicide risk? Please provide all pertinent documents and communications.
4. Please provide the Committee with the complete, unredacted version of Dr. Glenmullen's report. Along with that report, please provide the appendix and all documents that are referred to in the report, in the order that they are referenced.
5. Please provide the Committee with the accompanying children and adolescents report. Along with this report, please provide the appendix and all documents that are noted in the report, in the order that they are referenced.

Thank you again for your continued assistance in this matter. Because I understand that these documents are already available in electronic format, I would appreciate receiving the documents and information requested by no later than February 14, 2008.

Sincerely,

Charles E. Grassley
Ranking Member
Committee on Finance