

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

January 30, 2008

Via Electronic Transmission

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.

The purpose of this letter is to determine what action, if any, GlaxoSmithKline (GSK) took after receiving a leaked manuscript of a study prior to its publication on May 21, 2007 in *The New England Journal of Medicine* (NEJM).¹ This study reported a link between heart attacks and Avandia, a drug GSK sells to control glucose levels in diabetics.

GSK representatives informed the Committee last summer that a peer reviewer leaked the study to them weeks before it was published. GSK later acknowledged to the Committee that the peer reviewer was Dr. Haffner. Dr. Haffner confirmed this fact noting also that he was peer reviewing the study for *NEJM* when he faxed the study to GSK. According to documents filed at the FDA, GSK has paid Dr. Haffner around \$75,000 in consulting fees and speaking honoraria since 1999.

Dr. Haffner told Committee investigators that no one at GSK asked him to send them this study about Avandia. Nonetheless, I am interested in what GSK did after receiving the study. Did GSK return the study to Dr. Haffner? Did GSK contact the *NEJM* to report this violation of publishing ethics? I would appreciate a detailed description of what GSK did after receiving the unpublished study regarding one of their leading drugs. Accordingly, please respond to the following questions and request for documents:

¹ Steven E. Nissen et. al. "Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes" *The New England Journal of Medicine*, May 21, 2007.

1. Please provide a list of all GSK employees who received and/or learned of the results contained in the leaked copy of the manuscript prior to publication by *NEJM*.
2. Please provide copies of all documents, records, and recordings of telephone messages regarding the *NEJM* manuscript that was leaked to GSK before publication.
3. Please provide the following dates:
 - a. When did GSK first contact the data safety monitoring board of the RECORD trial to begin publication of interim results?
 - b. When did GSK begin pulling together the interim data of the RECORD trial?
 - c. When did GSK submit the interim results of the RECORD trial to *NEJM* for possible publication?
4. Please provide copies of all documents, records, communications, and recordings of telephone messages regarding the publication of the interim results of the RECORD trial.
5. Please provide copies of any other pre-publication study drafts that GSK received about one of its products. Please do not include these drafts if a GSK employee was an author on the study. This request covers the period of January 1, 2000 to the present.

Thank you again for your continued assistance in this matter. I would appreciate receiving the documents and information requested by no later than February 15, 2008. If you have any questions, please feel free to contact Paul Thacker or Emilia DiSanto of my Committee at (202) 224-4515. All formal correspondence should be sent electronically in PDF format to Brian_Downey@finance-rep.senate.gov or via facsimile to (202) 228-2131.

Sincerely,



Charles E. Grassley
Ranking Member