



Leaked NEJM Manuscript on Rosiglitazone (Avandia) Puts GSK Under Scrutiny

By Peggy Peck, Executive Editor, MedPage Today
Published: January 30, 2008

WASHINGTON, Jan. 30 -- Citing a bad case of poor judgment, an independent reviewer for the *New England Journal of Medicine* has conceded that he leaked privileged information to GlaxoSmithKline last May on a meta-analysis that cast the company's diabetes drug rosiglitazone (Avandia) in a bad light.

Although bound by a vow of pre-publication confidentiality, the reviewer, Steven Haffner, M.D., of the University of Texas Health Science Center in San Antonio, faxed a copy of the meta-analysis to GlaxoSmithKline 17 days before it was published online by the *NEJM*, said Sen. Charles Grassley (R-Iowa) of the Senate Finance Committee in a letter dated today.

Dr. Haffner said he told Sen. Grassley and others that his act was gratuitous, that no one at GlaxoSmithKline had asked him to share the manuscript, and he said he received no money for doing so. (See: [Meta-Analysis Links Rosiglitazone \(Avandia\) to Risk of Myocardial Infarction](#))

A news story in the Feb. 3 issue of *Nature* quoted Dr. Haffner as saying, "Why I sent it is a mystery. I don't really understand it. I wasn't feeling well. It was bad judgment."

Nevertheless, Sen. Grassley asked GSK for a detailed and documented accounting on what it did with the leaked manuscript after receiving it, implying it might have contributed to the company's rapid defense of the drug after the meta-analysis, published by the *NEJM* on May 21, linked rosiglitazone (Avandia) to an increased risk of myocardial infarction.

Sen. Grassley, in his letter today to GSK president Christopher Viehbacher, said that documents filed with the FDA indicated that, since 1999, Dr. Haffner has received about \$75,000 in honoraria and

consulting fees from the company.

Dr. Haffner faxed the manuscript to Alexander Cobitz, a GSK employee whom Dr. Haffner knew through his involvement in a rosiglitazone trial. According to Dr. Haffner, Cobitz didn't ask for the manuscript.

In addition to a broad inquiry, Sen. Grassley made a number of specific requests in today's letter.

He asked for a list of all GSK employees who received and/or learned of the results contained in the leaked copy of the meta-analysis as well as copies of all documents, records, and recordings of telephone messages regarding the *NEJM* manuscript before it was published.

A key part of GSK's rapid defense of rosiglitazone after the meta-analysis was published was the early publication of an interim analysis of the RECORD trial.

Sen. Grassley asked GSK when it first made contact with the data safety monitoring board of the RECORD trial to set in motion that publication and when did the company begin assembling data needed for that publication, as well as the date of submission of the data to the *NEJM*, which on June 5, 2007 published the RECORD results online (See: [RECORD Fails to Confirm or Refute Cardiovascular Risk for Rosiglitazone \(Avandia\)](#))

Senator Grassley set a Feb. 15 deadline for GSK to respond to his request.

In today's letter Sen. Grassley said he was "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?"

Although GSK responded with a flurry of publications within weeks of the meta-analysis publication, the company had no immediate response when *MedPage Today* initially asked GSK to comment on the study. Calls and emails to GSK on the morning of May 21 went unanswered. The company released a statement later that day, about an hour after *MedPage Today* posted its first report on the meta-analysis.

Dr. Haffner's action marks the second time in less than a year that an *NEJM* reviewer leaked a manuscript to industry, and both reviewers have close ties to industry.

About two months before the rosiglitazone analysis was published, Martin Leon, M.D., an interventional cardiologist at Columbia

University, leaked details of the COURAGE trial. ([COURAGE Embargo Break: Slip of the Tongue or Sabotage?](#))

When the Courage data were leaked, Dr. Leon was charged with an embargo break and he was sanctioned by the American College of Cardiology and the *NEJM* said it would no longer allow him to review manuscripts. Additionally, he would not be permitted to submit editorials, review articles, or commentaries for at least five years. (See: [ACC Sanctions Martin Leon, M.D., for COURAGE Embargo Break](#))

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