

Drug Maker Hired Writing Company for Doctors' Book, Documents Say

By DUFF WILSON

Published: November 29, 2010

Two prominent authors of a 1999 book teaching family doctors how to treat psychiatric disorders provided acknowledgment in the preface for an "unrestricted educational grant" from a major pharmaceutical company.

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Enlarge This Image We thank SmithKline Beecham Pharma ricted educational grant to Scientific Thera evelopment of this handbook. The editori harmD, and the staff of Scientific Therape cknowledged. We also appreciate the supp sychiatric Press, Inc.

roff, MD, PhD

From the book "Recognition and Treatment of Psychiatric Disorders: A Psychopharmacology Handbook for Primary Care."

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But the drug maker, then known as SmithKline Beecham, actually had much more involvement than the book described, newly disclosed documents show. The grant paid for a writing company to develop the outline and text for the two named authors, the documents show, and then the writing company said it planned to show three drafts directly to the pharmaceutical company for comments and proposed a timeline for the writing company to furnish the doctors and SmithKline with draft text and final page proofs for approval.

"That doesn't sound unrestricted to me," Dr. Bernard Lo, a medical ethicist and chairman of an <u>Institute of Medicine</u> group that wrote <u>a 2009 report</u> on conflicts of interest, said

after reviewing the documents. "That sounds like they have ultimate control."

The 269-page book, "Recognition and Treatment of Psychiatric Disorders: A Psychopharmacology Handbook for Primary Care," is so far the first book among publications, namely medical journal articles, that have been criticized in recent years for hidden drug industry influence, colloquially known as ghostwriting.

"To ghostwrite an entire textbook is a new level of chutzpah," said Dr. <u>David A. Kessler</u>, former commissioner of the <u>Food and Drug</u> <u>Administration</u>, after the letter and other documents were described to him. "I've never heard of that before. It takes your breath away."

The book has never been in wide circulation and has not been sold for a few years. Guidelines restricting the use of industry money to support medical journal articles or doctors' research have come into wide acceptance within the last several years, to try to minimize the influence of companies' marketing on medical practices.

The book's listed co-authors were Dr. Charles B. Nemeroff, chairman of <u>psychiatry</u> at the <u>University of Miami</u> medical school since 2009 and <u>Emory University</u> before that, and Dr. Alan F. Schatzberg, who was chairman of psychiatry at the <u>Stanford</u> <u>University</u> School of Medicine from 1991 until last year.

The letter documenting the relationship between Dr. Nemeroff, a writing company and SmithKline was dated Feb. 4, 1997. It and a "<u>preliminary draft"</u> of the book, dated Feb. 21, 1997, and adding Dr. Schatzberg's name were released Monday by the Project on Government Oversight, a Washington advocacy group. They were attached to <u>a letter</u> of complaint to Dr. <u>Francis S. Collins</u>, director of the <u>National Institutes of Health</u>. In the letter, Danielle Brian, executive director of the project, and Paul Thacker, an investigator, formerly with the staff of Senator <u>Charles Grassley</u> of Iowa, also cited other examples of what they termed ghostwriting and asked the N.I.H. for better policing of such practices.

The documents were separately obtained by The New York Times from the Los Angeles law firm of Baum Hedlund, which received them as part of discovery in lawsuits against the drug company, now known as <u>GlaxoSmithKline</u>, involving <u>Paxil</u>. Leemon B. McHenry, a bioethicist with <u>California State University</u>, Northridge, who consults for the law firm, said many similar documents remain sealed. "This is only the tip of the iceberg," he said.

Responding to questions by e-mail last week, Dr. Nemeroff and Dr. Schatzberg emphasized the "unrestricted" nature of the grant from the drug maker to develop the book and said they did most of the work. SmithKline "had no involvement in content," Dr. Schatzberg said, adding, "An unrestricted grant does not give the company any right of sign-off on content and in fact they had no sign-off in content."

Dr. Nemeroff said he and Dr. Schatzberg "conceptualized this book, wrote the original outline and worked on all of the content."

But the writing company, Scientific Therapeutics Information of Springfield, N.J., had developed "a complete content outline" for Dr. Nemeroff's comment, according to the 1997 letter from one of the company's officials. The company also said it had "begun development of the text." The writing company did not respond to requests for comment.

Kevin G. Colgan, a spokesman for GlaxoSmithKline, said the company's role in the book was described in its preface. In recent years, he added, the company has tightened its internal guidelines for medical writers.

Ron McMillen, chief executive of American Psychiatric Publishing, which published the book, said he reviewed files on it Monday and found no evidence of influence by the writing company or GlaxoSmithKline. But Mr. McMillen also said he had been unaware of the plan outlined in the two-page letter to Dr. Nemeroff.

"This would show more involvement than we would accept," he said after reviewing it.

The book sold about 26,000 copies, including 10,000 bought by SmithKline Beecham for American family doctors and 10,000 purchased by the Dutch pharmaceutical company Organon, Mr. McMillen said. The authors together received a 15 percent royalty of the \$120,000 sales, or about \$18,000, he said.

Since there are about 100,000 family physicians in the United States, the book reached only a small percentage of them and has probably declined in usage since 1999. Dr. Howard A. Brody, an author, blogger and professor of family medicine at the <u>University</u> <u>of Texas</u> Medical Branch at Galveston, speculated that family doctors may have had some resistance to a book from a psychiatric press.

Mr. McMillen said the book was co-published with the <u>American</u> <u>Medical Association</u>. He said it was distributed until a few years ago.

Dr. Nemeroff said the book was written to fill an unmet need in educating family doctors and primary care physicians on how to provide adequate treatment for people with mental illness. "Remarkably, the book remains quite accurate and relevant to clinical practice today," he said.

Dr. Nemeroff said he and Dr. Schatzberg "scrutinized every page and rewrote and edited as we deemed necessary," keeping control of the final draft.

Dr. Schatzberg said he had not seen the 1997 letter to Dr. Nemeroff. He termed it "a theoretical proposal that bears little, if any relationship to what actually happened." Dr. Lo, who is a professor of medicine and director of the medical ethics program at the <u>University of California, San Francisco</u>, said that medical textbooks and handbooks should make it clear — as peer-reviewed journals now do — whose idea it was, who wrote the first draft, and who edited. Dr. Lo and other experts said ghostwriting has receded in recent years with tougher journal standards.

Dr. Nemeroff and Dr. Schatzberg have been listed on other titles, including co-editors of the Textbook of Psychopharmacology, a book for <u>psychiatrists</u> and medical students, whose third edition appeared in 2003. In 2008, Emory University imposed a two-year ban on Dr. Nemeroff receiving N.I.H. grants after a Senate inquiry found that he had <u>failed to disclose at least \$1.2 million in industry</u> <u>financing</u> over seven years from pharmaceutical companies, including GlaxoSmithKline.

This article has been revised to reflect the following correction:

Correction: December 1, 2010

An article on Tuesday about a drug maker's involvement in writing a 1999 book that teaches family doctors how to treat psychiatric disorders misstated, in some editions, part of the curriculum vitae of Dr. Charles B. Nemeroff, one of the doctors whose names appeared as authors of the volume. He was once a psychiatry professor at Emory University, not Tulane University.

This article has been revised to reflect the following correction:

Correction: December 8, 2010

A headline on Nov. 30 with an article about SmithKline Beecham's role in the publication of a book about treating psychiatric disorders overstated SmithKline's actions. While documents show that SmithKline (now known as GlaxoSmithKline) hired a writing company for the book, they do not indicate that the company wrote the book for the authors, Dr. Charles B. Nemeroff and Dr. Alan F. Schatzberg. The article also described incorrectly, in some editions, events outlined in a letter from the writing company to Dr. Nemeroff. The correspondence proposed a timeline for the writing company to furnish the doctors and SmithKline with draft text and final page proofs for approval; the letter did not say that the company had already provided those materials for final approval. And the article misstated the context under which Dr. David A. Kessler, the former commissioner of the Food and Drug Administration, commented about the book's production. The letter and other documents were described to him; he did not personally review the documents.

A version of this article appeared in print on November 30, 2010, on page B3 of the New York edition.



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