

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

December 17, 2008

Via Electronic Transmission

William J. Pesce
President and Chief Executive Officer
John Wiley & Sons Inc.
Corporate Headquarters
111 River Street
Hoboken, NJ 07030-5774

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs. Accordingly, the Committee has a responsibility to the more than 80 million Americans who receive health care coverage under those programs, to oversee the proper administration of the programs, including the payment for prescription drugs regulated by the Food and Drug Administration (FDA or Agency). As Ranking Member of the Committee, I have a duty to ensure that the FDA upholds its responsibility to the public's health by properly regulating the nation's drug supply and ensuring that the drugs Americans use are safe and effective.

I am writing about my concerns with the conflict of interest policies relating to medical and scientific journals published by John Wiley & Sons Inc. (Wiley). As part of an inquiry into the lack of disclosure of outside income by Dr. Charles Nemeroff, I received and reviewed documents provided to me by Emory University (Emory). I was drawn to a letter that Dr. Nemeroff wrote to himself back in 2000 on the letterhead of the journal *Depression and Anxiety*.^[1] At the time he wrote the letter to himself, Dr. Nemeroff was Co-Editor-in-Chief of *Depression and Anxiety*. It is my understanding that Dr. Nemeroff today serves as a member of the editorial board.

More specifically, Dr. Nemeroff addressed the letter to "Dear Me" and wrote that he was paying himself \$3,000 to write an article for a special supplement of *Depression and Anxiety* (Supplement). Dr. Nemeroff then submitted a request for additional compensation to Emory.^[2] The request for compensation contains a section to justify the \$ 3,000 payment and reads:

Honorarium for organizing supplement (\$3,000) and sharing honorarium for manuscript preparation for *Depression and Anxiety* supplement w/ co-author Dr. Kerry Ressler (\$1,500). This work performed outside normal work day.

^[1] Charles Nemeroff, Letter to "Dear Me" (Dr. Charles Nemeroff), Co-Editor-in-Chief, *Depression and Anxiety*, dated February 9, 2000.

^[2] Emory University Payroll Department Request for Supplemental Pay, submitted for Nemeroff, Charles B., MD PhD, September 29, 2000.

This particular Supplement is identified as a special edition, devoted to venlafaxine, known as Effexor. Dr. Nemeroff also wrote the editorial for the Supplement, which reads:

It is my hope that this volume will communicate to clinicians in both academia and in the community the enthusiasm that the authors have for this dual reuptake inhibitor. Indeed, venlafaxine offers an important treatment option for both the psychiatrist and primary care physician for achieving a state of “wellness” in a broad spectrum of patients.^[3]

In response to my inquiries, Emory informed me that the account from which Dr. Nemeroff was paid to organize the Supplement received an unrestricted grant from Wyeth Ayerst in 2000. According to Emory “each of the fourteen faculty members who contributed to the special edition on depression in the journal...received \$3,000.”^[4]

Wyeth markets venlafaxine under the brand name Effexor. However, I could not locate any disclosures in the Supplement explaining that the editor and the other authors of this Supplement were paid by Wyeth.

One thing that concerns me in this scenario is that supplements, such as the one edited by Dr. Nemeroff, may soon be used to promote drugs off-label.^[5] I am attaching the pertinent FDA draft guidance on the dissemination of off-label information for your review. Because of this concern, I am writing to inquire about Wiley’s policies that address, among other things, honoraria payments to authors to write articles for your company’s journals. I would also like to understand Wiley’s conflict of interest and disclosure policies, requiring authors and journal editors to report outside income received.

Accordingly, I request that you respond to the following questions and requests for information. For each response, please repeat the enumerated request and follow with a complete and detailed answer.

- 1) Were any ethical rules and/or policies and procedures of *Depression and Anxiety* and/or John Wiley & Sons, Inc. violated if Dr. Nemeroff and other authors of the Supplement articles on venlafaxine were paid an honorarium by Wyeth? Please explain.

^[3] Charles Nemeroff, “More than one-half of a decade of experience with venlafaxine dual serotonin-norepinephrine reuptake inhibitor.” *Depression and Anxiety*, Volume 12, Supplement 1:1 (2000).

^[4] Jane E. Jordan, Deputy General Counsel, Emory University, “Letter to Senator Grassley,” dated December 5, 2008.

^[5] Food and Drug Administration Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (Draft Guidance). See also: <http://www.fda.gov/oc/op/goodreprint.html>

- 2) Were any ethical rules and/or policies and procedures of *Depression and Anxiety* and/or John Wiley & Sons, Inc. violated if these honoraria were not disclosed? Please explain.
- 3) Please explain the policies and procedures in effect during calendar year 2000 regarding disclosure of conflicts of interest for authors of articles published in journals owned by John Wiley & Sons.
- 4) Please explain the policies and procedures regarding disclosure of conflicts of interest by editors of journals published by John Wiley & Sons.
- 5) Do these policies and procedures differ for supplements? If yes, please explain.
- 6) Does John Wiley & Sons receive payments from companies to write supplements for their journals? If yes, do these sponsored supplements inform readers of the sponsorship?
- 7) Please provide a complete list of science/medical journals published by John Wiley & Sons for the past five year period, 2003 to the present.
- 8) Please provide a copy of all contracts, agreements, memoranda of understanding, and/or policies and procedures signed by Dr. Charles Nemeroff regarding his duties as editor, peer-reviewer, and/or author for materials published by John Wiley & Sons.

In cooperating with the Committee's review, no materials, documents, records, data or information related to these matters shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.

In addition and for ease of review, I have attached several documents to this letter including:

- Dr. Nemeroff's letter on *Depression and Anxiety* letterhead, addressed to "Dear Me."
- Dr. Nemeroff's request for supplemental pay.
- Dr. Nemeroff's editorial in *Depression and Anxiety*.
- Research review in *Depression and Anxiety* authored by Drs. Nemeroff and Ressler.
- Table of Contents for *Depression and Anxiety* special supplement on venlafaxine.
- FDA Draft Guidance: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices.

I look forward to hearing from you by no later than January 7, 2009. All documents responsive to this request should be sent electronically in PDF format to Brian_Downey@finance-rep.senate.gov. If you have any questions, please do not hesitate to contact Paul Thacker at (202) 224-4515.

Sincerely,



Charles E. Grassley
Ranking Member
Committee on Finance

Attachments