

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

October 2, 2008

Via Electronic Transmission

James W. Wagner, Ph.D.
President
Emory University
201 Dowman Drive
Atlanta, GA 30322

Dear Dr. Wagner:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs and, accordingly, a responsibility to the more than 80 million Americans who receive healthcare coverage under these programs. As Ranking Member of the Committee, I have a duty to protect the health of Medicare and Medicaid beneficiaries and safeguard taxpayer dollars appropriated for these programs. The actions taken by thought leaders, like those at Emory University (Emory), often have profound impact upon the decisions made by taxpayer funded programs like Medicare and Medicaid and the way that patients are treated and funds expended.

I would like to expand on concerns I brought to your attention regarding problems with the disclosures of outside income filed with Emory by Dr. Charles Nemeroff, Chair of the Department of Psychiatry. I have previously cited discrepancies pertaining to Dr. Nemeroff's disclosures filed with Emory and reports that I received by several companies regarding payments made to Dr. Nemeroff. I also raised concerns about Dr. Nemeroff's conflicts of interest relating to several National Institutes of Health (NIH) grants.

Federal regulations place numerous requirements on a university or hospital when its researchers apply for NIH grants.^[1] These regulations are intended to ensure a level of objectivity in publicly funded research, and state in pertinent part that NIH investigators must disclose to their institution any "significant financial interest"^[2] that may appear to affect the results of a study. NIH interprets "significant financial interest" to mean at least \$10,000 in value or five percent ownership in a single entity.

From the summer of 2003 until the summer of 2008, Dr. Nemeroff was the primary investigator on a collaborative grant between Emory, GlaxoSmithKline (GSK)

^[1] Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought, 42 C.F.R. 50 (1995). See also <http://grants.nih.gov/grants/partners/0706NIHExtramuralNexus.pdf>.

^[2] "Significant Financial Interest" is defined by the regulation as anything of monetary value, including but not limited to: salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties from such rights).

and the National Institute of Mental Health (NIMH) — the Emory-GSK-NIMH Collaborative Mood Disorders Initiative (Initiative). This Initiative examined five novel GSK antidepressant candidates. The NIH budgeted approximately \$3.95 million over this grant's five year period with about \$1.35 million paid directly to Emory for overhead costs. Apparently, Dr. Nemeroff also received some payment for his salary from this grant, although the exact amount has not yet been made available to the Committee.

On several occasions during the life of this grant, it appears that Dr. Nemeroff failed to report to Emory that he was participating actively on the speaker's bureau for GSK. For instance, in an email regarding his outside activities dated October 1, 2003, Dr. Nemeroff wrote:

...I have to dig up the agreement and send it to you, GSK no standing contract, I chair their ad board 2-3 times per year and I am paid per board meeting at a standard rate of \$5K per weekend.^[3]

However, and based upon information in our possession, in 2003 GSK paid Dr. Nemeroff about \$119,000 in speaking fees and expenses. Based upon information provided from Emory, Dr. Nemeroff did not report that he was giving promotional talks for GSK on Paxil and Lamictal.

On March 19, 2004, Dr. Nemeroff again addressed his relationship with GSK in response to questions from Emory's Conflicts of Interest (COI) Committee. Again, it appears that Dr. Nemeroff did not mention the fees he was receiving for promotional speaking on behalf of GSK. In a letter to the Assistant Dean for Administration, Dr. Nemeroff wrote:

Apart from speaking at national symposia, such as the American Psychiatric Association, for which GSK might serve as a sponsor, my consultation to the company is limited to chairing their Paroxetine Advisory board and for that, I am remunerated \$15,000 per year.^[4]

However, on March 16, 2004, three days prior to signing this letter, GSK paid Dr. Nemeroff \$3,500 for a talk he gave on Paxil at the Citrus Club, a members only business establishment in Orlando, Florida. On March 17, 2004, he gave another \$3,500 talk about Paxil in Kissimmee, Florida. The week after he signed this letter, Dr. Nemeroff gave three talks on Paxil, for \$3,500 each, at various venues in New York State.

In June 2004, Emory's COI Committee released a report on Dr. Nemeroff's company sponsored grants and outside activities.^[5] Dr. Nemeroff was provided a copy of the report which stated in pertinent part:

^[3] Emory internal email; from Charles B. Nemeroff to Claudia R. Adkison, dated October 1, 2003.

^[4] Letter to Brenda J. Seiton, Assistant Dean for Administration, signed Charles B. Nemeroff, dated March 19, 2004.

^[5] Confidential Memo to Dr. Charles B. Nemeroff, MD, PhD, from Conflict of Interest Committee, dated June 24, 2004.

The Committee concluded that you did not follow procedures and policies regarding the review of your consulting agreements and that you failed to disclose your potential conflicts of interest in research in your Annual Disclosure Form for 2002-2003, your Sponsored Projects Approval Forms, and your IRB and IACUC forms.^[6]

In response to this report, Dr. Nemeroff wrote a memorandum to the executive associate dean on July 6, 2004, explaining how he would manage his conflicts in the future.^[7] He included the last page of the COI Committee's report with his signature to indicate "that I will follow the management plans for my conflicts of interest."^[8] As part of this management plan, Dr. Nemeroff wrote, "In view of the NIMH/Emory/GSK grant, I shall limit my consulting to GSK to under \$10,000/year and I have informed GSK of this policy."^[9]

Barely a week after this promise, on July 12, 2004, GSK paid Dr. Nemeroff \$3,500 in fees and \$505.40 in expenses for a talk he gave regarding Paxil at the Larkspur Restaurant and Grill in Las Vegas, Nevada. The following day, Dr. Nemeroff gave two more talks in exchange for \$7,000 from GSK (\$3,500 per talk).

On July 19, 2004, Dr. Nemeroff received an invitation from the marketing team of Lamictal to attend their national advisory board meeting on November 15-16.^[10] Dr. Nemeroff responded by email^[11]:

I cannot attend this meeting, unfortunately for two reasons. First I have a prior commitment presenting grand rounds at St. Louis University on the 16th and a chairs meeting at Emory on the 15th. Secondly because I serve as the Principal Investigator of the Emory/GSK/NIMH grant from NIH on Antidepressant Drug Discovery, I am very limited in my ability to consult with GSK as this is viewed as a conflict of interest.^[12]

^[6] Id.

^[7] PERSONAL AND CONFIDENTIAL, Letter to Dr. Claudia R. Adkison, from Charles B. Nemeroff, dated July 6, 2004.

^[8] Id.

^[9] Id.

^[10] Lamictal is a bipolar disorder drug sold by GSK.

^[11] Email from Charles B. Nemeroff to Cynthia Yager, dated July 19, 2004.

^[12] Id.

Records supplied from GSK show that Dr. Nemeroff was most likely in St. Louis on the 16th of November. On November 17th, GSK paid Dr. Nemeroff \$7,000 for two clinical roundtables at two physicians' offices in St. Louis, and \$3,500 for a lecture he gave at Kemoll's Italian Restaurant.

On July 15, 2004, Emory's Office of the Dean sent Dr. Nemeroff a letter regarding the Emory-GSK-NIMH Collaborative Moods Disorders Initiative grant.^[13] The letter concerned the COI Committee's review of his relationship with GSK. The letter stated:

The [COI] Committee understands that you serve on the GlaxoSmithKline Paroxetine Advisory Board and provide advice to GSK on their products that are already on the market. For these services, you receive approximately \$15,000 annually. You do not have any stock options or equity interests in GSK. Please correct the record if this is not correct....

The [COI] Committee found that you have a significant financial interest in GSK because your consulting fees are more than the *de minimis* amount established by Emory's University Policy, the AAMC guidelines, and PHS regulations, which is currently \$10,000 annually....

In order to manage this conflict of interest, the [COI] Committee requires that you keep your consulting fees from GSK to an amount equal to or less than \$10,000 on an annual basis throughout the grant period, its renewals, and final collection of data.^[14]

In response, Dr. Nemeroff sent a letter to the executive associate dean on August 4, 2004.^[15] Dr. Nemeroff wrote:

However, to reiterate, I have already taken the necessary steps to be in compliance with the recommendations of the COI Committee, namely my consulting fees from GSK will be less than \$10,000 per year throughout the period of this NIH grant, its renewals and final collections of data. GSK has been informed of this change and certainly understand the reasons for this decision and is supportive of my compliance with the university recommendations.^[16]

^[13] Letter from Emory University School of Medicine, Office of the Dean to Charles B. Nemeroff, dated July 15, 2004.

^[14] Id.

^[15] Letter from Charles B. Nemeroff to Claudia R. Adkison, Executive Associate Dean, dated August 4, 2004.

^[16] Id.

According to GSK reports, Dr. Nemeroff exceeded the \$10,000 limit within that very same month. On August 23, 2004, Dr. Nemeroff was paid \$3,500 for a teleconference with the Louisiana State University Psychiatry Department. GSK reports that this was a “non product” talk. However, Dr. Nemeroff gave talks on the 25th and 26th at two restaurants in New York regarding Paxil — one at Passion Fish Restaurant in Woodbury and the second at Burton and Doyles in Great Neck. For each talk, GSK paid Dr. Nemeroff a \$3,500 speaking honorarium. On August 31, 2004, Dr. Nemeroff held a “non product” teleconference for an additional \$3,500.

On October 29, 2004, the assistant dean for administration sent Dr. Nemeroff a letter concerning his grants.^[17] Relying on Dr. Nemeroff’s promise to maintain his consulting fees from GSK below \$10,000, Emory informed him that he did not have a conflict with the Emory-GSK-NIH Collaborative Mood Disorders Institute.

However, GSK reports that Dr. Nemeroff’s final lecture on Paxil was given on January 26, 2006. That day he gave two talks in Springfield, Missouri. He gave one lecture at the Burrell Behavioral Health and the second at Mille’s Turn of the Century Café. GSK paid Dr. Nemeroff \$7,000 for the lectures along with \$174.98 in expenses.

Based upon information provided to me, it appears that Dr. Nemeroff denied giving these lectures. For instance in a letter on November 20, 2006, Dr. Nemeroff wrote the following to the Emory dean about his outside activities:^[18]

I was somewhat surprised by the suggestion that I serve as [primary investigator] or co-PI in any research protocols funded by a company with which I have a financial relationship. This is absolutely untrue. Quite some time ago, I made that decision based on the 2004 letter from Dr. Adkison and have stuck to it. Thus, this is not an issue.^[19]

However, during the years that Dr. Nemeroff served as the primary investigator of the Emory/GSK/NIMH Initiative it seems he failed to report approximately half a million dollars in fees and expenses from GSK. These fees covered dozens of talks given to promote drugs sold by the company.

Accordingly, I request that your institution respond to the following questions and requests for information. For each response, please repeat the enumerated request and follow with the appropriate answer.

^[17] Letter to Charles B. Nemeroff, from Brenda J. Seiton, Assistant Dean for Administration, dated October 29, 2004.

^[18] Letter from Charles B. Nemeroff to Thomas J. Lawley, Dean Emory University School of Medicine, dated November 20, 2006.

^[19] Id.

- 1) For each year that the Emory/GSK/NIMH grant was active, please provide the following:
 - a. Total amount of grant;
 - b. Amount provided to Emory for overhead; and
 - c. Amount of grant provided as salary to Dr. Nemeroff.
- 2) Please provide all communications regarding this investigation and/or Dr. Nemeroff's outside consulting. This information may be held by Dr. Nemeroff and/or his assistant and/or supervisors to Dr. Nemeroff. The time span of this request covers November 2007 to the present.
- 3) According to documents provided to us by Emory, Dr. Nemeroff wrote a memo to himself on the letterhead of the journal *Depression and Anxiety*, stating that he was paying himself \$3,000 to write a supplement for that journal^[20]. Dr. Nemeroff then filled out an Emory form for payment, with the money being withdrawn from Emory account 9-30410-2170. Please provide documents and explanation for the source of funds that were placed in this account.

Thank you again for your continued cooperation and assistance in this matter. As you know, in cooperating with the Committee's review, no documents, records, data or information related to these matters shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.

I look forward to hearing from you by no later than October 16, 2008. 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

cc: Elias A. Zerhouni, M.D.
Director
National Institutes of Health

The Honorable Daniel R. Levinson
Inspector General
U.S. Department of Health and Human Services

Attachments

^[20] Letter from Charles B. Nemeroff to "Dear Me," dated February 9, 2000.

Dr. Charles Nemeroff's Disclosures on GlaxoSmithKline

Year	Company	Disclosure Filed in March 2008	Amount Company Reported
2000	GlaxoSmithKline	No amount provided ^a	\$190,918
2001	GlaxoSmithKline	No amount provided ^a	\$135,460
2002	GlaxoSmithKline	\$15,000	\$232,248
2003	GlaxoSmithKline	Not reported	\$119,756
2004	GlaxoSmithKline	\$9,999	\$171,031
2005	GlaxoSmithKline	\$9,999	\$78,097
2006	GlaxoSmithKline	No amount provided ^b	\$32,978

^a Consulting agreement for two weekends a year.

^b Speaker's Bureau, \$3,500 per talk; \$5,250 for rotating speakers series.

Note 1: When a Physician named a company in a disclosure but did not provide an amount, the text reads "no amount reported." When a Physician did not list the company in the disclosure, the column reads "not reported."

Timeline

