



September 16, 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 health care 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 key experts 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.

Moreover, and as has been detailed in several studies and news reports, funding by pharmaceutical companies may influence scientific studies, continuing medical education, and the prescribing patterns of doctors. Because I am concerned that there has been little transparency on this matter, I have sent letters to almost two dozen research universities across the United States. In these letters, I asked questions about the conflict of interest disclosure forms signed by some of their faculty. Universities typically require doctors to report their related outside income, but I am concerned that these requirements are disregarded sometimes.

I have also been taking a keen interest in the almost \$24 billion annually appropriated to the National Institutes of Health (NIH) to fund grants at various institutions such as yours. As you know, institutions are required to manage a grantee's conflicts of interest.¹ But I am learning that this task is made difficult because physicians do not consistently report all the payments received from drug companies.

To bring some greater transparency to this issue, Senator Kohl and I introduced the Physician Payments Sunshine Act (Act). This Act will require pharmaceutical companies to report publicly any payments that they make to doctors, within certain parameters.

¹ Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought, 42 C.F.R. 50 (1995).

The purpose of this letter is to assess the implementation of financial disclosure policies at Emory University (Emory/the University). In response to my letter of October 25, 2007, Emory provided me with the financial disclosure reports that Dr. Charles Nemeroff filed with Emory during the period of January 2000 through June 2007. Dr. Nemeroff is the Reunette W. Harris Professor and Chairman of the Department of Psychiatry and Behavioral Sciences at Emory and is one of the most widely published experts in the field of psychiatry.

My staff investigators carefully reviewed each of Dr. Nemeroff's disclosure forms and detailed the payments disclosed. I then asked that Emory confirm the accuracy of the information my staff compiled. In March 2008, Emory clarified previous statements and provided a chart of Dr. Nemeroff's outside income. This chart contained several reports of, among other things, Dr. Nemeroff's outside consulting that my staff did not find in his disclosure forms filed with Emory.

In addition, I contacted executives at several major pharmaceutical and device companies (the Companies) and asked them to list the payments that they made to Dr. Nemeroff during the years 2000 through 2007. These companies voluntarily and cooperatively reported additional payments that Dr. Nemeroff does not appear to have disclosed to Emory. For example, Dr. Nemeroff disclosed receiving \$7,500 in 2005 from Pfizer. But Pfizer reported to me that it paid Dr. Nemeroff \$138,000 in speaker honoraria (at least 40 speaking engagements) and consulting fees that same year. Based upon the information provided to me from both Emory and the Companies, it also appears that Dr. Nemeroff failed to disclose the vast majority of the over \$900,000 that he received in speaking fees and expenses related to talks he has given on behalf of GlaxoSmithKline (GSK).

Because Dr. Nemeroff's disclosures to Emory differ dramatically from those that I received from the Companies, I am attaching a chart that best represents a few of the disclosures made to me by the Companies. Specifically, the attached chart contains columns showing some of the payments disclosed by Dr. Nemeroff in March 2008 contrasted with the amounts reported to me by the Companies. However, I understand that some discrepancies may exist because Emory is uncertain if the disclosures were made during a calendar year or academic year.

INSTITUTIONAL AND NIH POLICIES

The disclosure policies at Emory, and in particular those of the school of medicine, allow faculty members to engage in private consulting up to 20 percent of their professional effort—known as the “20% effort” policy. However, consulting agreements by Emory faculty must have the prior approval of the Chair, Dean, and if necessary, the Conflict of Interest (COI) Committee. Pfizer reported to me that it paid Dr. Nemeroff approximately \$536,500 during the years of 2000 through 2007 for numerous speaking engagements and consulting activities. However, based upon the documents provided to the Committee by the Companies, Dr. Nemeroff did not report the existence of this financial relationship until 2004 when he reported receiving \$15,000 from Pfizer.

Pfizer's lawyers informed my staff that, because of inconsistencies in its databases, Pfizer's report on payments to Dr. Nemeroff do not always have the proper date for which Dr. Nemeroff provided a service. Still, Pfizer reported that it paid Dr. Nemeroff \$95,000 in 2004 for over 25 speaking engagements. This number is dramatically greater than the \$15,000 Dr. Nemeroff reported. Further, from 2005 until the present, Dr. Nemeroff appears to have underestimated the amount he received for the dozens of speaking engagements he gave on behalf of Pfizer.

Moreover and based upon my staff's review of Emory documents, I note that in May 2004 the COI Committee conducted a review² of Dr. Nemeroff's outside activities. Specifically, the COI Committee examined whether or not Dr. Nemeroff had any potential conflicts related to all company research grants that were ongoing in 2003 and 2004. The COI Committee's report found several instances in which Dr. Nemeroff violated Emory's Conflict of Interest policies. Some of the findings include that Dr. Nemeroff:

- received consulting fees and traveling expenses from multiple companies including Abbot, Astra Zeneca, GSK, Neurocrine Biosciences, and Wyeth-Ayerst and that he did not follow procedures regarding the review of his consulting agreements.
- failed to disclose his potential financial conflicts of interest in his Annual Disclosure Form for 2002-2003, his Sponsored Projects Approval Forms, his Institutional Review Board (IRB) forms, and his Institutional Animal Care and Use Committee (IACUC)³ forms.
- reported that he had no financial interest with the sponsor (Merck) of a trial⁴ on his IRB form, the IRB renewal form and the Sponsored Projects Approval form. However, the COI Committee determined that Dr. Nemeroff received \$40,000 and \$48,000 from Merck in 2002 and 2003, respectively.
- indicated no financial interest with the sponsor (Eli Lilly) of a trial⁵ on his IRB and Sponsored Project Approval Form. During the final review of the COI Committee's report, Dr. Nemeroff admitted receiving \$16,159 in fees and expenses in 2002 and \$6,000 in 2003 from Eli Lilly.

² Memorandum to Dr. Thomas J. Lawley, Dean of the Emory University School of Medicine, dated May 26, 2004.

³ The Institutional Animal Care and Use Committee (IACUC) is a self-regulating entity that, according to U.S. federal law, must be established by institutions that use laboratory animals for research or instructional purposes to oversee and evaluate all aspects of the institution's animal care and use program.

⁴ Clinical Trial using Existing Clinical Specimens sponsored by Merck, Measurement of Cerebrospinal Fluid Substance P Concentrations in Depression and Anxiety, began July 2002, end date of 2004.

⁵ Clinical Trial Sponsored by Eli Lilly, Open Label Treatment with Duloxetine Hydrochloride for stabilizing patients with Major Depression, began December 2002, end date December of 2004.

- failed to disclose his relationship with Eli Lilly to the COI Committee and the IACUC regarding a trial⁶ sponsored by Eli Lilly. This was a breach of the conflict of interest policy and potentially a violation of IACUC procedures.
- did not indicate a potential conflict with the sponsor (Janssen) of a grant.⁷ Accordingly, the grant did not receive a conflict of interest review.
- failed to indicate possible conflicts regarding a trial⁸ sponsored by Janssen to the IRB and the COI Committee. The COI Committee determined that this was a serious omission.

In June 2004, the very next month after the COI Committee's review of Dr. Nemeroff's possible conflicts, it sent a letter to Dr. Nemeroff detailing its findings.⁹ The COI Committee wrote:

The [COI] 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...

You must notify the [COI] Committee in writing whether any of your federally funded research involves compounds that are produced by companies with whom you have consulting relationships. Under federal regulations, these grants must be reviewed in light of your relationships with the companies. If conflicts are found, the University is required to notify the funding agency as to whether the conflicts can be managed.

Due to the many violations of the Conflict of Interest, consulting, and other policies and your leadership position as a Department Chair, which may implicate institutional conflicts of interest, a copy of this letter and its related files will be referred to the Dean for evaluation under the Research Misconduct Policy.¹⁰

However, it appears that the COI Committee review did not capture Dr. Nemeroff's other potential conflicts of interest with other companies. This appears to be the case because Dr. Nemeroff failed to report to Emory the money he received from

⁶ Non-clinical Research Grant sponsored by Eli Lilly, the Role of the Neurotensin System in the Antipsychotic Properties of Olanzapine, budget start September 29, 2000, project end September 28, 2003.

⁷ Clinical Trial sponsored by Janssen, Six Month, Double Blind, Randomized Trial to Evaluate Effects of Risperdone and Olanzapine in Subject with Schizophrenia or Schizoaffective Disorder, project start April 16, 2002, ended December 31, 2003.

⁸ Clinical Trial sponsored by Janssen, Neurocognitive and Functional Imaging Study of Comparative Effects of Risperdal and Zyprexa on Schizophrenia, project start March 1, 1999, ended December 1, 2003.

⁹ Confidential Memo to Dr. Charles B. Nemeroff, MD, PhD, from Conflict of Interest Committee, dated June 24, 2004.

¹⁰ Id.

Pfizer and GSK. Based upon the information that I received from the Companies, it appears that Dr. Nemeroff did not report over \$95,000 in fees from Pfizer in 2002, and he dramatically underreported his speaking fees and expenses from GSK for 2002. Additionally, Dr. Nemeroff reported \$15,000 in fees and expenses from GSK that year, but GSK reported to me that they paid him over \$230,000 in 2002.

Based upon my staff's review of the material received from Emory, the COI Committee's review did not include an examination of Dr. Nemeroff's numerous NIH grants for possible violations of federal regulations on conflicts of interest. But federal regulations place several requirements on a university/hospital when its researchers receive NIH grants.¹¹ 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"¹² 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.

I am also concerned that Dr. Nemeroff's actions or lack thereof may have placed Emory in violation of federal disclosure regulations regarding at least two NIH grants. First, from 2001 to late 2004, Dr. Nemeroff was the primary investigator on an NIH grant that studied whether fluoxetine is effective for treating psychological problems in adults who are the victims of child abuse.¹³ Eli Lilly sells a brand name of fluoxetine called Prozac. Regarding an Eli Lilly sponsored clinical trial, the COI Committee reported:

In an email to NAME REDACTED dated March 3, 2004, Dr. Nemeroff reported that he consults with Lilly 2-3 times per year and receives \$3,000 per visit. He claims that his remuneration does not exceed \$10,000....During the final review of this report, Dr. Nemeroff notified the [COI] Committee on March 19, 2004, that he received the following for consulting fees and travel expenses from Lilly: \$16,159.28 in 2002 and \$6,000 in 2003.

The COI Committee also found that Dr. Nemeroff indicated that he had no financial interests on his IRB application for this Eli Lilly trial in 2002 and again in 2003. Further in the Sponsored Projects Approval Form, Dr. Nemeroff answered "no" in response to whether he had a financial interest in Eli Lilly. However, the COI Committee found that Dr. Nemeroff's "failure to indicate his potential conflict of interest to the IRB and COI Committee was a violation of the COI policies and potentially the IRB policies."

During the same years that Dr. Nemeroff was found to have violated COI policies on his Eli Lilly grant, he was the primary investigator on an NIH grant that studied Eli

¹¹ 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>.

¹² "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).

¹³ Fluoxetine in Child Abuse, NIH Grant 5M01RR000039, start Oct 1974, end Nov 2004.

Lilly's drug Prozac. However, Dr. Nemeroff did not disclose the payments Eli Lilly made to him until 2004—two years later. Further, because Dr. Nemeroff did not follow IRB policies on his Eli Lilly sponsored trial, I am concerned that he may have done the same on the IRB form for this NIH grant.

Moreover, from December 2000 through November 2002, Dr. Nemeroff led an NIH sponsored study of Paxil, a drug manufactured by GSK.¹⁴ Dr. Nemeroff disclosed payments from GSK for activities including consulting and speaking during 2000 and 2001, but did not reveal the amount(s) of the payments.

However, GSK reported to me that it paid Dr. Nemeroff over \$190,918 in speaking fees and expenses in 2000. That year, Dr. Nemeroff gave over 50 different speaking engagements on Paxil. In 2001, GSK paid Dr. Nemeroff \$135,460 in speaking fees and expenses. That year, Dr. Nemeroff spoke about Paxil over 25 different times at restaurants around the country. In 2002, Dr. Nemeroff disclosed \$15,000 in payments from GSK, but GSK reported to me that it paid Dr. Nemeroff over \$232,000. Again, most of this work involved speaking about Paxil.

Based upon a review of the documents provided to me by Emory, it is very clear that university officials have attempted to address Dr. Nemeroff's outside consulting in 2000, 2004, and 2006. For example, following several reports in the *Wall Street Journal* in 2006 concerning Dr. Nemeroff's failure to report his outside income in a journal article, Dr. Nemeroff agreed to limit much of his outside activity. Specifically, on two separate occasions, Dr. Nemeroff wrote to the Dean of the medical school and the Executive Vice President for Health Affairs that he would no longer engage in promotional lectures on behalf of companies. Dr. Nemeroff wrote in pertinent part that:

I have already resigned from all industry-sponsored speakers' bureaus and have made it clear that I will not engage in "promotional" lectures on behalf of companies about their products.¹⁵

I will also not participate in any pharmaceutical-sponsored "promotional" lectures or speaker's bureaus.¹⁶

However, the Companies' reports available to me seem to contradict these statements. For instance, Eli Lilly reported two payments to Dr. Nemeroff for speaking in 2007 – \$4,000 on April 4, 2007 and \$5,500 on June 20, 2007. Pfizer reported one speaking honoraria to Dr. Nemeroff on April 13, 2007, in the amount of \$1500.

¹⁴ Paroxetine—Treatment of Exaggerated Platelet Reactivity with Major Depression (NIH Grant 5M01RR000039).

¹⁵ Letter to Michael M.E. Johns, MD, Executive Vice President for Health Affairs and Thomas J. Lawley, MD, Dean Emory School of Medicine, signed by Charles B. Nemeroff, MD, PhD, Reunette W. Harris Professor and Chair, dated November 20, 2006.

¹⁶ Letter to Michael M.E. Johns, MD, Executive Vice President for Health Affairs and Thomas J. Lawley, MD, Dean Emory School of Medicine, signed by Charles B. Nemeroff, MD, PhD, Reunette W. Harris Professor and Chair, dated December 21, 2006.

In light of the information set forth above, I ask for your continued cooperation in examining conflicts of interest. In my opinion, universities across the United States must be able to rely on the representations of their faculty to ensure the integrity of medicine, academia, and the grant-making process. At the same time, should the Physician Payments Sunshine Act become law, institutions like yours will be able to access a database that will set forth the payments made to all doctors, including your faculty members.

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

- 1) For each of the NIH grants received by Dr. Nemeroff, please confirm that he reported to Emory's designated official "the existence of [a] conflicting interest." Please provide separate responses for each grant received for the period from January 1, 2000 to the present, and provide any supporting documentation for each grant identified.
- 2) For each grant identified above, please explain how Emory ensured "that the interest has been managed, reduced, or eliminated." Please provide an individual response for each grant that Dr. Nemeroff received from January 1, 2000 to the present, and provide any documentation to support each claim.
- 3) For each grant identified above, please provide the amount of money paid directly to Dr. Nemeroff for "salary". Please detail this information by grant number, year, and salary amount.
- 4) Please provide and update on any reports of research misconduct or reviews of the discrepancies in disclosures by Dr. Nemeroff, including what action, if any, Emory is/will consider.
- 5) Please provide any reports on research misconduct regarding Dr. Nemeroff.
- 6) Please report whether a determination can be made as to whether or not Dr. Nemeroff violated guidelines governing clinical trials and the need to report conflicts of interest to an IRB. Please respond by naming each clinical trial for which Dr. Nemeroff was the principal investigator, along with confirmation that conflicts of interest were reported, if possible.
- 7) Please provide any notifications to the Office of Human Research Protection regarding potential violations of human subject research protection and research by Dr. Nemeroff. This request covers the period of 2000 through 2007.
- 8) Please provide any notifications and/or communications to the NIH regarding conflicts of interest and research by Dr. Nemeroff. This request covers the period of 2000 through 2007.

- 9) Please provide a total dollar figure for all NIH monies annually received by Emory. This request covers the period of 2000 through 2007.
- 10) Please provide a list of all NIH grants received by Emory. This request covers the period of 2000 through 2007. For each grant please provide the following:
 - a. Primary Investigator;
 - b. Grant Title;
 - c. Grant number;
 - d. Brief description; and
 - e. Amount of Award.

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 7, 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

Attachment

**Selected Disclosures by Dr. Nemeroff and Related Information Reported by
Pharmaceutical Companies and Device Manufacturers**

Year	Company	Disclosure Filed in March 2008	Amount Company Reported
2000	Bristol Myers Squibb	No amount provided	\$15,277
	GlaxoSmithKline	No amount provided ^a	\$190,918
	Johnson & Johnson/Janssen	Not reported	\$71,319
	Eli Lilly	No amount provided	\$1,000
	Merck	No amount provided	n/a
	Pfizer	Not reported	\$2,500
2001	Bristol Myers Squibb	No amount provided	\$3,828
	GlaxoSmithKline	No amount provided ^a	\$135,460
	Johnson & Johnson/Janssen	Not reported	\$32,000
	Merck	No amount provided	n/a
	Pfizer	Not reported	\$15,000
2002	Bristol-Myers Squibb	\$10,000	\$10,869
	Cyberonics	\$50,000	n/a
	GlaxoSmithKline	\$15,000	\$232,248
	Johnson & Johnson/Janssen	\$38,239	\$38,761
	Eli Lilly	\$16,159	\$16,427
	Otsuka	\$65,000	n/a
	Merck	\$40,000	n/a
	Pfizer	Not reported	\$95,500
2003	Bristol-Myers Squibb	No amount provided ^b	\$29,750
	Cyberonics	Not reported	\$50,000
	GlaxoSmithKline	Not reported	\$119,756
	Johnson & Johnson/Janssen	\$25,000	\$25,641
	Eli Lilly	\$6,000	\$6,892
	Merck	\$48,000	n/a
	Pfizer	Not reported	\$112,000
2004	GlaxoSmithKline	\$9,999	\$171,031
	Otsuka	\$50,000	n/a
	Cyberonics	\$50,000	n/a
	Johnson & Johnson/Janssen	Not reported	\$13,500

Year	Company	Disclosure Filed in March 2008	Amount Company Reported
	Eli Lilly	Not reported	\$8,000
	Merck	\$56,000	n/a
	Pfizer	\$15,000	\$95,000
2005	Cyberonics	<\$75,000	\$75,000
	GlaxoSmithKline	\$9,999	\$78,097
	Eli Lilly	No amount provided	\$5,500
	Otsuka	\$50,000	n/a
	Pfizer	\$7,500	\$138,000
2006	AstraZeneca	\$4,000	\$4,150
	Cyberonics	<\$75,000	\$75,000
	GlaxoSmithKline	No amount provided ^c	\$32,978
	Pfizer	\$5,000	\$76,500
2007	Cyberonics/Intermed	<\$75,000	\$5,000
	Johnson & Johnson	No amount provided	\$3,750
	Eli Lilly	Not reported	\$9,500
	Pfizer	Not reported	\$1,500

^a Consulting agreement for two weekends a year.

^b Consulting agreement for \$500 per hour or \$5000 per day.

^c Speaker's Bureau, \$3500 per talk; \$5250 for rotating speakers series.

Note 1: Based on reports to the Committee by Emory, Dr. Nemeroff disclosed receiving over \$1.2 million in payments from pharmaceutical companies and device manufacturers during the period of January 2000 through June 2007. However, this number is obviously an underestimate. In many cases, Dr. Nemeroff only disclosed the name of a company, but did not report an amount. And in many cases, Dr. Nemeroff failed to report even the existence of a relationship. Information reported by the pharmaceutical companies and device manufacturers the Committee contacted indicate that they made additional payments that are not reflected in Dr. Nemeroff's disclosures.

Note 2: 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." The Committee contacted several companies for payment information and the notation "n/a" (not available) reflects that a company was not contacted.