



February 24, 2009

Via Electronic Transmission

The Honorable Daniel R. Levinson
Inspector General
Department of Health and Human Services
Office of Inspector General
330 Independence Ave, SW
Washington, DC 20201

Dear Inspector General Levinson:

The United States Senate Committee on Finance (Committee) has jurisdiction over, among other things, 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. In this capacity, I have a duty under the Constitution to conduct oversight into the actions of executive branch agencies, including the activities of the National Institutes of Health (NIH/Agency). Specifically I am committed to ensuring that NIH properly fulfills its mission to advance the public's welfare and makes responsible use of the public funding provided for medical studies. This research often forms the basis for action taken by the Medicare and Medicaid programs.

Over the last year, I have been investigating the lack of oversight regarding the almost \$24 billion that the NIH spends annually for extramural grants. I have found that NIH provides very little oversight to ensure that conflicts of interest are adequately reported and/or managed by institutions receiving these grants.

My inquiry revealed several problems at Emory University (Emory) concerning Dr. Charles Nemeroff, chair of the department of psychiatry. A number of those concerns are outlined below.

1. Possible Violation of NIH Conflict of Interest Rules

My concerns regarding Dr. Charles Nemeroff were outlined in two letters that I sent to Emory^[1]. In those letters, I noted that that Dr. Nemeroff may have violated NIH conflict of interest (COI) rules for several Agency grants. In fact, Emory's own COI Committee concluded in 2004 that Dr. Nemeroff failed to disclose his potential financial

^[1] Letters to James Wagner, President of Emory University, dated September 16, 2008 and October 2, 2008.

conflicts of interest in his Annual Disclosure Form for 2002-2003.^[2] Under current regulations, Emory is required to report conflict of interests to the NIH. But I have learned from the NIH that it was generally not aware of Dr. Nemeroff's conflicts until I made the issue public last fall.

2. Possible Violations of IRB Protocols, and Failure to Report IRB violations to the Office of Human Subject Research Protection (OHRP)

According to publically available documents, Emory's COI Committee concluded in 2004 that Dr. Nemeroff failed to report his conflicts of interest on his Institutional Review Board (IRB) forms.^[3] When my staff contacted the Office of Human Research Protection (OHRP), they explained that Emory never notified them of these violations of IRB policies.

3. Possible Violations of Federal Contracting Rules regarding Commitment of Time for NIH grants

Dr. Nemeroff has been the primary investigator for several NIH grants from which he has been paid a portion of his annual salary in return for committing a percentage of his professional time to the NIH effort. However, I do not understand how Dr. Nemeroff could have complied with his commitments to these federal grants while, at the same time, spending hundreds of days on the road giving promotional talks for, among others, drug companies. Accordingly, I would appreciate a review of, among other things, Dr. Nemeroff's NIH grants, Emory's employment policies, as well any information on the promotional talks that Dr. Nemeroff gave to third parties. In particular, I am seeking an assurance that NIH received the time and efforts expected under each NIH grant involving Dr. Nemeroff.

4. Possible Misleading Information Provided to the NIH

In a December 5, 2008 letter to me, Emory stated that Dr. Nemeroff's talks for GlaxoSmithKline were "focused on substantive medical educational topics such as depression and bipolar disorder and were not product specific or promotional." In response, I asked GSK to clarify the nature of the information that I made public on September 16, 2008, regarding Dr. Nemeroff's promotional talks for its drugs. GSK responded that the public document "contained information for product talks." Other activities such as National Advisory Board meetings were also identified, but GSK did not identify Dr. Nemeroff's promotional talks as "substantive" or "focused on medical education." Indeed, Emory and Dr. Nemeroff have continued to maintain that these talks by Dr. Nemeroff were educational in nature and "CME-like."

^[2] Internal Emory documents related to the Senate Finance Committee investigation were made public at a Finance Committee hearing on September 16, 2008. The documents can be found online at: <http://finance.senate.gov/sitepages/hearing091608.htm>

^[3] Confidential Memo to Dr. Charles B. Nemeroff, MD, PhD, from Conflict of Interest Committee, dated June 24, 2004.