



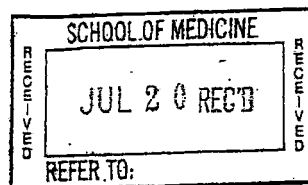
EMORY
UNIVERSITY
SCHOOL OF
MEDICINE

Department of Psychiatry and Behavioral Sciences

Charles B. Nemeroff, MD, PhD
Reunette W. Harris Professor and Chairman

PERSONAL AND CONFIDENTIAL

July 6, 2004



Claudia R. Adkison, JD, PhD
Executive Associate Dean
Administration and Faculty Affairs
Office of the Dean
WHSCAB

Dear Dr. Adkison:

This is a reply to your letter of June 24, 2004 concerning the findings of the Conflict of Interest Committee regarding my potential conflicts of interest. I am enclosing the last page of your letter with my signature indicating that I will follow the management plans for my conflicts of interest. I regret any shortcomings in my adherence to these policies, oversights on my part for which I take full responsibility. I have now put into place a system in my office to ensure complete adherence to the School of Medicine and University policies. In the space below I review, where appropriate, the issues raised in your comprehensive letter and provide additional information and correction or clarification where needed.

I wish to be clear about the fact that at no time was any clinical or basic research compromised in any way from the high standards that we demand. None of the consulting relationships that I have with the pharmaceutical industry have influenced, in any way, the conduct of research in the department. No faculty are expected to participate in any industry-sponsored research activities but they are given the opportunity to do so, only if they desire. In all cases in which conflict of interest issues have been raised, I have responded promptly and precisely to the directions suggested by Ms. Seiton's office and/or conflict of interest committee. I wish to personally assure the committee of my commitment to adhere strictly to the conflict of interest policies currently in place.

First, all new consulting agreements have been forwarded to Brenda Seiton, JD, Assistant Dean, for approval. Of these, I have signed the Quintiles agreement. I have received from Ms. Seiton the agreements from both Otsuka Pharmaceuticals and Jazz Pharmaceuticals and have signed the former. It is unlikely that I will sign the Jazz agreement. Concerning the companies listed in the second part of the second paragraph on page 1, I no longer consult with Comprehensive



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with a selective benzodiazepine (BZ) subunit agonist was awarded from Merck in 2002. That research program has also been discontinued by Merck but our preclinical work will be completed. It is a project of my MD, PhD student, [REDACTED] (The Response of CRF Neuronal Systems to Chronic Treatment with L-838,417, \$60,800 total).

3. Lilly Research Laboratories – I no longer have any active consulting agreement with Lilly, and have cancelled all scheduled visits for 2004 to Lilly Research laboratories nevertheless. The duloxetine trial noted on page 5, for which I served as PI, was transferred to Dr. [REDACTED] (option B on page 6) as soon as the conflict was brought to my attention. At the time I signed the IRB forms in 10/2002 and 3/2003, I estimated my yearly consultant fee with Lilly to be less than \$10,000/ year, which is also true in 2004.

The fluoxetine study is an investigator-initiated study, an extension of our NIMH-funded Conte Center for the Psychobiology of Early Life Trauma. In terms of footnote (8) on page 7. Our department administrator is negotiating with Lilly about the financial status of this study – we believe that Lilly owes funds to our group which are required to complete the study. The study is ongoing and likely will represent a landmark study on the treatment of depressed women who were sexually abused as children. The committee was incorrect in stating that “..... your omission to be a significant breach of policy because you are being paid by Lilly to provide advice on fluoxetine, the drug that is being studied and the study involves direct intervention with human subjects”. Fluoxetine is no longer promoted by Lilly, as their patent has expired for this SSRI antidepressant. It is available in several generic forms and has been for several years. I have not advised Lilly on fluoxetine for many years. Nevertheless, I transferred the grant PI role to Dr. [REDACTED] from myself in February 2004. Any publications emanating from this research will have my full financial disclosures. In view of my current lack of activity as a Lilly consultant, the committee should provide guidance as to whether the steps outlined on page 9 are still required. The discussion of the non-clinical grant from Lilly on page 9 is accurate and I will certainly comply with all of the recommendations outlined in the letter.

4. Janssen – The committee’s account is accurate. I will comply with all of the recommendations outlined in the letter.
5. 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. I wish to inform the committee that I presently hold 60,000 shares of Corcept, awarded to me as a member of their Scientific Advisory Board, 6000 shares of Acadia from recently exercised options, and I own a small equity position (4%) in a privately held biotech start-up company, Reevax. Please let me know if the committee needs to be informed whenever I exercise stock options for companies that I have consulted with, or when I sell stock.

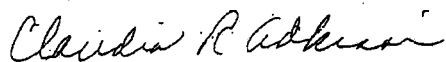
Conclusion

I am grateful to the committee and to both Brenda Seiton and yourself for the time taken to help with these complex issues. I have enhanced processes in my office which will ensure compliance

Charles B. Nemeroff, M.D., Ph.D.
June 24, 2004
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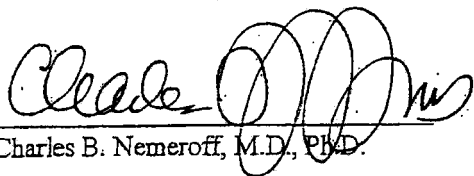
management plans that are specified above and with the University and School policies.

Sincerely,



Claudia R. Adkison, J.D., Ph.D.
Executive Associate Dean/Administration & Faculty Affairs

I have read this letter. I understand the content and the related policies. I accept and agree to follow the management plans for my conflicts of interest that are specified in this letter and the related University and School policies and procedures.


Charles B. Nemeroff, M.D., Ph.D.

7/19/04
Date

CRA/bjs

cc: [REDACTED], M.D.

Ms. [REDACTED]

[REDACTED]
Thomas J. Lawley, M.D.