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Department of Psychiatry and Behavioral Sciences

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

MEMORANDUM

To: Brenda Seiton, J.D.
Assistant Dean for Administration

From: Charles B. Nemeroff, M.D., Ph.D.
Reunette W. Harris Professor and Chair

Date: November 19, 2003

Subj: Memorandum of November 17, 2003

I am in receipt of your memo concerning a number of my consulting agreements and in the space below, I provide you with my response based on the meeting notes of the Conflict of Interest Committee.

1. *2003-047-01: Charles B. Nemeroff, M.D., Ph.D., Lilly Research Labs, Open Label Treatment with Duloxetine Once-Daily Dosing for Evaluation of Stabilization Dose in Patients with Major Depression, IRB #937-2002.*

Please note one correction in your description of the study, namely, that duloxetine has now been approved by the Food and Drug Administration and will be on the market in the United States very shortly for the treatment of depression. From the options provided by the Committee, I choose Option 2 and identify [redacted], M.D., Director of the Mood and Anxiety Disorders Program in the department as Principal Investigator. I will remain as a co-investigator in the study and will not be involved in recruiting patients, obtaining informed consent, having contact with study subjects, gathering or analyzing raw data or reviewing or evaluating adverse events. I shall inform Dr. [redacted] and other members of the Mood & Anxiety Disorders Program about this conflict of interest. Moreover, as in all of my publications, presentations or press releases, I will provide full financial disclosure. All of my commercial relationships and my relationship with Lilly will, therefore, be included. An annual report will be provided concerning the progress of what I assume is the research related to this protocol, my relationship with Lilly, and the steps as noted above to comply with the management plan.

2. *2003-048-01: Charles B. Nemeroff, M.D., Ph.D., Lilly Research Labs, Does Fluoxetine Reverse the Effects of Early Life Stress on CNS CRF Systems and Improve Psychological and Neuroendocrine Function? A Therapy Outcome Study in Women with Childhood Abuse Experiences, IRB #488-97.*

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As noted in your letter, this trial has been ongoing since 1998. This is an investigator-initiated trial which I designed as a logical extension of our NIH-funded Conte Center for the Neurobiology of Major Mental Disorders. It should be noted that Eli Lilly no longer manufactures or promotes fluoxetine because it is now available in a generic form. I would chose Option 2 for this study and identify [redacted] Ph.D. as the new Principal Investigator. I will remain on this study as a co-investigator and will not engage in recruiting patients, obtaining informed consent, having contact with study subjects or analyzing the raw data or reviewing or evaluating adverse events. All members of the team, namely [redacted] Ph.D. and [redacted] Ph.D., as well as [redacted] M.D. and D. [redacted] M.D. will be informed about this conflict of interest. As noted above, my relationship with all pharmaceutical companies, sponsoring agencies and foundations are disclosed in all of my publications, presentations, or press releases. Publications emanating from this work will be provided to the Conflict of Interest Committee with the disclosure statement highlighted. A report of the progress of this research and my relationship with Lilly will be provided on an annual basis.

3. *2003-052-01: Charles B. Nemeroff, M.D.,Ph.D., Janssen, RIS-USA 275A, Six Month Double-Blind, Randomized, International Multicenter Trial to Evaluate the Glucoregulatory Effects of Risperidone and Olanzapine in Subjects with Schizophrenia or Schizoaffective Disorder, IRB #263-2002.*

This study is completed and it was a clear omission that I was not listed as a co-investigator for this trial in the IRB Office recent records. I will discuss this oversight with [redacted] M.D., Principal Investigator of this study. Publications, presentations and press releases would include my full financial disclosures including my relationship with Janssen.

4. *2003-053-01: Charles B. Nemeroff, M.D., Ph.D., Janssen, A Neurocognitive and Functional Imaging Study of the Comparative Effects of Risperdal and Zyprexa on Memory Deficits Associated with Schizophrenia, IRB #552-98.* 558-92 -See attached

[redacted], Ph.D. is the Principal Investigator of this study and I have served as a co-investigator. Enrollment in the study is complete. In response to your letter, I will disclose all financial relationships with Janssen and Lilly and any publications, presentations and press releases related to this study provide the conflict of interest committee with any publications highlighting the disclosure statement. I shall also insure that all volunteers in this study are informed of my relationship with Janssen and Lilly.

In terms of the request to identify a non-conflicted reviewer from outside of the department, I will discuss this issue with [redacted] Ph.D., Principal Investigator, and we together shall choose someone to review the data. That individual will be identified and his or her name will be reported to the committee. An annual report concerning the progress of this research and any

changes in my relationship with Janssen and Lilly will be provided to the committee. Thank you for providing me with this information. I apologize for any oversights on my part and look forward to your response to my recommendations.

c: [redacted]
[redacted], M.D.
[redacted], Ph.D.
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