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PERSONAL **CONFIDENTIAL**

June 24, 2004

Charles B. Nemeroff, M.D., Ph.D.
Professor and Chair of Psychiatry & Behavioral Sciences
[redacted]
Emory Campus

RE: **Conflict of Interest Review**

Dear Dr. Nemeroff:

At the request of Dr. Lawley, the Conflict of Interest Committee reviewed your outside activities and your grants from companies with whom you consult. This letter details the findings of the Conflict of Interest Committee regarding your conflicts of interests; details instances in which the University and School of Medicine Conflict of Interest and Consulting Policies were violated; and provides the on-going management plans. The Committee focused only on your current research as of October 2003 and agreements with outside companies. The Committee did not inquire into potential conflicts associated with your research grants that ended before 2002. If additional agreements and related grants have occurred since October 2003 that have not been submitted and properly reviewed, please attend to these. Further, after you have read and reflected on the content of this letter, if you believe there are conflicts of interest that occurred before 2002 and should be addressed, please attend to those as well.

The Committee reviewed your written, compensated, consulting agreements from Acadia Pharmaceuticals, Bristol Myers Squibb, Corcept Therapeutics, Cyberonics, Cypress Bioscience, Janssen Pharmaceutical Products, Lilly Research Laboratories, Merck, Otsuka, Somerset, and SCIREX. Of all of these agreements, only the SCIREX agreement was provided to the Dean's Office for the required review under the School's Consulting Policy. The Committee also reviewed the November 2002 *Nature Neuroscience* article, the New York Times articles from August 2003, and the article appearing in the August 13, 2003 edition of *The Scientist.* The Committee reviewed your e-mail communication to me dated October 1, 2003, in which you noted that you have verbal agreements with the following companies: Abbott, Astra Zeneca, Comprehensive Neuroscience, George West Mental Health Foundation, GlaxoSmithKline, Neurocrine Biosciences, and Wyeth-Ayerst. For these agreements, you receive fees and travel expenses related to consulting activities. In addition, the Committee reviewed your Annual Disclosure Form for Consulting Agreements and Financial Interests in Research for 2002-2003, your Sponsored Projects Approval Forms, your IRB/HIC forms, and your IACUC forms for your currently active grants. In all of these forms, you responded that you have no financial interests in the sponsors for your research.

The Committee was concerned about the time required by your consulting agreements under the School's "20% effort" policy. The Committee was also concerned that some of the agreements[1] provide for a flat

[1] Acadia Pharmaceuticals, Corcept Therapeutics, Somerset Pharmaceuticals, SciRex (terminated).

fee without specifying the services or times and whether these agreements are in compliance with various regulations. Another concern was that you were paid on a "milestone" basis under the Cypress agreement for helping the company succeed with its drug, although the Committee realizes that you have not conducted and are not conducting research on this "milestone" drug. In addition to the usual review by the Dean's Office, the Committee strongly suggests that you should work with the Emory Healthcare Compliance Office to ensure that your relationships with the pharmaceutical and device companies are in compliance with Medicare and Medicaid regulations.

The Committee discussed your relationships with industry in view of your role as a representative and university official of Emory and your leadership in the scientific community. The Committee indicated that you must disclose your relationships with a company when you discuss the company's products, whether in publications or presentations. This requirement goes beyond the presentation of research results; it applies to all your communications.

The Committee discussed whether faculty members in your department should be allowed to serve on grants as principal investigators (PIs) if you are a co-investigator and have a relationship with the sponsor that places you in a conflicted position, particularly when you obtain the grants and then assign the grants to the faculty member. While this might be easily managed when the PI and co-PI are both faculty members, your position as their Chairman places you in a special position with respect to management of such conflicts of interest. While the Committee prefers that such situations be avoided, nevertheless under the present circumstances it determined that it is important for the faculty to be able to serve as PIs and also to be mentored in their research by their Chair. However, you must disclose your relationship with the sponsor to the research team (co-investigators, post-doctoral trainees, and research staff), you must discuss with them why your position as a conflicted Chair on the particular research project means that you must take extra precautions to avoid even the appearance of creating bias in the evaluation of the study design and the data, and the grant must be reviewed by the Committee for further management plans. The best approach would be to avoid these situations in the future.

Findings of the Committee Regarding Specific Industry Relationships or Grants

Cypress Biosciences

You are a consultant to Cypress Biosciences and a member of their Board of Directors.[2] Although there is no conflict of interest in research, the Committee was concerned about the appropriateness of the relationship. According to the New York Times article, "Undisclosed Financial Ties Prompt Reproval of Doctor," dated August 3, 2003, you have two agreements. Under one, you received $36,000 in consulting fees in 2002. According to the article, you have a separate agreement under which you would receive $100,000 in cash or stock if you helped Cypress succeed with the drug, milnacipran.

You reported in an e-mail to Ms. Seiton dated March 3, 2004 that the New York Times article was incorrect. You reported that you are remunerated for serving on the Board of Directors, chairing the

[2] In an e-mail to Ms. Seiton dated March 26, 2004, you reported that you will be stepping down from the Cypress Board of Directors effective March 25, 2004. You will continue to serve as a consultant to the company for a period of two years. You will retain the stock that you have but will receive no additional shares. You forwarded the new agreement to the Dean's Office for review.

Science and Technology Committee, and serving on the Compensation Committee, and that you received 50,000 options when Cypress signed a deal with Forest Laboratories. According to your e-mail, the $100,000 bonus referenced in the New York Times article was changed to the 50,000 options.[3] You have not exercised any of your options. You also reported that you received $60,000 from Cypress in 2002 and $41,000 in 2003.

In relation to this specific review and in response to a direct request from the Dean's Office, you provided to the Committee a copy of a re-stated consulting agreement dated March 27, 2003. In this agreement, which covers additional work separate and beyond your responsibilities as a Director, you receive fees of $2,000 per day and 50,000 stock options that are contingent "upon the completion of a significant strategic collaboration with a third party with respect to the compound milnacipran; provided, that such collaboration is completed within 2 years from the date of the grant of options."

The Committee agreed that your discussion of the Cypress drug, milnacipran, in the *Nature Neuroscience* article did not violate any Emory policies. According to the journal's editors, your actions did not violate any of the journal's policies at the time. Nevertheless, the failure to disclose your personal financial relationship with the company, regardless of the particular journal's policy, is a concern, particularly since you are a Department Chair who is looked up to by your faculty and expected to set standards of conduct.

The Committee recognized that your role as a "matchmaker" for Cypress presents an appearance of conflict with your role as an academic leader in your field through your work and reputation generated at Emory and as a representative of Emory in the public, i.e., an administrative/institutional conflict. The Committee is very concerned about this appearance of conflict. Further, currently Cypress sponsors one research project in the Department of Psychiatry & Behavioral Sciences. The PI is [redacted] M.D., Ph.D., an Associate Professor of Psychiatry & Behavioral Sciences, under your supervision. The study began April 2002 and was scheduled to end October 2002, but was on a no-cost extension through April 2004. The Committee discussed whether, going forward, Cypress should ever be permitted to sponsor research in the Department of Psychiatry & Behavioral Sciences as long as you have this financial relationship; however, no conclusions were made. The Committee recognized that any such proposal should at least initiate a review by the Institutional Conflict of Interest Committee if you continue this role with the company because you, as an administrator who is a responsible for supervising and mentoring your faculty, have a significant financial relationship with Cypress that could reasonably appear to unduly influence your relationship and activities with your faculty members and their conduct of research.

On March 26, 2004, you notified the Committee that you stepped down from the Cypress Board of Directors, effective March 25, 2004. You will continue as a consultant to Cypress for two more years, and you forwarded this agreement to the Dean's Office for review and approval.

Merck

You served on Merck's US Strategic Advisory Board for Mental Health Disorders and provided advice, counsel, and assistance in the development, planning, and execution of commercial and scientific

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[3] The strike price is $2.51; the price of the stock was approximately $12.30 as of March 3, 2004.

initiatives related to Merck's Substance P (a neurokinin receptor) Antagonist and GABA-A Agonist programs for mental health disorders. You were contractually committed to provide 12 days of service per year. According to the agreement, you received $40,000 in 2002 and $48,000 in 2003, and in 2004, you were to receive $56,000. In addition to these fees, you also received travel expenses. You did not provide the consulting agreement to the Dean's Office as required by the School's Consulting Policy. You provided it to the Committee for this review in response to a direct request from the Dean's Office. This agreement was dated January 1, 2002.

COI Case 2003-046-01, Clinical Trial using Existing Clinical Specimens, sponsored by Merck, Measurement of Cerebrospinal Fluid Substance P Concentrations in Depression and Anxiety; project start date July 2002, end date of June 2004; grant is active according to University records.

You are the PI on a study that will examine whether depressed patients have elevated levels of substance P relative to normal and psychiatric controls and whether Cerebrospinal Fluid (CSF) substance P concentrations are altered by effective antidepressant treatment. Dr. [redacted] is the co-investigator on this study. This study will use CSF samples that had been obtained for pre-existing studies. The protocol was reviewed by the IRB in September 2002 through the expedited review process and renewed in August 2003. You indicated that you had no financial interests with the sponsor, Merck, on the IRB forms (original application dated September 1, 2002 and renewal application dated August 5, 2003)[4] and the Sponsored Projects Approval Form dated May 13, 2002. Therefore, there was no review by the Conflict of Interest Committee.

The Committee found that a conflict of interest exists because you received more $10,000 from Merck during 2002-2003, which is more than the *de minimis* consulting fees from a research sponsor that are permitted under the Conflict of Interest in Research Policy. The Committee felt that this conflict could be managed because the study does not involve patient contact for gathering spinal fluid samples specifically for this study; rather, "shelf" samples were analyzed. In addition, there are no clinical interventions in this study. Going forward, the Committee requires the following:

1. You must disclose your relationship with Merck in any publications, presentations, or press releases related to this research. The disclosure statement must appear on the first page of your manuscript or be announced during the presentation. Disclosures made only to the editors or conference directors are not acceptable. You should submit to the Committee a copy of the publication or presentation with the disclosure statement highlighted.

2. You must submit an annual report that describes the progress of your research, your relationship with Merck, and the steps that you have taken to comply with this management plan. You should submit the report for review by the Committee no later than September 20, 2004. If you continue to receive more than $10,000 from Merck and you apply for another research grant sponsored by Merck or apply for another research grant that studies products

[4] Your resignation from the Merck Advisory Board was not submitted to the Committee until December 2003, though you made the resignation retroactive to August 1, 2003.

of Merck, you should immediately notify the Committee in writing.[5]

Lilly Research Laboratories

You are a consultant to Lilly Research Laboratories (a division of Eli Lilly and Co.). You consult and perform activities for Lilly's duloxetine development team regarding opportunities in the treatment of depression; consult with Lilly's olanzapine/fluoxetine combination development team regarding opportunities in depression; consult with Lilly's neuroscience research and development team regarding new compounds for the treatment of a variety of psychiatric disorders; and consult with the Lilly professional relations group. You receive $3000/day for your services plus expenses. On your 2002-2003 Annual Disclosure Form, you reported that you provide services two weekends/year, which would equate to $12,000 per year in consulting fees. In an e-mail to Ms. Seiton dated March 3, 2004, you reported that you consult with Lilly 2-3 times per year and receive $3,000 per visit. You claim that your remuneration does not exceed $10,000. You did not forward your consulting agreement to the Dean's Office for review and provided it only upon the request of the Dean's Office for this review. The consulting agreement is dated January 7, 2002 and ended December 31, 2003. On your *curriculum vitae,* you reported that you were a member of the Lilly Psychiatry Advisory Board from 1990-2000 and the Lilly Bipolar Advisory Board from 1998-1999. None of these agreements was forwarded to the Dean's Office for review.

During the final review of this report, you informed the Committee on March 19, 2004 that you received the following for consulting fees and travel expenses from Lilly: $16,159.28 in 2002 and $6,000 in 2003. You also informed the Committee that you do not own any stock in Lilly.

COI Case 2003-047-01, Clinical Trial sponsored by Lilly, Open Label Treatment with Duloxetine Hydrochloride Once-Daily dosing for Evaluation of Stabilization Dose in Patients with Major Depression; project start date December 2002, end date December 2004; listed as active in University records.

You are the PI on a clinical trial that is an open-label, multicenter trial. Approximately 30 sites participate in the study, and sites may enroll up to 10 subjects. The objectives of this study include comparing the stabilized dose, safety, and tolerance to treatment in naive patients with patients switched immediately from an SSRI to duloxetine, generating pilot data for comparing the tolerability of duloxetine 30 mg QD versus 60 mg AD initial dosing. Duloxetine is a selective inhibitor of serotonin and norepinephrine re-uptake *in vitro* and *in vivo.* It is not approved by the FDA. The protocol was reviewed by the full IRB committee in October 2002. You indicated that you did not have financial interests in the sponsor on the IRB application dated October 10, 2002. The protocol was modified in March 2003 and no financial interests were indicated then either. On the Sponsored Projects Approval Form, you answered "No" to the question asking whether any investigators have financial interests in the sponsor of the research.

The Committee found that you have a conflict of interest because you received more than $10,000 annually from Lilly during the term of the project, and Lilly is sponsoring a clinical research project on

[5] The obligations outlined in this last sentence will not be required if you do not have an on-going, financial relationship with Merck.

which you serve as a the Principal Investigator. The Committee found that your failure to indicate your potential conflict of interest to the IRB and the COI Committee was a violation of the COI policies and potentially the IRB polices. It is a serious omission because you are specifically providing advice to Lilly on the duloxetine development board, duloxetine is the experimental drug on trial, and the trial involves the direct intervention with human subjects. The Committee found that this conflict could not be managed merely by disclosing your relationship with Lilly. The Committee provided two options:

Option A[6]

1. You must keep your fees to less than $10,000 annually from Lilly.

2. You would be able to remain as PI if you keep your fees to an amount that is less than $10,000, but you must disclose your relationship with Lilly in your publications under the policies of the journals.

Option B[7]

1. You may keep your consulting fees but withdraw as the PI.

2. You should identify a new PI for the study who does not have a potential conflict with Lilly and who has an arms' length relationship with you as Chair, with respect to the conduct of the research.

3. You may remain on the study as a co-investigator, but you cannot be involved in recruiting patients, obtaining informed consent, having any contact with the study subjects, gathering or analyzing raw data, or reviewing or evaluating adverse events. You should inform the members of the research team about your conflict of interest, and you must conduct yourself in a way that avoids even the appearance of potential for biasing the data or the design of the study.

4. You must disclose your relationship with Lilly in any publications, presentations, or press releases related to this study. The disclosure statement must appear on the first page of the manuscript or be announced during the presentation. Disclosures made only to the editors or the conference directors are not acceptable. You should submit to the Committee a copy of the publication or the presentation with the disclosure statement highlighted.

5. You must submit an annual report that describes the progress of your research, your relationship with Lilly, and the steps that you have taken to comply with this management

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[6] If you begin or continue your relationship with Lilly, you must notify the Committee in writing and forward the new consulting agreement for review by the Dean's Office.

[7] In February 2004 in response to an e-mailed preliminary summary of the Committee's findings, you notified the Committee that Dr. [redacted] is the PI for this study and you will be a co-investigator. You will not be directly involved in recruiting patients, obtaining informed consent, having contact with study subjects, gathering or analyzing raw data, or reviewing and evaluating adverse events.

plan. You should submit the report for review by the Committee no later than September 20, 2004. If you complete this research, apply for another research grant from Lilly, or apply for another research grant that studies products of Lilly, you should immediately notify the Committee in writing.

COI Case 2003-048-01, Clinical Trial sponsored by Lilly, 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; project start date August 1998, *end date August* 1999; *listed as active in University records.*[8]

You are the PI on a clinical trial that has been on-going since 1998. A total of 60 subjects were recruited and enrolled in this study, and you propose to enroll up to 75 volunteers. The study examines whether Prozac (fluoxetine) can reverse changes in the central corticotrophin-releasing factor systems induced by early life stress (child abuse) and how these alterations relate to psychopathology. All subjects were participants in a larger research project on the neurobiological consequences of early life stress and their relationship to the pathophysiology of major depression. This is an investigator-initiated clinical trial. The subjects are observed for 8 weeks.

On the original IRB application form dated August 7, 1997, you indicated that you did not have any financial relationships with the sponsor. On the Sponsored Project Approval Form dated March 25, 1998, you indicated that you did not have a financial relationship with the sponsor. In a review separate from the Committee, Ms. Seiton verified that on your 1998-1999 Annual Disclosure Form dated August 24, 1999, you did indicate that in your SEP IRA account you owned 300 shares of Eli Lilly valued at $21,487.50 and that you had a consulting agreement with Lilly.[9] However, you did not forward the agreement to the Dean's Office for review. On your IRB renewal form dated October 21, 2002, you indicated that you did not have any financial relationships with the sponsor.

The Committee found that you have a conflict of interest because you received more than $10,000 annually from Lilly during the term of the project, and Lilly is sponsoring a clinical research project on which you serve as a the Principal Investigator. The Committee found that your failure to indicate your potential conflict of interest to the IRB and the COI Committee was a violation of the Conflict of Interest Policy and potentially a violation of the IRB policy. They found 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 approved by the

[8] In an e-mail to Ms. Seiton dated March 3, 2004, you reported that this project is active and recruiting patients; however, Lilly will not be sending additional funds.

[9] On March 19, 2004, you notified the Committee that you no longer own any stock in Lilly.

FDA. The Committee found that you are not uniquely qualified to serve as the PI for this trial.[10] The Committee provided you with two options:

Option A

1. You must keep your fees to less than $10,000 annually from Lilly.

2. You would be able to remain as PI if you keep your fees to an amount that is less than $10,000, but you must disclose your relationship with Lilly in your publications or presentations.

Option B[11]

1. You may keep your consulting fees but withdraw as the PI on the clinical study.

2. You should identify to the Committee and the IRB a new PI for the study who does not have a potential conflict of interest with Lilly and who has sufficient arms length automony from you so that there is not even an appearance of potential bias in the evaluation of the study design or in the data.

3. You may remain on the study as a co-investigator, but you cannot be involved in recruiting patients, obtaining informed consent, having any contact with the study subjects, gathering or analyzing raw data, or reviewing or evaluating adverse events. You should inform the members of the research team about your conflict of interest, and you must conduct yourself in a way that avoids even the appearance of potential for biasing the data or the design of the study.

4. You must disclose your relationship with Lilly in any publications, presentations, or press releases related to this study. The disclosure statement must appear on the first page of the manuscript or be announced during the presentation. Disclosures made only to the editors or the conference directors are not acceptable. You should submit to the Committee a copy of the publication or the presentation with the disclosure statement highlighted.

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[10] Sometimes conflicted investigators are permitted to be PIs in human subject research when the study is a carefully monitored pilot project, no other investigator can perform the procedures, and the public benefit is highly and broadly important.

[11] In February 2004, in response to an e-mailed preliminary summary of the Committee's findings, you notified the Committee that you have asked Dr. [redacted] to be the PI for this study and that you will be a co-investigator. You indicated that you will not be directly involved in recruiting patients, obtaining informed consent, having contact with study subjects, gathering or analyzing raw data, or reviewing and evaluating adverse events.

5. You must submit an annual report that describes the progress of your research, your relationship with Lilly, and the steps that you have taken to comply with this management plan. You should submit the report for review by the Committee no later than September 20, 2004. If you complete this research, apply for another research grant from Lilly, or apply for another research grant that studies products of Lilly, you should immediately notify the Committee in writing.

COI Case 2003-049-01, Non-clinical Research Grant sponsored by Lilly, The Role of the Neurotensin System in the Antipsychotic Properties of Olanzapine; budget start date 9/29/00 (project start date 4/18/94); *project ended 9/28/03.*

You were the Principal Investigator on a research project involving animals that examined the role of the neurotensin system in the antipsychotic properties of olanzapine. These studies included comparing the effects of olanzapine, risperidone, and haloperidol in two behavioral tests used to screen for antipsychotic efficacy. Ms. [redacted] Director of the IRB and IACUC offices, informed the Committee that the IACUC protocol covering the studies in this grant is no longer funded by Lilly according to information received by the IACUC. The Committee found that your failure to notify the Committee when your received more than $10,000 annually from Lilly was a breach of the Conflict of Interest Policy and potentially a violation of the IACUC procedures.

The Committee found that you had a conflict of interest with this research because you received more consulting fees from the sponsor of the research project than permitted by the University policy. The Committee requires the following:

1. You must disclose your relationship with Lilly in any publications, presentations, or press releases related to this study. The disclosure statement must appear on the first page of the manuscript or be announced during the presentation. Disclosures made only to the editors or the conference directors are not acceptable. You should submit to the Committee a copy of the publication or the presentation with the disclosure statement highlighted.

2. You must identify an independent reviewer to review any manuscripts related to this research. This individual will be apprised of your relationship with Lilly and may review any primary data. You must provide to the COI Office the name and credentials of the independent reviewer and a brief explanation about the independence.

3. You should submit an annual report that describes your relationship with Lilly and the steps that you have taken to comply with this management plan. You should attach copies of any publications related to this research. You should submit the report for review by the Committee no later than September 20, 2004. If you apply for another research grant from Lilly or for another research grant that studies products of Lilly, you should immediately notify the Committee in writing.

Janssen

You are a consultant for Janssen and provide services during two weekends on an annual basis. According to your agreement, you provide these ongoing consulting services related to market research; commercial strategy development; clinical development input; competitive issue management; treatment resistant depression pre- clinical rationale; manuscript development/review of pivotal trials; data presentations at major congresses; and content development for advisory boards. For these services, you receive $4,000 per day and/or $5,000 per day when traveling away from home. On your 2002-2003 Annual Disclosure Form, you reported that you spend two weekends per year consulting for Janssen. The contract is dated January 31, 2003; however, you did not submit it to the Dean's Office as required by Emory policies. On your *curriculum vitae,* you indicate that you have been a consultant with Janssen since 1998; however, none of these agreements were received by the Dean's Office until you provided the copy of your most recent agreement for purposes of this review.

On March 19, 2004, you reported that you received the following from Janssen: $38,238.53 (includes travel expenses) in 2002 and $25,000 (consulting fees only) in 2003. You also reported that you hold 101 shares of Johnson & Johnson stock, which is valued at $5,983.04. Johnson & Johnson is the parent company of Janssen. This stock was an investment and not remuneration from consulting activities.

COI Case 2003-052-01, Clinical Trial sponsored by Janssen, RIS-USA-275 A Six Month, Double-Blind, Randomized, International Multicenter Trial to Evaluate the Glucoregulatory Effects of Risperidone and Olanzapine in Subjects with Schizophrenia or Schizoaffective Disorder; project start date 4/16/2002, project end date 12/31/03; listed as active on University records; IRB protocol terminated in August 2003.

You were a co-investigator on Dr. [redacted] grant sponsored by Janssen. The trial was a randomized, double-blind, parallel group comparison of the glucoregulatory and metabolic effects of maintenance therapy with risperidone or olanzapine in approximately 600 subjects with schizophrenia or related disorders. The patients were studied for six months. The investigators studied the comparative effects of risperidone and olanzapine on the glucoregulatory parameters in patients with schizophrenia. The trial at Emory was budgeted for fifty subjects. It began in April 2002 and was budgeted to end in December 2003. The IRB protocol was terminated by Dr. [redacted] in August 2003. The IRB office also reported that you were not listed as a co-investigator for this trial in their most recent record,[12] though you were listed as a co-investigator on the Sponsored Programs Approval Form.

This grant did not receive a Conflict of Interest review because neither Dr. [redacted] nor you indicated that a potential conflict existed. The Committee found that you have a conflict of interest with this protocol because you receive consulting fees from the sponsor of a clinical research project that are in excess the *de minimis* amounts permitted by Emory policies. In order to manage this conflict of interest, the Committee requires the following:

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[12] In February 2004, you notified the Committee that Dr. Musselman has notified the IRB that the records for this study should be corrected to properly reflect that you are a co-investigator.

1. You must disclose your relationship with Janssen in any publications, presentations, or press releases that result from this study. Disclosures should appear on the first page of the paper or presentation and should be announced during the presentation. Disclosures made only to the editor or the conference director are not acceptable. You should submit to the Committee a copy of the document with the disclosure statement highlighted.

2. You must identify an independent reviewer who will review any manuscripts related to this research that you author. This individual will be apprised of your relationship with Janssen and may review any primary data. You must provide to the COI Office the name and credentials of the independent reviewer and a brief explanation about the independence.

COI Case 2003-053-01, Clinical Trial sponsored by Janssen, A Neurocognitive and Functional Imaging Study of the Comparative Effects of Risperdal and Zyprexa on Memory Deficits Associated with Schizophrenia; project start date 3/1/99, *project end date 12/1/03; listed as active with a no-cost extension through 12/03.*

You are a co-investigator on Dr. [redacted] clinical trial sponsored by Janssen. In this trial, you and Dr. [redacted] are studying the effects of Risperdal (produced by Janssen) and Zyprexa (produced by Lilly) on memory deficits in patients with schizophrenia. Your hypothesis is that Risperdal will be associated with an improvement in memory function and distinct related effects on the anatomy of memory systems compared to Zyprexa. You tested this hypothesis using PET image analysis and other clinical assessments. The study group of 22 patients is compared to 11 normal volunteers. The clinical study began in March 1999 and was budgeted to end in February 2000. According to the IRB renewal application (558-98) dated October 9, 2003, enrollment is complete.

In addition to your relationship with Janssen, you are a consultant to Lilly Research Laboratories (a division of Eli Lilly and Co). This relationship is discussed above on page 5.

The Committee found that you have a conflict of interest because you receive more than $10,000 annually from both Janssen and Lilly. Janssen is sponsoring a clinical research project on which you serve as a co-investigator, and Lilly produces the challenge drug for this trial. The Committee felt that your failure to indicate your potential conflicts of interest to the IRB and the COI Committee was a serious omission.

In order to manage your conflict of interest, the Committee requires the following:

1. You must disclose your relationship with Janssen and Lilly in any publications, presentations, or press releases related to this study. The disclosure statement must appear on the first page of the manuscript or be announced during the presentation. Disclosures made only to the editors or the conference directors are not acceptable. You should submit to the Committee a copy of the publication or the presentation with the disclosure statement highlighted.

2. You must notify the volunteers who are currently in the study about your relationship with

Janssen and Lilly and ask them to sign a new consent form at their next appointment.[13]

3. You must identify an independent reviewer who will review any manuscripts related to this research. This individual will be apprised of your relationship with Janssen and may review any primary data.[14] You must provide to the COI Office the name and credentials of the independent reviewer and a brief explanation about the independence.

4. You should submit an annual report that describes the progress of your research, your relationship with Janssen and Lilly, and the steps that you have taken to comply with this management plan. You should submit the report for review by the Committee no later than September 20, 2004. If you complete this research, apply for another research grant from Janssen or Lilly, or apply for another research grant that studies products of Janssen or Lilly, you should immediately notify the Committee in writing.

Conclusion

The Committee found that you did not follow procedures and policies regarding the review of your consulting agreements[15] 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.[16] The Committee felt that these omissions were serious lapses and violated the School of Medicine's policy on the review of consulting agreements and the Policies and Procedures for Faculty Involved in Technology Transfer and Sponsored Research (University Conflict of Interest Policy for

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[13] In February 2004, in response to an e-mailed preliminary summary, you notified the Committee that Dr. [redacted] has notified all the patients involved in this study that due to the possibility of a conflict of interest, you will not be directly involved in recruiting patients, obtaining informed consent, having contact with study subjects, gathering or analyzing raw data, or reviewing or evaluating adverse events.

[14] In February 2004 in response to an e-mailed, preliminary summary of the Committee's finding, you notified the Committee that Dr. [redacted] will be reviewing data for this study.

[15] Under the School of Medicine Policies on Commitment, Private Consulting, and Extraordinary Contributions, faculty members must submit any consulting agreements for review by the Chair and the Dean's Office. In a memorandum to Dean Lawley dated December 20, 1999, you provided a list of companies with whom you had consulting agreements at the time. Dean Lawley sent a letter dated May 15, 2000 to you requesting copies of all consulting agreements to be sent to Ms. Seiton and questioning your time commitment. You responded to the question about commitment in a letter to Dean Lawley dated May 22, 2000 but did not provide your agreements to Ms. Seiton. At the request of Dr. Adkison, you provided Ms. Seiton copies of your current consulting agreements in October 2003 for this review.

[16] Each of these forms asks whether the investigator receives any compensation in excess of $10,000 from the sponsor. You responded "no" to the questions. You did send a list of companies for whom you consult with your 2002-2003 Annual Disclosure Form for Consulting Agreements and Financial Interests, but you did not indicate amounts of money received, identify potential conflicts, or provide copies of the agreements to Ms. Seiton, as specified in the form.

Research). In addition, these lapses may violate the University policies and procedures of the Institutional Review Board, IACUC, and Office of Sponsored Projects. If you had followed the policies and procedures that have been in place, many of these issues resulting from your conflicts and consulting could have been addressed and resolved. In the future, you must complete these forms correctly so that potential conflicts can be identified prior to the initiation of the research. If a potential conflict arises during a research project, you should immediately notify the Committee in writing.

You must notify the Committee in writing whether any of your federally funded research involves compounds that are produced by companies with whom you have consulting relationships.[17] 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 leadershp 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.

Conflicts are often inevitable in our complex technology transfer and funding environment and many of our outstanding and completely ethical faculty are managing similar conflicts. However, University policy and increasingly stringent federal law mandate that the faculty member has a responsibility to provide full disclosure and seek in advance approval and conflict management plans for all consulting and research activities that might raise even the appearance of conflict, and also to recognize that when he/she chooses to enter the commercial market privately for financial gain in areas that overlap with his/her academic pursuits, the consequences may include restrictions that hinder what the faculty may then do in academic research and in training students and fellows. The University has a mandatory joint responsibility with the faculty member either to develop an impeccable plan to manage the conflict or to eliminate it – to preserve the public trust in the knowledge discovered and disseminated by the University, and also to protect both the University and the faculty member from even the appearance of data bias, self-dealing, or other forms of undue influence. It is often the case that the perception of a conflict by the public is more harmful than any actual actions taken by the faculty member or the University.

If you have any questions, please do not hesitate to contact Dr. [redacted] Chair of the Committee, at [redacted] or me. I would be very glad to walk through the issues with you in person, if that would be helpful. Please sign and date the enclosed copy of this letter and return it to: Brenda J. Seiton, J.D., Assistant Dean for Administration, 113D WHSCAB, indicating that you will accept and comply with the

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[17] You consult for GlaxoSmithKline and receive $15,000 annually for these services. You forwarded a copy of the grant to NIMH for the Emory-GK-NIMH Collaborative Mood Disorders Institute. The Committee reviewed the grant at its April 2004 meeting. The Committee requested that you to keep your consulting fees from GSK to an amount that is less than $10,000 annually during the term of the grant and until all manuscripts are published. By following this plan, your conflict of interest, as defined by federal regulations, will be eliminated. You have verbally agreed to this plan.

management plans that are specified above and with the University and School policies.

Sincerely,

Claudia R Adkison

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. Date

CRA/bjs

cc: [redacted], M.D.
Ms. [redacted]
[redacted], J.D.
Thomas J. Lawley, M.D.