EMORY
UNIVERSITY
SCHOOL OF
MEDICINE

Office of the Dean

MEMORANDUM

TO: Thomas J. Lawley, M.D., Dean
FROM: School of Medicine Conflict of Interest Committee
DATE: May 26, 2004
RE: Review of Dr. Nemeroff's Grants and Outside Activities
CC: Claudia R. Adkison, J.D., Ph.D., Executive Associate Dean/Faculty Affairs & Administration

OVERVIEW

At your request, the Committee[1] reviewed Dr. Nemeroff's outside activities and his grants sponsored by companies with whom he has consulting relationships during its monthly meetings of October, November, and December 2003. The Committee reviewed his 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 had ever been 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 Dr. Nemeroff's e-mail communication to Dr. Adkison dated October 1, 2003, in which he noted that he has verbal agreements with the following companies: Abbott, Astra Zeneca, Comprehensive Neuroscience, George West Mental Health Foundation, GlaxoSmithKline, Neurocrine Biosciences, and Wyeth-Ayerst. He receives fees from these companies, and they pay him for any travel expenses related to his consulting activities. In addition, the Committee reviewed Dr. Nemeroff's Annual Disclosure Form for Consulting Agreements and Financial Interests in Research for 2002-2003, his Sponsored Projects Approval Forms, his IRB/HIC forms, and his IACUC forms for his currently active grants. In all of these

[1]Please note that Dr. [redacted] and Dr. [redacted] who are members of the Committee and who are faculty members in the Department of Psychiatry & Behavioral Sciences, abstained from voting on the conflict of interest management plans for specific grants and were not present for the discussions regarding Dr. Nemeroff's potential administrative conflicts of interest.

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forms, he responded that he had no financial interests in the sponsors for his research.

The Committee found that Dr. Nemeroff did not follow procedures regarding the review of his consulting agreements[2] and that he failed to disclose his potential conflicts of interest in research in his Annual Disclosure Form for 2002-2003, his Sponsored Projects Approval Forms, and his IRB and IACUC forms.[3] The Committee felt that these omissions were serious lapses and violated the Policies and Procedures for Faculty Involved in Technology Transfer and Sponsored Research (University Conflict of Interest Policy for Research). In addition, these lapses may violate the University policies and procedures of the Institutional Review Board, IACUC, and Office of Sponsored Projects. If Dr. Nemeroff had followed the policies and procedures that have been in place, many of these issues resulting from his conflicts and consulting could have been addressed and resolved. In the future, Dr. Nemeroff 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, he should immediately notify the Committee in writing.

Dr. Nemeroff must notify the Committee in writing whether any of his federally funded research involve compounds that are produced by companies with whom he has consulting relationships[4]. Under federal regulations, these grants must be reviewed in light of his 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.

The Committee was concerned about the time required by his consulting agreements under the School's "20% effort" policy. The Committee was also concerned

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

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

[4] On March 19, 2004, Dr. Nemeroff notified the Committee that he has a consulting relationship with GlaxoSmithKline and receives $15,000 annually for these services. Dr. Nemeroff forwarded a copy of the grant to NIMH for The Emory-GSK-NIMH Collaborative Mood Disorders Institute. The Committee reviewed the grant at its April 2004 meeting. The Committee requested Dr. Nemeroff to keep his 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, Dr. Nemeroff's conflict of interest, as defined by federal regulations, will be eliminated. Dr. Nemeroff has verbally agreed to this plan.

that some of the agreements[5] provide for a flat fee without specifying the services or times and whether these agreements are in compliance with various regulations. Another concern was that Dr. Nemeroff was paid milestones under the Cypress agreement for helping the company succeed with its drug; however, Dr. Nemeroff did not and is not conducting research on this "milestone" agent. In addition to the usual review by the Dean's Office, the Committee strongly suggests that Dr. Nemeroff should work with the Emory Healthcare Compliance Office to ensure that his relationships with the pharmaceutical and device companies are in compliance with medicare and medicaid regulations.

The Committee discussed Dr. Nemeroff's relationships with industry in light of his role as a representative of Emory and his leadership in the scientific community. The Committee felt that Dr. Nemeroff must disclose his relationships with industry if he discusses the company's products, whether in publications or presentations. This requirement goes beyond the presentation of research results; it applies to all his communications.

The Committee discussed whether faculty members in his department may serve on grants as principal investigators (PIs) if Dr. Nemeroff is a co-investigator and has a relationship with the sponsor that places him in a position of having a potential conflict of interest. The Committee determined that it is important for the faculty to be able to serve as PIs and work with their Chair; however, Dr. Nemeroff must disclose his relationship with the sponsor to the research team and the grant must be reviewed by the Committee for further management plans.

FINDINGS OF THE COMMITTEE REGARDING SPECIFIC RELATIONSHIPS OR GRANTS

Cypress Biosciences

Dr. Nemeroff is a consultant to Cypress Biosciences and a member of their Board of Directors[6]. 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, Dr. Nemeroff had two agreements. Under one, he received $36,000 in consulting fees in 2002. According to the article, he has a separate agreement under which he would receive $100,000 in cash or stock if he helped Cypress succeed with the drug, milnacipran. Dr. Nemeroff reported in an e-mail to Ms. Seiton dated March 3, 2004 that

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

[6] In an e-mail to Ms. Seiton dated March 26, 2004 (check year), Dr. Nemeroff reports that he will be stepping down from the Cypress Board of Directors effective March 25, 2004. He will continue to serve as a consultant to the company for a period of two years. He will retain the stock that he has, but will receive no additional shares. He will be forwarding the new agreement to the Dean's Office for review.

the New York Times article was incorrect. He reported that he is remunerated for serving on the Board of Directors, chairing the Science and Technology Committee, and serving on the Compensation Committee and that he received 50,000 options when Cypress signed a deal with Forest Laboratories. According to Dr. Nemeroff, the $100,000 bonus referenced in the New York Times article was changed to the 50,000 options[7]. He has not exercised any of his options. He reported that he 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, Dr. Nemeroff 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 his responsibilities as a Director, Dr. Nemeroff receives 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 Dr. Nemeroff's discussion of the Cypress drug, milnacipran, in the *Nature Neuroscience* article did not violate any Emory policies. According to the journal's editors, his actions did not violate any of the journal's policies at the time.

The Committee recognized that Dr. Nemeroff's role as a "matchmaker" for Cypress presents an appearance of conflict with his role as an academic leader in his field and a representative of Emory in the public, i.e., an administrative conflict. The Committee is very concerned about this appearance of conflict. 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. 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 at Emory in the Department of Psychiatry & Behavioral Sciences as long as Dr. Nemeroff has 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 Dr. Nemeroff continues this role with the company because Dr. Nemeroff, as an administrator who is a responsible for supervising and mentoring his faculty, has a significant financial relationship with Cypress that could reasonably appear to unduly influence his relationship and activities with his faculty members.

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

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

Merck [8]

Dr. Nemeroff serves on Merck's US Strategic Advisory Board for Mental Health Disorders and provides advice, counsel, and assistance in the development, planning, and execution of commercial and scientific initiatives related to Merck's Substance P (a neurokinin receptor) Antagonist and GABA-A Agonist programs for mental health disorders. He is contractually committed to provide12 days of service per year. In 2002, he received $40,000; in 2003, he received $48,000; and in 2004, he will receive $56,000. Dr. Nemeroff also receives travel expenses. Dr. Nemeroff did not provide the consulting agreement to the Dean's Office as required by the School's Consulting Policy. He 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

Dr. Nemeroff is 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. Dr. Nemeroff indicated that he 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[9]) 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 Dr. Nemeroff receives more $10,000 from Merck, 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:

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[8] In December 2003, Dr. Nemeroff sent the Committee a notice indicating that he is no longer a member of Merck's Advisory Board, retroactively effective August 1, 2003.

[9] Dr. Neneroff's resignation from the Merck Advisory Board was not submitted until December 2003, though he made the resignation retroactive to August 1, 2003.

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

2. Dr. Nemeroff must submit an annual report that describes the progress of his research, his relationship with Merck, and the steps that he has taken to comply with this management plan. He should submit the report for review by the Committee no later than September 20, 2004. If he continues to receive more than $10,000 from Merck and he applies for another research grant sponsored by Merck or applies for another research grant that studies products of Merck, he should immediately notify the Committee in writing[10].

Lilly Research Laboratories

Dr. Nemeroff is a consultant to Lilly Research Laboratories (a division of Eli Lilly and Co.). He consults and performs activities for Lilly's duloxetine development team regarding opportunities in the treatment of depression; consults with Lilly's olanzapine/fluoxetine combination development team regarding opportunities in depression; consults with Lilly's neuroscience research and development team regarding new compounds for the treatment of a variety of psychiatric disorders; and consults with the Lilly professional relations group. He receives $3000/day for his services plus expenses. On his 2002-2003 Annual Disclosure Form, Dr. Nemeroff reported that he provides 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, 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. Dr. Nemeroff did not forward his 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 his *curriculum vitae,* Dr. Nemeroff reported that he was 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, Dr. Nemeroff notified the 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. He does not own any stock in Lilly.

COI Case 2003-047-01, Clinical Trial sponsored by Lilly, Open Label Treatment with

[10] The obligations outlined in this last sentence will not be required if Dr. Nemeroff has no financial relationship with Merck.

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

Dr. Nemeroff is 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 tolerability in treatment 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 reuptake *in vitro* and *in vivo*. The safety and pharmacokinetic profile of duloxetine has been studied in more than 25 clinical studies at doses up to 80mg twice daily. A study to assess the safety and tolerability of duloxetine once-daily doses in the range of 60-120 mg is underway. Duloxetine is not approved by the FDA. The protocol was reviewed by the IRB in October 2002 by the full committee. Dr. Nemeroff indicated that he had no 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. On the Sponsored Projects Approval Form, he answered "NO" to the question asking whether any investigators have financial interests in the sponsor of the research.

The Committee found that Dr. Nemeroff has a conflict of interest because during the term of the project he received more than $10,000 annually from Lilly, and Lilly is sponsoring a clinical research project on which he serves as a the Principal Investigator. The Committee found that his failure to indicate his 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 he is 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 his relationship with Lilly. The Committee provided two options for Dr. Nemeroff:

Option A[11]

1. Dr. Nemeroff must keep his fees to less than $10,000 annually from Lilly.

2. He would be able to remain as PI if he keeps his fees to an amount that is less than$10,000 but he may be required to disclose his relationship with Lilly in his publications under the policies of the journals.

[11] If Dr. Nemeroff begins or continues his relationship with Lilly, he must notify the Committee in writing and forward the new consulting agreement for review by the Dean's Office.

Option B[12]

1. Dr. Nemeroff may keep his consulting fees but withdraw himself as the PI.

2. Dr. Nemeroff should identify a new PI for the study.

3. Dr. Nemeroff may remain on the study as a co-investigator but he 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. He should inform the members of the research team about his conflict of interest.

4. Dr. Nemeroff must disclose his 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. Dr. Nemeroff should submit to the Committee a copy of the publication or the presentation with the disclosure statement highlighted.

5. Dr. Nemeroff should submit an annual report that describes the progress of his research, his relationship with Lilly, and the steps that he has taken to comply with this management plan. He should submit the report for review by the Committee no later than September 20, 2004. If he completes this research, applies for another research grant from Lilly, or applies for another research grant that studies products of Lilly, he 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*[13]

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[12] In February 2004 in response to an e-mailed preliminary summary of the Committee's findings, Dr. Nemeroff notified the Committee that Dr. [redacted] is the PI for this study and he will be a co-investigator. He 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.

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

Dr. Nemeroff is 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 they may 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. The aims are (1) to compare the indices of central CRF activity before and after treatment with either fluoxetine or placebo between women with a personal history of childhood abuse and current major depression, women with a history of childhood abuse without major depression, and women without a history of childhood abuse and major depression; (2) to compare indices of central CRF activity before and after treatment with either fluoxetine or placebo within the study groups; and (3) to correlate changes in CNS CRF systems with psychological outcome measures. 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, Dr. Nemeroff indicated that he did not have any financial relationships with the sponsor. On the Sponsored Project Approval Form dated March 25, 1998, he indicated that he did not have financial relationship with the sponsor. In a review separate from the Committee, Ms. Seiton verified that on his 1998-1999 Annual Disclosure Form dated August 24, 1999, he did indicate that in his SEP IRA account he owned 300 shares of Eli Lilly valued at $21,487.50 and that he had a consulting agreement with Lilly[14]. However, he did not forward the agreement to the Dean's Office for review. In his IRB renewal form dated October 21, 2002, he indicated that he did not have any financial relationships with the sponsor.

The Committee found that Dr. Nemeroff had a conflict of interest because he received more than $10,000 annually from Lilly during the term of the project, and Lilly is sponsoring a clinical research project on which he served as a the Principal investigator. The Committee found that his failure to indicate his 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 his omission to be significant breach of policy because he is being paid by Lilly to provide advice on fluoxetine, the drug that is being studied, and the study involved direct intervention with human subjects. Fluoxetine is approved by the FDA. The Committee found that Dr. Nemeroff is not uniquely qualified to serve as the PI for this trial[15]. The Committee provided two options for Dr. Nemeroff:

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[14] On March 19, 2004, Dr. Nemeroff notified the Committee that he no longer owns any stock in Lilly.

[15] 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

Option A

1. Dr. Nemeroff must keep his fees to less than $10,000 annually from Lilly.

2. He would be able to remain as PI if he keeps his fees to an amount that is less than $10,000 but he should disclose his relationship with Lilly in his publications or presentations because he was over the threshold limits during several years of the study.

Option B[16]

1. Dr. Nemeroff may keep his consulting fees but withdraw himself as the PI on the clinical study.

2. Dr. Nemeroff should identify a new PI for the study.

3. Dr. Nemeroff may remain on the study as a co-investigator but he 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. He should inform the members of the research team about his conflict of interest.

4. Dr. Nemeroff must disclose his 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. Dr. Nemeroff should submit to the Committee a copy of the publication or the presentation with the disclosure statement highlighted

5. Dr. Nemeroff should submit an annual report that describes the progress of his research, his relationship with Lilly, and the steps that he has taken to comply with this management plan. He should submit the report for review by the Committee no later than September 20, 2004. If he completes this research, applies for another research grant from Lilly, or applies for another research grant that studies products of Lilly, he should immediately notify the Committee in writing.

COI Case 2003-049-01, Non-clinical Research Grant sponsored by Lilly, the role of the

[16] In February 2004 in response to an e-mailed preliminary summary of the Committee's findings, Dr. Nemeroff notified the Committee that Dr. [redacted] is the PI for this study and he will be a co-nvestigator. He 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.

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.

Dr. Nemeroff was the Principal Investigator on a research project involving animals that examines 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] informed the Committee that the IACUC protocol covering the studies is this grant is no longer funded by Lilly according to information received by the IACUC. Once he entered a financial relationship with Lilly through which he received more than $10,000, he failed to disclose this relationship to the Committee or the IACUC. This was a breach of the Conflict of Interest Policy and potentially a violation of the IACUC procedures.

The Committee found that Dr. Nemeroff had a conflict of interest with this research because he received more consulting fees than permitted by the University policy. The Committee requires the following:

1. Dr. Nemeroff must disclose his 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. Dr. Nemeroff should submit to the Committee a copy of the publication or the presentation with the disclosure statement highlighted.

2. An independent reviewer will be assigned to review any manuscripts related to this research. This individual will be apprised of Dr. Nemeroff's relationship with Lilly and may review any primary data.

3. Dr. Nemeroff should submit an annual report that describes the progress of his research, his relationship with Lilly, and the steps that he has taken to comply with this management plan. He should submit the report for review by the Committee no later than September 20, 2004. If he applies for another research grant from Lilly or applies for another research grant that studies products of Lilly, he should immediately notify the Committee in writing.

Janssen

Dr. Nemeroff is a consultant for Janssen and provides services during two weekends on an annual basis. According to his agreement, he provides 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, he receives $4,000 per day and/or $5,000 per day when traveling away from home. On his 2002-2003 Annual Disclosure Form, Dr. Nemeroff reports that he spends two weekends per year consulting for Janssen. The contract is dated January 31, 2003. Dr. Nemeroff disclosed that he had a consulting agreement with Janssen on his 2002-2003 Annual

Disclosure Form dated April 2003, but he did not forward the agreement to the Dean's Office for review as required by the School's Consulting Policy and as requested by the Annual Disclosure Form. On his *curriculum vitae,* he reports that he has been a consultant with Janssen since 1998.

On March 19, 2004, Dr. Nemeroff reported that he received the following from Janssen: $38,238.53 (includes travel expenses) in 2002 and $25,000 (consulting fees only) in 2003. Dr. Nemeroff also reported that he holds 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

Dr. Nemeroff is a co-investigator on Dr. Musselman's grant sponsored by Janssen. The trial is 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 will be studied for six months. The investigators will study the comparative effects of risperidone and olanzapine on the glucoregulatory parameters in patients with schizophrenia. The trial at Emory is budgeted for fifty subjects. It began in April 2002 and was budgeted to end in December 2003. The IRB protocol was terminated by Dr. Musselman in August 2003. The IRB office also reported that Dr. Nemeroff was not listed as a co-investigator for this trial in their most recent record,[17] though he was listed as a co-investigator on the Sponsored Programs Approval Form.

This grant did not receive a Conflict of Interest review because neither Dr. Musselman nor Dr. Nemeroff indicated that a potential conflict existed. The Committee found that Dr. Nemeroff had a conflict of interest with this protocol because of his financial relationship with Janssen and that any publications, presentations, or press releases should include a disclosure statement about Dr. Nemeroff's relationship with Janssen. An independent reviewer will be assigned to review any manuscripts related to this research. This individual will be apprised of Dr. Nemeroff's relationship with Janssen and may review any primary data.

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*

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

date 12/1/03, listed as active with a no-cost extension through 12/1/03

Dr. Nemeroff is a co-investigator on Dr. [redacted] clinical trial sponsored by Janssen. In this trial, the investigators are studying the effects of Risperdal (produced by Janssen) and Zyprexa (produced by Lilly) on memory deficits in patients with schizophrenia. Their 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. They 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. They are on a no-cost extension through December 2003. According to the IRB renewal application (558-98) dated October 9, 2003, enrollment is complete.

In addition to his relationship with Janssen, Dr. Nemeroff is a consultant to Lilly Research Laboratories (a division of Eli Lilly and Co). This relationship is discussed above on page 6.

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

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

1. Dr. Nemeroff must disclose his 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. Dr. Nemeroff should submit to the Committee a copy of the publication or the presentation with the disclosure statement highlighted.

2. Dr. Nemeroff must notify the volunteers who are currently in the study about his relationship with Janssen and Lilly and ask them to sign a new consent form at their next appointment.[18]

3. An independent reviewer will be assigned to review any manuscripts related to this research. This individual will be apprised of Dr. Nemeroffs relationship with Bristol Myers Squibb and may review any primary data.[19]

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[18] In February 2004 in response to an e-mailed, preliminary summary, Dr. Nemeroff 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, Dr. Nemeroff 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.

[19] In February 2004 in response to an e-mailed, preliminary summary of the Committee's finding, Dr.

4. Dr. Nemeroff should submit an annual report that describes the progress of his research, his relationship with Janssen and Lilly, and the steps that he has taken to comply with this management plan. He should submit the report for review by the Committee no later than September 20, 2004. If he completes this research, applies for another research grant from Janssen or Lilly, or applies for another research grant that studies products of Janssen or Lilly, he should immediately notify the Committee in writing.

CONCLUSION

This report details the findings of the Conflict of Interest Committee regarding Nemeroff's conflicts of interests, details instances in which the Conflict of Interest Policies were violated, and provides the on-going management plans. The Committee focused only on his current research and agreements with outside companies. The Committee did not inquire into potential conflicts associated with Dr. Nemeroff's research grants that ended before 2002, according to University records.

The Committee felt addressing recommendations that deal with Dr. Nemeroff's breach of University policies is beyond its purview.

Nemeroff notified the Committee that Dr. [redacted] will be reviewing data for this study.