

From: Charles B. Nemeroff [REDACTED]@emory.edu
Sent: Thursday, July 20, 2006 9:18 PM
To: Adkison, Claudia R
Cc: Tom Lawley
Subject: Re: Comments on corrigendum and the broader topic

Charles's response

Dear Claudia,

First and foremost again, please know that I am very grateful to you and Tom for your continued support. As I have said to you many times, I don't think we have very many differences of opinion in this arena. I would like to clarify several points that you raised that are actually not accurate and I think very important in the chain of events outlined below. I will really try to be brief. Cyberonics is a Houston based company that markets VNS for the treatment of Pharmacoresistent Epilepsy, This use is approved by the FDA. When it was noted that many epileptic patients exhibited mood improvement after VNS even if their seizure disorder was not improved, studies to test its efficacy in severe depression were initiated and ultimately it was approved for treatment of refractory depression by the FDA. A Scientific Advisory Board of psychiatrists was formed to advise the company and after a few meetings I was asked to form a smaller Mechanism of Action (MOA) Advisory Board to advise the company on research directions to begin to understand how this treatment produces effects on the brain that improve depression. THE MOA ADVISORY BOARD WAS NOT FORMED TO WRITE A REVIEW ARTICLE. IT WAS FORMED TO MEET ONCE PER YEAR AND GO OVER PUBLISHED REPORTS, DATA PRESENTED AT MEETINGS AND TO SUGGEST RESEARCH DIRECTIONS THAT WOULD HELP ELUCIDATE THE MOA OF VNS. DURING ONE SUCH MEETING LAST YEAR, THE GROUP OF BASIC AND CLINICAL NEUROSCIENTISTS SUGGESTED THAT THERE WAS NO SINGLE PLACE WHERE ALL THE DATA ON MOA OF VNS WAS SUMMARIZED AND SUGGESTED TO THE COMPANY THAT SUCH A REVIEW WOULD HELP STIMULATE RESEARCH IN THE FIELD. WE ASKED FOR SUPPORT FOR THE PROJECT AND THE UNRESTRICTED EDUCATIONAL GRANT WAS USED TO PAY FOR THE HOTEL ROOM RENTAL AND TRAVEL OF THE PARTICIPANTS AS WELL AS THE EDITORIAL ASSISTANT. THERE WERE NO PAYMENTS TO THE BOARD MEMBERS FOR THIS PUBLICATION, WHICH WAS CONSIDERABLE. ALL OF US WERE PAID A FEE FOR SERVICE ON THIS BOARD, WHICH DID NOT CHANGE BASED ON THIS PROJECT. Therefore Claudia your point 3 is simply not true. The members of the board include several IOM members with diverse backgrounds and expertise including the chair of neuroscience at Duke, the Dean of the School of Medicine at Mt. Sinai in NYC, the Chair of the Dept of Pharmacology at San Antonio, etc. Why them? Because they have expertise in epilepsy and molecular neurobiology, clinical pathophysiology of psychiatric disorders and mechanisms of drug action, respectively. All the data from the original research reports were reviewed as were data from meeting proceedings and unlike almost all reviews published in medicine, WE SPECIFICALLY NOTED WHEN A FINDING WAS BASED ON A PRESENTATION INSTEAD OF A PEER REVIEWED JOURNAL ARTICLE. In terms of Item 5, I have conducted an extensive search of the top 5 journals in Psychiatry (including Neuropsychopharmacology), and other top journals in medicine such as the NEJM, Nature, Science, etc. and I could find not one review article that separated the papers reviewed by potential conflicts of interest of the authors or institution. If you are aware of any, I would like to see them. Moreover, as regards your number 9, [REDACTED], the editorial assistant is NOT any employee of Cyberonics and never has been. As for (10), each of the 9 coauthors as I alluded to above, are experts in their respective fields. Thus I surely could not have reviewed the functional brain imaging as well as [REDACTED], or the rodent microdialysis work as well as [REDACTED] or the Epilepsy MOA data as well as [REDACTED].

8/7/2006

[REDACTED] or [REDACTED] As far as the reprints(11), I obviously had little to do with this but I find a review on mechanism of action of VNS that would be given to physicians to be a plus in terms of their education; please remember this was a review on MOA, not clinical efficacy. The consulting agreements reviewed by Brenda were indeed accurate because the decision to synthesize such a review from the extant literature occurred during the course of the meeting and was never discussed as part of our mission. In fact it was the members of the MOA group that came up with the idea because of their enthusiasm for it. As regards the omission of the financial disclosures, the unfortunate chain of events were as follows. After each of the authors made substantive changes in the manuscript on several drafts and they were collated, added to the text, the final draft was sent out for approval by all the authors. A few more changes were suggested and the final manuscript was submitted to the journal together with ALL of our financial disclosures. (Parenthetically I have submitted all of my financial disclosures for the last 3 years with every manuscript and book chapter that I have submitted since the previous debacle. On at least 3 occasions, the journal refused to publish my financial disclosures and Drs. Carroll and Rubin sent letters to the editor of these journals criticizing me. In each of these cases which included for example the J. Psychiatric Research and more recently Trends in Endocrinology and Metabolism, the editors have informed Drs. Carroll and Rubin that I had indeed submitted these disclosures and therefore refused to publish their letters. This has not stopped them in any way. Incidentally, the Textbook of Psychopharmacology that I edit with Alan F. Schatzberg is the only Textbook I know in medicine that not only has the editors complete financial disclosures but all of the chapter contributors as well. This should at least let you know that I do pay attention to your advice and where the bar should be.) Back to this chain of events: Because I am Editor in Chief of the journal, any manuscripts that I submit are handled by another Field Editor, in this case [REDACTED] MD, newly appointed Dean of the University of Wisconsin School of Medicine. He sent the manuscript out to 3 reviewers and the manuscript was sent back to me requiring revisions. I revised the manuscript and sent it back in. Because of my role as an author, I had no input into the editorial process. When I submitted the manuscript with all of the authors' financial disclosures, I assumed that it was understood that we wanted this contained in both the online and print publication. Unfortunately the disclosures were not included in the manuscript. Please note that the final revised submitted manuscript was approved by all 9 authors, the Field Editor, the 3 reviewers, the Neuropsychopharmacology office staff and the Nature Publishing staff. No one noticed the omission of the financial disclosures and the galley proofs were sent to me as first author and frankly I missed it again. Any one wishing to see my financial disclosure could have done so in a variety of places. If Drs. Carroll and Rubin had given us a few days to correct the omission on the journal website and to make a correction in the next issue of the journal, prior to sending their letter about this omission to literally hundreds of individuals including the WSJ and other news services, this adverse publicity would not have occurred. The adverse publicity is, of course, what their true goals are. Please remember that when their letter to Nature Neuroscience was rejected by the editor in chief who stated that their policy did not include such a requirement (I was really naive back then), they sent it to the NY Times, Newsweek and several other magazines and newspapers. Only the NY Times published it.

I hope I have clarified a few points. I am mortified that I have caused you, Tom and Emory any pain or embarrassment. You have known me a long time and you know how much I love Emory and have always tried to bring a positive light to our school. I would appreciate it if you could keep the contents of this email confidential and use its contents as you see fit to help with damage control. I will, of course, copy Tom on it as well. I am in tomorrow until late afternoon, going up to Niagra Falls with my wife for the weekend and then I am off to South Africa for a 2 week vacation leaving Monday morning. I will have email and cell phone access in Capetown on Tues, Wed and Thurs but after that I will likely be hard to reach. If you need me, you can call my home number ([REDACTED]) and my wife can let me know you need to talk to me when I call in.

Claudia as a lawyer and a scientist, you are uniquely qualified to understand the complexities of these relationships (No wonder you chair the AAMC committee on Conflict of Interest) and I appreciate your

view that no policy can cover every scenario. However, my approach of complete financial disclosures on every publication and every scientific presentation, I thought was sufficient. Clearly, however, when glitches occur, as in this case and there are those, ever vigilant, waiting to point fingers, the result is tragic. I hope this long winded monologue is helpful in clarifying some of the issues raised.

Charlie

At 08:07 PM 7/20/2006, you wrote:

Thank you, Charlie. I learned a new word – corrigendum.

Charlie, continuing our long string of emails, I want you to know that I can't remember when I have gotten so many complaints about the action of one or more of our faculty from inside and outside the institution, including negative comments from administration higher than the SOM, most implying that I should do something about this matter and all ranging from sarcasm to being incensed. In working on handling the reporter, I tried to make this story go away because Emory's name is in the middle of it. I am deeply concerned about the ding to your reputation and that of our other faculty authors that this has potentially caused. I have been grateful that the reporter was not sophisticated enough to ask all the right questions. Not only have our colleagues seen the actual paper, but the AAMC has sent it out as part of its weekly scan of medical schools in the news, so all the deans of medical schools, all the associate deans, chairs, the GREAT group, the GRAND group, and anybody else in academics who subscribes to this weekly newsletter has seen this. There is no way we can respond to all that. And blaming the reporter for partially mis-reporting is not the answer, since he was mostly right. He just doesn't know all the facts.

As to the corrigendum, I am increasingly of the viewpoint that the current form of disclosure in journals is not enough to protect the integrity of academic literature. (1) The consultantship for each of you was to get money from Cyberonics as individuals (2) to be on a special board within Cyberonics (3) that was specifically formed to pull a group of authors together and write this review (4) of original papers mostly funded by Cyberonics (potentially biased in the first place, if those authors were Cyberonics consultants also) (5) in which you did not review the potential conflicts in the papers reviewed. (6) Cyberonics gave you, the lead author and editor of the journal and department chair, a financial gift to your department in relation to this activity (despite the fact it was labeled unrestricted, which would have implied your bending over backwards to use it for anything but a Cyberonics activity), and (7) at least some or all of which was used to co-employ an editorial assistant (8) who was also an employee of Cyberonics (9) who writes marketing for them. (10) One or two authors could have written this paper, but the team of 9 was likely pulled together because they are prestigious and from prestigious institutions, thereby adding weight to the paper, (11) which will be used by Cyberonics in advertising (I think I saw that they ordered 10,000 reprints). (12) Two of you had your consulting agreements reviewed by the SOM as required by policy, but (13) possibly none of you explained what the consulting agreement was actually for so that appropriate COI consideration could have been given (I have asked to see the actual contract, if Brenda still has it). (14) All authors no doubt had access to the page proofs that excluded whatever disclosures there were, if this journal operates like others I know and not one of you told the journal to include the disclosures (though I assume all of you actually did read the page proofs).

Now that would be a disclosure that would give the reader the needed information to decide whether to believe the opinions voiced in the review paper. As I said before, no matter how stringent the science and no matter how careful the controls to avoid bias and no matter how pure the intentions of the authors (and I might give you the benefit of the doubt on all those points), I can't believe anyone in the public or in academia would believe anything except that this paper was a piece of paid marketing, and that hurts your reputation as a faculty author with a duty to present both the truth and the appearance of the truth, role modeling and leadership duties from senior faculty members aside.

In my view, doing the right thing here would have been (1) take no personal money from Cyberonics, (2) look into the COIs of the authors on the original papers, (3) take no money into the dept from Cyberonics, (4) pull the collaborating authors together independent of Cyberonics. This would have been a paper you could be proud to have your name and Emory's on.

I know I have already written some of this to you, but the continued string of complaints has upset me and I am embarrassed and uncomfortable that I have to write to colleagues around the country to try to defend this when I know all the issues. As I have said before, we cannot possibly write a policy that covers every

conceivable wrinkle about disclosure to Emory and COI review. We must depend on faculty to take the intent and apply it with common sense.

I am pasting below Emory's policy on the responsible conduct of scholarship and research, which should be read with all of our COI policies and all our internal and external guidelines that we try to follow. You know that I will be glad to discuss all this with you further. I thought this was a chapter closed and lesson learned, until I continued to get so many more complaints and comments today.

Sincerely,
Claudia

Guidelines for the Responsible Conduct of Scholarship and Research

March 18, 1993

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I. Preamble

These guidelines describe a standard of practice for the conduct of scholarship and research at Emory University. The University complies with all applicable laws and regulations. (See appendix). The guidelines are intended as a statement of desirable practices. They are based on three important principles:

1. The University is obligated to protect and foster the academic freedom and intellectual integrity of all members of the University community in their pursuit of knowledge;
2. The University is accountable to outside funding sources that support the research and scholarship of its faculty; and

Every scholar has ultimate responsibility for the accuracy and validity of his/her own work and that of junior co-investigators, fellows, and students. Each scholar shares this responsibility with colleagues with whom she/he establishes collaborative relationships.

II. Areas of Applicability

This document applies to research in all areas of intellectual inquiry. A separate section addresses issues specific to scientific research. These guidelines are intended to heighten awareness of potential ethical problems and to instruct individuals regarding appropriate procedures for resolving and documenting ethics-related matters. The focus is on the individual scholar; the purpose is to emphasize that his/her responsibility includes a duty to maintain high scholarly and ethical standards, and a commitment to instill those standards in co-investigators, students and trainees.

Scientific inquiry, scholarly contributions, creativity, and academic accomplishment can take many forms and may vary among disciplines. The issues addressed by these guidelines are essential to all scholarly activity within the

University community. Scholarly responsibility, quality of scholarly activity, security of scholarly contributions and their sources, responsible authorship, and provision for training in ethics of each discipline

are issues inherent to all areas. The implications of these guidelines apply as fully to the scholar who co-authors a history textbook as to the laboratory scientist who reports a biological discovery, or the clinician who publishes a case report.

The guidelines address the following concerns:

1. the scholar's authority and responsibility for research activities;
2. the establishment of the quality of research;
3. authorship of publications, including multiple publications and requisites for authorship;
4. the supervision of students and other trainees;
5. the education of trainees in research ethics and integrity;
6. access to and retention of scientific research protocols and data; and
7. the social responsibility of the scholar.

III. The Conduct of Research and Scholarship

A. Authority and Responsibility for Research Activities

The head of each division, department or program is responsible for assuring that each fellow or student has a specific faculty research director or dissertation advisor. Usually a dissertation advisor or research director will be a full-time faculty member of a University department. This responsibility should not be construed as carrying rights of authorship, consultation, or approval of manuscripts prior to publication.

B. Establishing the Quality of Research

1. Primary assurance of the quality of research stems from the scholarly qualifications of individual faculty members. All faculty members are ultimately responsible for the scholarly character, accuracy, and reliability of their own research and for that conducted under their supervision. Each scholar is also responsible for the integrity and originality of his/her own research. The most effective single process for ensuring research of high quality is peer review, both formal and informal. Informal review occurs through departmental and interest-group seminars and research discussion groups. Each division, department, or program should encourage such informal review procedures. Formal review will be accomplished by existing review committees (e.g., tenure and promotion committees) that are charged with the task of evaluation of the merit and relevance of research. (An example of an external committee is an NIH study section.)

2. Faculty should establish an intellectual atmosphere that promotes high academic and moral standards and in which issues of social responsibility and professional ethics are addressed.

3. Emory University's formal policy governing investigations of misconduct in research ("Policies and Procedures for Investigation of Misconduct in Research" Emory University, 2 March 1989.) should be followed when allegations of research improprieties have been made. That document, which is incorporated by reference, should be on file in the office of each laboratory head and faculty member and should be distributed to all members of the research team.

C. Authorship of Publications

1. By virtue of the multiplicity of sources of concepts and information upon which any piece of scholarship is based, it is essential that proper attribution be emphasized in the presentation of ideas and the publication of manuscripts.

2. Authorship should be granted to, and only to, those persons who have made appropriate contributions to the conceptualization, design, execution, or interpretation of the work reported. Individuals who have made lesser contributions such as providing advice, analyses, subject material, or who may have supported the research in other ways, should be acknowledged. The principal author should determine if such individuals should be listed as authors. In some fields, written permission may be required for acknowledgments. In factual or scientific reports, authors should take care to cite relevant data including that which does not support the hypothesis being presented. It is an author's responsibility to be familiar with and to cite other publications relevant to his/her work. It is unethical, and inimical to the scholarly

endeavor, to submit the work of others, in whole or in part, as one's own, to fabricate research results, or to suppress or alter information. (Modified from "Ethical Guidelines for Publication of Research", *Endocrine Reviews*, 10:1, 1989 and "Authorship and Other Credits", N. Fotion and C.C. Conrad, *Annals of Internal Medicine*, 100:592, 1984.) Authors who wish to cite information learned personally or from unpublished materials should obtain written permission from the source.

3. It is inappropriate to submit abstracts of research, or reports of the same research to more than one publisher unless the action is authorized by the editors of each publication or multiple submission is the accepted standard of practice in a discipline/field. Preliminary accounts of abstracts of work already published should be referenced in any complete report of that work.

4. Multi-authorship raises issues such as criteria for inclusion as an author, ability or each author to evaluate all aspects of a study, and sequence of listing of authors. Authors should discuss these issues openly

before initiating a multi-author project and repeatedly during the course of such work. The submitting or primary author has responsibility for coordinating the completion and submission of the work, and for assuring that the contributions of all collaborators are appropriately recognized. All authors should approve the final version of a manuscript and should be prepared to take public responsibility for the work. ("Ethical Guidelines for Publication of Research" and "Authorship and Other Credits").

5. Every author and co-author is responsible for composing, reviewing, and verifying those portions of a manuscript, publication, or presentation that represent his/her contribution. Each author should sign a standard form or statement of verification attesting to the authenticity of the manuscripts. The signatures should be appended to the final manuscript. All co-authors are entitled to make appropriate copies of a manuscript, including figures and appended documents.

D. Supervision of Student Scholarship

1. The academic institution's responsibility to educate and prepare students to enter society and to practice their disciplines with high ethical standards does not cease with formal course work. The University and its faculty have an obligation to the academic community, the public, and the student to ensure that all students and trainees engage in scholarship and research responsibly, using the highest professional standards.

2. Dissertation advisors, research directors and administrative heads share responsibility for guaranteeing an open and equitable research environment that protects the interests of students, assistants and other vulnerable trainees. They should ensure that students are given due recognition for original work, that demands made upon students are reasonable, and that they are treated in interpersonal relationships with the same professional courtesy granted peer colleagues. Avenues must be available for students who feel their supervision or training is inadequate to bring this to the attention of the advisor, director or, if necessary, to the appropriate administrative head.

3. Dissertation advisors and research directors should meet regularly with students, fellows, and other collaborators to review their work and progress.

4. Dissertation advisors and research directors should serve as role models and maintain the highest standards in performance of research. They should encourage students to be open and to share ideas and information with other members of the scholarly community. They should ensure that the experience of their students serves to prepare them to become independent scholar and researchers.

E. Education of Graduate Students in Research Ethics and Integrity

1. Ethical issues and questions in the conduct of scholarship should be made an integral part of the education of all graduate students. Research directors are responsible for establishing a training environment in which value-related issues are discussed freely. The director should expect and foster at least a minimal level of familiarity with ethics as related to scholarship. The goals should be to teach students and other trainees how to identify ethical issues and how to address the common ethics-related questions that arise in the course of investigation and publication.

2. Heads of departments, divisions, and programs are responsible for fostering the teaching of ethics within their unit. An ethics component of the curriculum should provide students and faculty with the intellectual tools and interactional skills to apply ethical thinking to everyday problems encountered in their research. Ethical issues, concepts and theoretical grounding should be introduced as part of the orientation of all graduate students and trainees.

F. The Social Responsibility of the Scholar

Scholars have an obligation to ensure that scholarship is not misused and that it does not become a tool for abuse. Scholars are more likely than others to know the limits and conditions of current knowledge in their own fields, and the problematic aspects of using this knowledge to make public policy. Scholars have a right and a responsibility to make their voices heard when their scholarship and their contribution to society are being misquoted, misunderstood, or misapplied. (Adapted from S.J. Bird, President's Remarks, "Professional Responsibility", AWIS Magazine, 20:2, 1991.) Scholars are also responsible for being familiar with all University policies related to research including copyright and patent policies, Policies and Procedures for Investigation of Misconduct in Research, and these guidelines.

IV. The Conduct of Scientific Research

The following paragraphs refer specifically to scientific research and serve as an addendum to the broader guidelines described above.

A. Authorship and Responsibility for Scientific Research Activities

The head of each division, department, or program is responsible for assuring that (1) every laboratory or research unit has a designated preceptor (i.e., supervisor, mentor, or director), and (2) that each trainees (e.g., post-doctoral fellow, junior investigator, graduate or undergraduate student) has a specific faculty research preceptor. Usually a research preceptor will be a full-time faculty member of a University department or a

laboratory head in an Emory-affiliated research facility or hospital.

B. Establishing the Quality of Scientific Research

1. The research director is responsible for assuring close personal supervision of the research of students including the design of research protocols, approval by appropriate committees, data gathering and recording, statistical analysis, interpretation of results, preparation of manuscripts, submission and revision of manuscripts for publication, and presentations at scholarly meetings.

2. The laboratory head is responsible for informing each new staff person and investigator (faculty, student, or fellow) of applicable federal, state and institutional regulations for conduct of studies involving humans, animals, radioactive and other hazardous materials, and recombinant DNA. Laboratory heads are responsible for informing personnel in their laboratories about existing Emory University policies and these guidelines. The laboratory head is also responsible for explaining and discussing the relevant requirements for the responsible conduct of research with trainees, fellows, and visiting scientists in the laboratory, and to ensure that such requirements are met.

3. The distinction between intellectually-driven inquiry and commercially-targeted research is sometimes vague. Many respected faculty are committed to developing and to studying tools, techniques and processes whose primary purpose is to promote the health or welfare of society in areas having potential commercial value. The preceptor is responsible for assuring that such investigations meet the same standards of quality and reproducibility as investigations of a more basic nature. Furthermore, any faculty member that has financial interests in a company sponsoring his/her research should disclose such financial interests to the chair and dean/director to avoid potential or real conflicts of interest.

4. In keeping with the principle of fostering reproducibility in science, and in the absence of patent or copyright considerations, novel compounds and reagents used for experiments should be made available or appropriately described means for obtaining these should be given to other competent members of the research community upon request and after execution of a material substance transfer agreement. The senior investigator should have the latitude to make a fair and balanced response to requests for all research substances, including novel compounds and reagents.

5. Clinical research requires special attention to issues of informed consent and confidentiality. Because patients have a right to assume that decision about their treatments are made in their best interests, the physician-investigator should disclose all significant alternatives and risks to patient-subjects so that they can make an informed judgment about participation. Signed copies of informed consent must be placed in the patient's clinical records as well as with research records. Clinical research records remain the property of the University; the administrative heads of the department/division of the faculty conducting clinical trials are responsible for maintenance of the records. Faculty members may make copies of the records upon departure from the University, as well as the company which sponsors the clinical trials.

C. Access to and Retention of Scientific Research Protocols and Data

1. Both the research director and the University have responsibilities and, hence, rights concerning access to, use of, and maintenance of original research data. ("Ownership of Research Data". Estelle A. Fishbein, *Academic Medicine*, 66:129, 1992 and "Workshop Summary". L.J. Rhoades, *Data Management in Biomedical Research: Report of a Workshop*, USPHS, pp. 2-9, 1990.) Consistent with the precepts of academic freedom and intellectual integrity, the investigator/scholar has the primary authority to make judgments involving the use and dissemination of the data.

2. Each faculty member/preceptor is ultimately responsible for the maintenance and proper retention of research records. These records should include sufficient detail to permit examination for the purposes of replicating the research, responding to questions that may result from unintentional error or misinterpretation, establishing their authenticity, and confirming the validity of the conclusions.

3. Each preceptor should maintain a laboratory manual that describes all major procedures. Correspondence with institutional review committees and records of the use of controlled substances and radioactive materials should be maintained as part of the research record in accordance with governmental, regulatory, and University policies.

4. A standardized system of data organization should be adopted and should be communicated to all members of a research group and to the appropriate administrative person. The appropriate administrative person should be determined by the sub-unit.

5. Where feasible, all original primary data are to be retained by the faculty member or by his or her designee. Accepted practices for retaining data vary among disciplines and depends on the perishability nature and logistics of retaining each type of data. Each investigator should treat data properly to ensure authenticity, reproducibility and validity and to meet the requirements of relevant grants and other agreements concerning the retention of data. Primary data should be reserved for a reasonable duration to ensure that any questions raised by the researcher, colleagues, or readers of any published results can be answered. It is recommended that, where feasible, data be retained for seven years; in circumstances where there are no federal or other

requirements such as those referred to in the Appendix, sub-units of the University may wish to establish uniform standards and procedures for retention and destruction of data. Data should not be destroyed without proper notification of and approval by an appropriate administrative person. In unusual cases (e.g., data used for a patent application filed by the University), it may be necessary for original data to be kept at the University. Potentially patentable data should be signed and dated by the preceptor at the time they are entered into notebooks or maintained by other methods of retention in the event the results are questioned.

6. In the event the scholar leaves the University, an Agreement of Disposition of Research Data may be negotiated by the scholar and the department chair or dean to allow the scholar's data, notebooks, and other data retention materials (other than clinical research records) to be transferred to the new institution. Consistent with the same precepts, and to fulfill its obligations to funding sources and others, the University will ensure in such agreements access to the transferred data for purposes of review. In unusual cases (e.g., data used for a patent application filed by the University) it may be necessary for original data to be kept at the University. In such cases an individual written agreement shall be signed which preserves the scholar's right to access and copy (where practical) such data. In cases of multi-institutional studies, the institution of the primary study director is ultimately responsible for guaranteeing appropriate access to, use of, and retention of original data.

V. References

"Policies and Procedures for Investigation of Misconduct in Research", Emory University, 2 March 1989. Modified from "Ethical Guidelines for Publications of Research", *Endocrine Reviews*, 10:1, 1989.
 "Authorship and Other Credits", N. Fotion and C. C. Conrad, *Annals of Internal Medicine*, 100:592, 1984. Adapted from S. J. Bird, President's Remarks, "Professional Responsibility", *AWIS Magazine*, 20:2, 1991.
 "Ownership of Research Data", Estelle A. Fishbein, *Academic Medicine*, 66:129, 1992.

"Workshop Summary", L. J. Rhoades, *Data Management in Biomedical Research: Report of a Workshop*, USPHS, pp. 2-9, 1990.

Appendix

Record Retention: Grants and Other Types of Agreements

General Regulation:

OMB (Office of Management and Budget) Circular A-110 (Uniform Administrative Requirements for Grants and Agreements of Higher Education, Hospitals and Other Non-Profit Organizations). This regulation applies to all federally funded grants and other types of agreements.

Records must be retained for at least three (3) years from the date of the submission of the final expenditure report.

Specific Agencies (for example):

- Health and Human Services: 45 CFR (Code of Federal Regulations) 74(D): Records must be retained for at least three (3) years from submission of last expenditure report.
- US Department of Education: 34 CFR 74(A): Records must be retained for at least three (3) years from submission of last expenditure report.

Records and Reports: Clinical Trial Agreements

- Food and Drug Administration: 21 CFR 312.62: In general, records must be retained for at least two (2) years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, until two (2) years after the investigation is discontinued and FDA is notified.
- Food and Drug Administration: 21 CFR 56.115: Regarding IRB records: Records required by this regulation shall be retained for at least three (3) years after completion of the research.

Agreement on Disposition of Research Data

This form is to be used ONLY where original data are to be kept by the faculty member. In unusual cases, for example data used for a patent application filed by the University, it may be necessary for original data to be kept at the University. In such a case, an individual written agreement shall be signed which preserved the faculty member's right to access and copy (where practical) such data. Any dispute shall be resolved by the Provost. Patient medical records shall remain at the University and copying shall be only as permitted by law. In recognition of both the right of the undersigned faculty member, who is leaving the employ of Emory University, to continue his/her research, and the necessity for the University to be able to fulfill its contractual and legal commitments, respond to any allegations of research misconduct, and carry out its administrative, ethical, or moral duties, the faculty member and the University agree as follows:

1. Research data developed or generated by the faculty member while employed by the University shall

be preserved for a period of not less than seven (7) years (or such lesser period as designated below) from the later of the date on which the data were created or the date of the first publication utilizing such data.

2. Lesser period* (if applicable)

3. Years _____ Faculty Initial _____ University _____

4. The faculty member shall have the right and responsibility to remove and preserve the data provided that he/she shall make the data available (including the right to copy) to authorized representatives of the University, at the University's request, for any lawful purpose including, but not limited to, the carrying out of a legal, contractual, administrative, ethical or moral duty. In case of dispute, the University's Provost shall make the final decision which shall be binding on both the University and the faculty member.

Dated this _____ day of _____, 199 _____.

EMORY UNIVERSITY _____ By: _____ Faculty Member _____ Department Chair or Dean

* Please note that federal regulations require retention of records for a period of at least three (3) years after termination of a grant or other agreement. The FDA requires records of clinical trials to be retained for at least two (2) years following the date a marketing application is approved (21 Code of Federal Regulations 312.62).

From: Charles B Nemeroff [mailto:_____@emory.edu]
Sent: Thursday, July 20, 2006 4:14 PM
To: Adkison, Claudia R; _____@emory.edu
Subject: Fwd: Corrigendum

Dear Claudia and Tom,

Please see attachment sent to the Wall Street Journal and placed on the Neuropsychopharmacology web site today. It will also appear in the print form of the journal.

Charlie

Subject: Corrigendum
Date: Thu, 20 Jul 2006 13:35:24 -0500
X-MS-Has-Attach:
X-MS-TNEF-Correlator:
Thread-Topic: Corrigendum
Thread-Index: AcasK5QtFu7rQIz1QnCPo237qu06ug==
From: "_____" <_____@ACNP.ORG>
To: "Nemeroff Charles B." <_____@emory.edu>
X-Brightmail-Tracker: AAAAAA==
X-imss-version: 2.041
X-imss-result: Passed
X-imss-scores: Clean:99.90000 C:2 M:3 S:5 R:5
X-imss-settings: Baseline:4 C:2 M:1 S:1 R:1 (1.0000 1.0000)

<<Corrigendum (2).doc>>

Executive Director
American College of Neuropsychopharmacology
545 Mainstream Drive, Suite 110
Nashville, TN 37228
Telephone: _____
Fax number: _____
Cell phone: _____

E-mail: [REDACTED]@acnp.org
www.acnp.org

Adkison, Claudia R

From: Charles B. Nemeroff [REDACTED]@emory.edu]
Sent: Sunday, July 23, 2006 1:03 AM
To: Adkison, Claudia R; Tom Lawley
Subject: Fwd: NYTimes.com: Our Conflicted Medical Journals

Dear Claudia and Tom,

I didn't want you to be blindsided by the NY Times Editorial today, Sunday, July 23. It has a great many inaccuracies. I sent you a detailed summary of the events. The ACNP has issued a statement that this was an editorial office oversight,. At any rate, I am sorry for the adverse publicity.

Charlie

Date: Sat, 22 Jul 2006 23:33:59 -0400 (EDT)
From: [REDACTED]@emory.edu
Reply-To: [REDACTED]@emory.edu
To: [REDACTED]@emory.edu
Subject: NYTimes.com: Our Conflicted Medical Journals
Sender: [REDACTED]
X-Originating-IP: [170.140.121.116]
X-Initiated-By: [nytimes.com website user]
X-imss-version: 2.041
X-imss-result: Passed
X-imss-scores: Clean:99.90000 C:2 M:3 S:5 R:5
X-imss-settings: Baseline:4 C:2 M:1 S:1 R:1 (1.0000 1.0000)



E-mail This

This page was sent to you by: hmayber@emory.edu

Message from sender:

so much for not saying there would be no story. see you when you get back have a safe trip to africa [REDACTED]

OPINION | July 23, 2006

Editorial: Our Conflicted Medical Journals

Leading medical journals seem to be having a difficult time disentangling themselves from the pharmaceutical and medical device industries.

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4. [For the Pennsylvania Dutch, a Long Tradition Fades](#)

5. Indictment of Doctor Tests Drug Marketing Rules

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[REDACTED]

From: Charles B. Nemeroff [REDACTED@emory.edu]
Sent: Sunday, July 23, 2006 5:48 PM
To: Adkison, Claudia R
Subject: FW: Letter to Editor in Neuropsychopharmacology
Attachments: Nature Pub letter.wpd

Dear Claudia,

To give you a flavor of the two individuals who have been harrasing me and sending letters to various newspapers, journal editors, etc. is the attached letter to ACNP from the two of them, unhappy about

the response of the Stanford psychiatry chair to their submitted letter of Neuropsychopharmacology.

They have now

decided to bring charges against both the ACNP and Nature Publishing. You will be pleased to know that because of their

prior charges against me, I recused myself from this particular episode.

I am off to Africa tomorrow but will have email and cell phone contact for the first 4 days of the trip. Let me know if you need any further information from me. Again, thanks for your help.

Charlie

Subject: FW: Letter to Editor in Neuropsychopharmacology
Date: Thu, 20 Jul 2006 09:40:01 -0500
X-MS-Has-Attach:
X-MS-TNEF-Correlator:
Thread-Topic: Letter to Editor in Neuropsychopharmacology
Thread-Index: AcarkNs2Psgzs+GbTiqLYnyBW0vCeAAeYFZw
From: "[REDACTED] <[REDACTED]@ACNP.ORG>
To: "Nemeroff Charles B." <[REDACTED]@emory.edu>, [REDACTED] <[REDACTED]@kumc.edu>, [REDACTED] <[REDACTED]@hms.harvard.edu>
Cc: "[REDACTED] <[REDACTED]@ACNP.ORG>, [REDACTED] <[REDACTED]@ACNP.ORG>
X-Brightmail-Tracker: AAAAAA==
X-imss-version: 2.041
X-imss-result: Passed
X-imss-scores: Clean:99.90000 C:2 M:3 S:5 R:5
X-imss-settings: Baseline:4 C:2 M:1 S:1 R:1 (1.0000 1.0000)

I will be talking to our attorney and to Nature today to get an initial assessment of this situation. I will give you an update on what I learn as soon as possible.

[REDACTED]

From: [REDACTED] [mailto:[REDACTED]]
Sent: Wednesday, July 19, 2006 7:10 PM
To: Council
Cc: [REDACTED]
Subject: Letter to Editor in Neuropsychopharmacology

8/7/2006

re: Dr. [REDACTED] and Dr. [REDACTED]

Please see attached letter dated July 18, 2006.

Sincerely,

[REDACTED]
Office Assistant
Rohde & Victoroff
1880 Century Park East
Suite 411
Los Angeles, CA 90067
[REDACTED] Phone
[REDACTED] Fax

This message may contain confidential information.
If you are an unintended recipient of this email, please inform the sender immediately and delete it from your system. Thank you.

8/7/2006

Adkison, Claudia R

From: Charles B. Nemeroff [redacted@emory.edu]
Sent: Tuesday, July 25, 2006 1:37 PM
To: Adkison, Claudia R
Subject: RE: Today's NYTimes article

Dear Claudia,

Be glad to discuss this entire issue when I return. Again thanks for your continued support.
Charlie

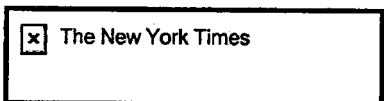
At 01:34 PM 7/25/2006, you wrote:

Charlie, this matter continues to cause much discussion here. We should talk when you return. My emails somehow are not making the point that some things just shouldn't be done, no matter how much disclosure. Even if correctly done, disclosure alone is not enough to make some situations OK. In this case, the right decision would have been to take no personal money or money from the company to support the paper, if you wanted to write and publish this review article. It's all over again.

From: Charles B. Nemeroff [mailto:redacted@emory.edu]
Sent: Tuesday, July 25, 2006 1:21 PM
To: Adkison, Claudia R; Tom Lawley
Subject: Fwd: Today's NYTimes article

Dear Claudia and Tom,
FYI.
Charlie

From: [redacted@aol.com]
Date: Tue, 25 Jul 2006 09:49:53 EDT
Subject: Today's NYTimes article
To: [redacted@emory.edu]
X-Mailer: 9.0 Security Edition for Windows sub 5318
X-Spam-Flag: YES
X-imss-version: 2.041
X-imss-result: Passed
X-imss-scores: Clean:99.90000 C:1 M:6 S:5 R:5
X-imss-settings: Baseline:4 C:2 M:1 S:1 R:1 (1.0000 1.0000)



July 25, 2006
Commentary

Correcting the Errors of Disclosure

By BENEDICT CAREY

By now, tales of scientific conflict of interest have become all too familiar. In recent weeks, two top medical journals have been in the news for failing to disclose the financial ties of the academic authors of published papers, one involving antidepressant drugs, the other a medical device approved to treat depression.

But nondisclosure is only part of the story. Companies don't just hire doctors to do research — a practice that in theory ought to help keep businesses scientifically honest — they also trade on the researchers' names. Like producers shopping a new movie, they go for star power, an A-list cast with names that themselves sell a product, and pull other doctors along, even when the evidence for a treatment is not strong.

Last week, an influential psychiatry journal, *Neuropsychopharmacology*, said it would print a correction, after revelations that it did not disclose the financial ties of authors of a paper reviewing a new treatment for depression. The treatment, a \$15,000 chest implant that sends pulses of electricity to the brain, was approved for depression in 2005 after intense debate over its effectiveness.

At least as important as the failure to disclose financial ties were the authors themselves, and other consultants that the device manufacturer, Cyberonics Inc. of Houston, had hired.

Among them are Dr. Charles Nemeroff, one of the nation's most influential research psychiatrists and the editor of *Neuropsychopharmacology*; Dr. Dennis S. Charney, of the Mount Sinai School of Medicine, the editor of *Biological Psychiatry*; and Dr. A. John Rush of the University of Texas Southwestern Medical Center, who led the largest-ever long-term government study on depression.

These are precisely the sorts of experts the field relies on to help evaluate highly disputed data, like those Cyberonics has presented for the treatment.

In a bitter debate over the interpretation of these results, more than 20 experts at the Food and Drug Administration opposed the approval of the device for depression before being overruled by a senior official, according to a Senate Finance Committee investigation.

The device begged for some more public analysis. But few if any outside experts knew the data well enough to raise questions. And the scientists who did know the science and the data were all on the company's payroll.

This is what companies do, try to get top researchers to accept large grants for research, or to consult, because they know those names make them look more legit," said Dr. Daniel Carlat, editor in chief of *The Carlat Psychiatry Report*, a well-regarded monthly newsletter, who in January reviewed the evidence for the implant and found it unconvincing.

The very presence of those names on papers reviewing the treatment, he said, "is a big part of the salesmanship that comes after getting approval."

One of the company's primary consultants, Harold Sackeim, a professor of psychiatry and radiology at Columbia, said that if device makers could not hire the field's top experts, effective new devices would never be approved. "This is not like pharmaceuticals, where the companies are much bigger and have their own experts," he said.

He added that he and other academic doctors advising the company "are a pretty small group, we all know each other, and the gestalt in the group carries a lot of weight."

By the time Cyberonics published its data widely — in *Biological Psychiatry*, the journal edited by Dr. Charney — the product was already approved and the game over. Doctors around the country are now

discussing using the implant for chronically depressed patients, who are thought to number more than four million.

The company has focused on promotion, as have some of its consultants. At an American Psychiatry Association meeting in May, Dr. Rush sat in the Cyberonics booth, describing the benefits of the therapy to curious psychiatrists. In one of several presentations about the device, doctors reviewed its use for obesity, anxiety and Alzheimer's disease, purposes for which it is not approved.

And the recent review article that appeared without full disclosure was not focused on whether the device worked for depression, or for whom. It was a speculative essay about its mechanism of action — about how it worked. <

One of the supposed strengths of American science is that it is decentralized and diverse: there are dozens of top researchers who are competitive and critical, enforcing a high standard. But when many or most of the leading figures are playing for the same team — an all-star team — that lineup itself may carry the day, regardless of the science.

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