



MEMORANDUM

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

THROUGH: Vincent Tolino
Acting Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Kathleen L. Walker /S/ 1/5/07
Chief, Integrity, Committee and Conference Management Branch
Division of Ethics and Management Operations, OMO
Center for Devices and Radiological Health

SUBJECT: Conflict of Interest Waiver for H. Hunt Batjer, M.D.

I am writing to request a waiver for H. Hunt Batjer, M.D., a member of the Neurological Devices Panel of FDA's Medical Devices Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a). Waivers under section 208(b)(3) may be granted by the appointing official where "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved" and where the individual has made a disclosure of the financial interests at issue. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant Dr. Batjer a waiver under section 208(b)(3).

Section 208(a) prohibits Federal executive branch employees, including special Government employees, from participating personally and substantially in matters in which the employee or his employer has a financial interest. Since Dr. Batjer is a special Government employee, this individual is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to him or his employer.

Dr. Batjer has been asked to participate in the Panel discussions on:

- (1) A premarket notification application (510(k)) from Neuronetics, Inc. for the *Neuronetics NeuroStar System* indicated for the treatment of major depressive disorder. The *Neuronetics NeuroStar System* is a computerized electromechanical instrument that produces and delivers noninvasive, magnetic stimulation using brief duration, rapidly alternating, or pulsed, magnetic fields to induce electrical currents in the cortex of the brain.

(2) A post-approval study report for a recently approved neurological device premarket approval application (PMA) for Cyberonics, Inc.'s *VNS Therapy™ System* for treatment resistant chronic or recurrent depression. This PMA was discussed at the June 15, 2004 Panel meeting.

These matters are coming before the Neurological Devices Panel for consideration and are particular matters involving specific parties.

Dr. Batjer's employer has financial interests that could potentially be affected by his participation in these matters. His institute, Northwestern University, was a clinical site for the Neuronetics study which lasted from [-----] to [-----]. Dr. Batjer had no direct personal involvement with the study, had no knowledge of its funding and had no management responsibilities over the study. The study was conducted in the Department of Psychiatry; principal investigator, [-----], has no supervisory role with regard to Dr. Batjer. Dr. Batjer is Chairman of the Department of Neurological Surgery.

As Department Chair, Dr. Batjer provides approval for all departmental research proposals involving Department of Neurological Surgery faculty members who act as Principal Investigator, Co-Investigator or Sub-Investigator on any research studies, whether the studies are initiated in the Dept. of Neurological Surgery or initiated by Principal Investigators based in other departments who are collaborating with Dept of Neurological Surgery faculty members. There were no Dept. of Neurosurgery faculty members involved in the Neuronetics trial.

The Office of Device Evaluation within the Center for Devices and Radiological Health provided the following relevant [-----] study data:

- Total number of investigational sites: [-]
- Total number of patients enrolled/treated in the study: [-] enrolled/[-]treated
- Total number of patients treated at Northwestern University: [-]
- Percentage of patients treated at Northwestern University: [---]
- Date of first study enrollment: [-----]
- Date of last study enrollment: [-----]
- Amount to institute: [-----]

Dr. Batjer reported his institute's contract with [-----]
[-----], a matter unrelated to the agenda topics. This company is a competing technology firm to Neuronetics and Cyberonic. The total funding to the institute is [-----] (approximately [-----]/year) of which [-----] has been disbursed. Dr. Batjer receives no personal compensation for his management role with the contract. The principal investigator, [-----], reports directly to Dr. Batjer. The study will run from [-----] to [-----].

The functions of the committee, as stated in its Charter, are to review and evaluate available data concerning the safety and effectiveness of marketed and investigational devices and advise the Commissioner of Food and Drugs regarding recommended classification of these devices into one of three regulatory categories; recommend the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advise on any possible risks to health associated with the use of devices; advise on formulation of product development protocols and review premarket approval applications for those devices classified in the premarket approval category; review classification as appropriate; recommend exemption to certain devices from the application of portions of the Act; advise on the necessity to ban a device; and respond to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. As a member of the Neurological Devices Panel, Dr. Batjer potentially could become involved in matters that affect Neuronetics, Inc. and [-----]. Under section 208, Dr. Batjer is prohibited from participating in such matters. However, as noted above, you have the authority under 18 U.S.C. §208(b)(3) to grant a waiver permitting this individual to participate in such matters, as you deem appropriate.

For the following reasons, I believe it would be appropriate for you to grant a waiver to Dr. Batjer allowing this individual to participate in matters identified below.

First, although Dr. Batjer's institute was involved in the Neuronetics trial, he had no knowledge of study data, had no direct, personal involvement and received no compensation. As Dept. Chair, the SGE's role with the [-----] contract is limited to management responsibilities. The fact that these financial interests are imputed to him from his employer should lessen any potential concern for bias.

Second, Dr. Batjer's institute contributed a statistically insignificant portion [----] of the Neuronetics trial data. This limitation should help to mitigate any concern that his impartiality might be called into question during Panel deliberations.

Third, the Panel's role is only advisory in nature, the Agency officials making the decisions are not bound by the recommendations of the Panel. Therefore, the Agency will take into consideration the involvement of the SGE's employer when making a final decision.

Fourth, recommendations of the Panel are unlikely to affect the continuing relationship between Dr. Batjer's employer and the firms involved.

Fifth, there are over [-] firms marketing or pursuing development of a directly competing product or a competing technology to treat major depression. The availability of multiple competitors should mitigate the potential perception of bias on the part of this SGE.

Attachment

Limited waiver is granted to allow full voting participation in all official matters before the Panel related to the discussions of Neuronetics, Inc.'s 510(k) for the Neuronetics NeuroStar System and the post-approval report for Cyberonics, Inc.'s VNS Therapy™ System. Dr. Batjer is not granted a waiver for the Panel's discussion of Confluent Surgical Inc.'s Dural Sealant System for use as an adjunct to sutured dural repair during cranial surgery to provide watertight closure, and he will not participate in this session.