

MEMORANDUM

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

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

FROM: Kathleen L. Walker /S/ 1/4/07
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 Thomas Brott, M.D.

I am writing to request a waiver for Thomas Brott, M.D., a member (chairperson) 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. Brott 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. Brott 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. Brott has been asked to participate in the Panel's discussion on 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. These matters are coming before the Neurological Devices Panel for consideration and are particular matters involving specific parties.

Dr. Brott's employer has a financial interest that could potentially be affected by his participation in this matter. His employing institute, the Mayo Clinic, has two of its facilities in Jacksonville, Florida and Rochester, Minnesota participating as clinical sites for the Neuronetics study. Although he is Director of Research at the Jacksonville site, he has no direct relationship with this study or to the identified investigator. He assumed the role of Director of Research in [----- ----], after the study enrollment ended. Therefore, he has no prior knowledge of the study and has not reviewed any study details. The principal investigator, [-----], is in the Department of Basic Science and has no supervisory role with regard to Dr. Brott. Dr. Brott works in the Department of Neurology.

Dr. Brott also serves as the Vice Chairperson of the Mayo Clinic Research Committee (includes 3 sites: Rochester, Minnesota; Jacksonville, Florida; and Arizona). This Committee governs the strategy of research and does not review study protocols. Therefore, in this capacity, he was not privy to study details. [-----] is identified as the principal investigator.

The Office of Device Evaluation in CDRH provided the following study data:

Total number of patients enrolled: [-]; treated: [--]

Total number of investigational sites: [-]

Data for Mayo Clinic in Florida:

Total number of patients enrolled/treated: [-]

Percentage of patients treated: [---]

Amount of funding to institute: [-----]

Enrollment dates: [-----] through [-----]

Data for Mayo Clinic in Minnesota:

Total number of patients enrolled/treated: [--]

Percentage of patient treated: [---]

Amount of funding to institute: [-----]

Enrollment dates: [-----] through [-----]

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. Brott potentially could become involved in matters that affect Neuronetics, Inc. Under section 208, Dr. Brott 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. Brott allowing this individual to participate in matters identified below.

First, although Dr. Brott's institution was involved in the Neuronetics trial, he had no direct, personal involvement and received no compensation. The fact that this financial interest is imputed to him from his employer should lessen any potential concern for bias.

Second, the Panel's role is advisory in nature and 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.

Third, 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.

Lastly, the Federal Advisory Committee Act requires that committee memberships be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee. Also, the committee's intended purpose would be significantly impaired if the Agency could not call upon experts who have become eminent in their fields, notwithstanding the financial interest and affiliations they may have acquired as a result of their demonstrated abilities. Dr. Brott is Professor of Neurology and Director for Research in the Department of Neurology and Vice Chairperson of the Mayo Clinic Research Committee. Because he possesses a unique combined expertise in psychiatry and neurology, with specialized expertise in the area of stroke, we believe his participation in these Panel deliberations is invaluable and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

