

MEMORANDUM

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

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

FROM: Kathleen L. Walker _____ /S/ 12/19/06
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 Mary E. Jensen, M.D.

I am writing to request a waiver for Mary E. Jensen, 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. Jensen 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 her employer has a financial interest. Since Dr. Jensen 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 her or her employer.

Dr. Jensen 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. Jensen's employer has a financial interest that could potentially be affected by her participation in this matter. Her employing institute, the University of Virginia Health Science Center (Center for Psychiatric Clinical Research), was a clinical site for the Neuronetics study. Dr. Jensen had no personal or financial involvement with this trial and no knowledge of the study funding.

She is the Director of Interventional Neuroradiology and Professor of Radiology and Neurosurgery within the Department of Radiology. The principal investigator, [-----], who has no supervisory role with regard to Dr. Jensen, works in the Department of Psychiatry, separate from Dr. Jensen's department.

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

Total number of patients enrolled/treated in the study: [-] enrolled/[-] treated

Total number of patients treated at University of Virginia: [-]

Percentage of patients treated at University of Virginia: [----]

Date of first study enrollment: [-----]

Date of last study enrollment: [-----]

Amount to institute: [-----]

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

First, although Dr. Jensen's institution was involved in the Neuronetic's trial, she had no knowledge of the study, had no direct, personal involvement and received no compensation. The fact that this financial interest is imputed to her from her 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, Dr. Jensen's institute contributed a statistically insignificant portion [-----] of the trial data. This limitation should help to mitigate any concern that Dr. Jensen's impartiality might be called into question during Panel deliberations.

Fourth, 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. As previously noted, Dr. Jensen is Director of Interventional Neuroradiology and Professor of Radiology and Neurosurgery, Department of Radiology at University of Virginia Health Sciences Center. Because she possesses the unique combined expertise in neuroradiology and clinical studies, we believe her participation in these Panel deliberations is invaluable and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

