



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 Scott R. Evans, Ph.D.

I am writing to request a waiver for Scott R. Evans, Ph.D., a member on 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. Evans 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. Evans 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. Evans has been asked to participate in the Panel's discussion on a premarket notification (510(k)) application 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. Evans has advised the FDA that he has a financial interest which could potentially be affected by his participation in this matter. He reported serving as a scientific advisor for [-----]

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-----], an issue unrelated to the agenda topic. Relevant to this meeting, its parent, [-----  
-], manufactures a competing antidepressant drug. Dr. Evans expects to receive less than [----] for this ongoing consulting; the maximum amount he may receive would not exceed [-----].

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. Evans potentially could become involved in matters that affect [-----] and its parent, [-----]. Under section 208, Dr. Evans 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. Evans allowing him to participate in matters identified below.

First, given the nature of Dr. Evans' unrelated consulting and the diversity of [-----] product line, it is unlikely that recommendations of the Panel will impact the viability of this firm or his ongoing relationship with them. Therefore, potential concern that Dr. Evans' impartiality might be called into question during Panel deliberations should be diminished.

Second, 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. Evans is a research scientist, Center for Biostatistics in AIDS Research, Department of Biostatistics at Harvard School of Public Health. His research interests include clinical trials and statistical methodology. His statistical expertise will be a significant benefit during discussion of the complex, nonstandard statistical analysis of the study data and the sponsor's statistical reanalysis of pre-specified primary efficacy endpoint and secondary efficacy analyses. We believe Dr. Evans' participation during Panel deliberations is invaluable

