

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/_____ 1/3/07
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 Richard P. Malone, M.D.

I am writing to request a waiver for Richard P. Malone, M.D., serving as a consultant to the Center for Drug Evaluation and Research, and in this capacity, serving as a consultant to 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. Malone 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. Malone 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. Malone 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. Malone has advised the FDA that he has a financial interest which could potentially be affected by his participation in this matter. He reported that [-----] has invited him to a meeting [-----]. The meeting as well as the [-----] are not related to the agenda topic. As part of this [-----] consulting arrangement with [-- ----], Dr. Malone signed an agreement that is effective until [-----]. According to the agreement, he expects to be paid up to a maximum of [----]. Depending on the outcome of the meeting, this arrangement may be extended. Relevant to this meeting, [-- ----] is a manufacturer of a competing drug therapy.

Dr. Malone reported another consulting arrangement under negotiation with [-- ----]. This arrangement involves the study of [-----]. Dr. Malone anticipates this pending agreement should last no more than [---] months with compensation less than [----].

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 consultant to the Neurological Devices Panel, Dr. Malone potentially could become involved in matters that affect [-----]. Under section 208, Dr. Malone 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. Malone allowing him to participate in matters identified below.

First, given the nature of Dr. Malone's 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. Malone's impartiality might be called into question during Panel deliberations should be diminished.

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.

