



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/ 1/26/07
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 Gregory A. Ewald, M.D.

I am writing to request a waiver for Gregory A. Ewald, M.D., serving on the Circulatory System Devices Panel of FDA's Medical Devices Advisory Committee as a consultant, 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. Ewald 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. Ewald 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. Ewald has been asked to participate in the Panel discussion regarding a premarket approval application (PMA), sponsored by Medtronic, Inc., for the Chronicle Implantable Hemodynamic Monitoring System (CIHMS). This implantable device is intended to reduce hospitalization events or equivalent events for worsening heart failure in patients with moderate to advanced heart failure. These matters are coming before the Circulatory System Devices Panel for consideration and are particular matters involving specific parties.

Dr. Ewald reports that his employing institute has a financial interest that could potentially be affected by his participation in these matters. Dr. Ewald is Director, Section of Heart Failure and Cardiac Transplantation at Washington University School of Medicine (WUSM), St. Louis, Missouri. The WUSM is negotiating with Medtronic, Inc., [-----]. Potentially, this trial may [-----]. Patients will be recruited from [-----]. At this time, the trial details have not been completed by Medtronic’s contracting group and the institutional review board (IRB). Although the proposed principal investigator, Dr. [-----], a heart failure physician, works within the Section Dr. Ewald directs, Dr. [-----] will report study details to the Chief of Cardiology and not to Dr. Ewald. Dr. Ewald reported that he will have no personal involvement with the IRB and the contract arrangement, no management responsibilities over the study, and will receive no personal compensation.

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 Circulatory System Devices Panel, Dr. Ewald potentially could become involved in matters that affect Medtronic, Inc. Under section 208, Dr. Ewald 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. Ewald allowing this individual to participate in matters identified below.

First, since the pending grant for the [-----] is awarded to Dr. Ewald’s employing institute and not to him directly, the nature of Dr. Ewald’s relationship is one of an imputed financial interest. This relationship should lessen any potential concern for bias.

Second, 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.

