



MEMORANDUM

TO: Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy

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

FROM: Kathleen L. Walker _____/S/ 8/2/07
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 David J. Milan, M.D.

I am writing to request a waiver for David J. Milan, 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. Milan 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. Milan 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. Milan has been asked to participate in the Panel's discussion of issues regarding clinical trial designs for cardiac ablation devices designed to treat patients with medically refractory atrial fibrillation. These matters are coming before the Circulatory System Devices Panel for consideration and are particular matters of general applicability.

Dr. Milan has advised the FDA that he has an imputed financial interest which could potentially be affected by his participation in this matter. He reported that his spouse, a physician with an established reputation, is negotiating with [-----] to provide consulting services regarding [-----], a matter unrelated to the agenda topic. Relevant to this meeting, [-----] manufactures surgical ablation devices, permanent atrial pacemakers and surgical maze devices to treat atrial fibrillation. Based on estimated work hours, her earnings [-----]. Final details of the arrangement are not complete.

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

First, the issues to be addressed by the Panel are particular matters of general applicability, involving an entire class of products and granting no advantage to any individual manufacturer. Therefore, the Panel recommendations would not be expected to have a significant financial impact on any specific firm and the potential perception of bias on the part of the SGE should be mitigated.

Second, the SGE has no personal financial interest with [-----]; the interest involves his wife and is, therefore, imputed to him. It is unlikely that recommendations of the Panel will impact the viability of this large firm or his wife's ongoing relationship with them. Therefore, potential concern that Dr. Milan's impartiality might be called into question during Panel deliberations should be diminished.

Third, there are over 25 firms actively pursuing development or marketing various types of products to treat atrial fibrillation. The existence of multiple products/firms should help mitigate any appearance of bias on the part of the SGE.

Fourth, 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 SGE's interests when making a final decision.

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. The Panel meeting shall include a discussion of optimal ways to obtain evidence regarding atrial fibrillation trial data. The Agency acknowledges that it is critical to involve specialized electrophysiologists, cardiologists and surgeons in the discussion. Dr. Milan is Co-Director of the Clinical Cardiac Electrophysiology Training Program at Massachusetts General Hospital and Instructor of Medicine at Harvard Medical School. In addition to his academic and clinical experience as a cardiac electrophysiologist, he conducts research to better understand the electrophysiologic development of the heart, including specialized conduction tissue and complex arrhythmias. A major emphasis of his research is in the area of long QT syndrome (an EKG measurement that is a marker of sudden cardiac death). This is a critical safety problem affecting the safety profile of many devices and drugs. Of the six electrophysiologists scheduled to attend the meeting, Dr. Milan is the only panelist with expertise in this area. Therefore, Dr. Milan's participation is considered essential in addressing this extremely important safety concern.

Accordingly, I recommend that you grant Dr. Milan a waiver allowing him to participate fully in all official matters before the Panel regarding clinical trial designs for cardiac ablation devices designed to treat patients with medically refractory atrial fibrillation. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Milan outweighs the potential for a conflict of interest created by the financial interest involved.

CONCURRENCE: _____ /S/ _____ 8/13/07
Vincent Tolino Date
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

DECISION:

 X Waiver granted based on my determination made in accordance with section 208(b)(3), that the need for the individual's services outweighs the potential for conflict of interest created by the financial interest attributable to the individual.

_____ Waiver denied.

_____ /S/ _____ 8/30/07
Randall W. Lutter, Ph.D. Date
Deputy Commissioner for Policy