

MEMORANDUM

TO: Randall W. 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/ 3/6/07
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 Scott D. Ramsey, M.D., Ph.D.

I am writing to request a waiver for Scott D. Ramsey, M.D., Ph.D., a member of the Medical Devices Dispute Resolution 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. Ramsey 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. Ramsey 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. Ramsey has been asked to participate in the discussion regarding a scientific dispute between the Agency and Cardima Inc. related to the not-approvable determination for the premarket approval application (PMA) for the REVELATION® Tx Microcatheter with NavAblator Ablation System. The devices are indicated for the treatment of atrial fibrillation in patients with drug refractory paroxysmal atrial fibrillation by mapping, pacing, and ablating with a compatible radiofrequency generator, creating a set of continuous linear lesions along the lateral and septal walls and along the isthmus in the right atrium. The matters coming before the Medical Devices Dispute Resolution Panel for consideration are particular matters involving specific parties.

Dr. Ramsey has advised the FDA that he has a financial interest that could potentially be affected by his participation in this matter. He reported an unrelated consulting arrangement with [----], a competing technology (drug) firm to the PMA sponsor, regarding [-----], for which he received \$[----]. This relationship started December, 1, 2006 and is expected to end June 31, 2007.

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 Medical Devices Dispute Resolution Panel, Dr. Ramsey potentially could become involved in matters that affect [----]. Under section 208, Dr. Ramsey 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. Ramsey allowing him to participate in matters identified below.

First, given the nature of the unrelated consulting Dr. Ramsey provides to [----], it is unlikely that Panel recommendations will impact the economic stability of the company or his continued relationship with the company. The possibility that the SGE's impartiality will be called into question should be minimal.

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 SGE's involvement when making a final decision concerning the action to be taken.

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. Ramsey is an Associate Member at the Fred Hutchinson Cancer Research Center, Cancer Prevention Center. Dr. Ramsey is a general internist with expertise in cancer prevention and treatment evaluation, stemming from his active clinical practice and research. He has spent his career in technology assessment. His impressive credentials with emphasis on health outcomes research are ideal for the cross-cutting scientific nature of this Panel.

