

MEMORANDUM

TO: Randall Lutter, Ph.D.  
Associate Commissioner for Policy and Planning

THROUGH: Vincent Tolino /S/ 11/13/06  
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

FROM: Kathleen L. Walker /S/ 11/02/06  
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 Barry M. Massie, M.D.

I am writing to request a waiver for Barry M. Massie, M.D., serving on the Medical Device Dispute Resolution 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. Massie 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. Massie 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. Massie has been asked to participate in the discussion of a scientific dispute pertaining to the approvability of a premarket approval application (PMA) by Acorn Cardiovascular, Inc. for the *CorCap Cardiac Support Device (CSD)*. The device is indicated for use in adult patients who have been diagnosed with dilated cardiomyopathy and are symptomatic despite treatment with optimal heart failure medical management. The PMA was presented to the Circulatory System Devices Panel on June 22, 2005; the Panel recommended disapproval citing concerns regarding lack of clinical outcome data, missing effectiveness data and potential risk to patients. Subsequently, the Agency determined that the PMA was non-approvable. These matters are coming before the Medical Devices Dispute Resolution Panel for consideration and are particular matters involving specific parties.

Dr. Massie has advised the FDA that he has a financial interest which could potentially be affected by his participation in this matter. He reported that he currently provides unrelated consulting services to [-----], a competing technology firm to the PMA sponsor. Dr. Massie is a member of [-----] for a [-----], a matter unrelated to the agenda topic. The total amount expected is approximately [-----]. He anticipates [-----] will meet [-----].

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

First, given the nature of the unrelated consulting Dr. Massie provides to [-----], it is unlikely that Panel recommendations will impact the economic stability of the company or his continued relationship with them. 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.

