



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 James D. Neaton, Ph.D.

I am writing to request a waiver for James D. Neaton, Ph.D., serving as a consultant to the Center for Drug Evaluation and Research, and in this capacity, serving as a consultant to the Circulatory System 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. Neaton 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. Neaton 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. Neaton 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. Neaton has advised the FDA that he has financial interests which could potentially be affected by his participation in this matter. Dr. Neaton reported a consulting service with [-----]. His service involves [-----]. This agreement, which commenced in 2002, compensates him \$[----]per year.

He also serves on [-----]. Total fees for this arrangement, which began in 2005, are \$[---] per year. The end dates for these arrangements are unknown. While these consulting agreements are unrelated to the issues coming before the Panel, [-----], and [-----] are identified as manufacturers of various ablation devices intended to treat atrial fibrillation.

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. Neaton potentially could become involved in matters that affect [-----]. Under section 208, Dr. Neaton 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. Neaton 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, given the nature of Dr. Neaton's unrelated consulting arrangements with [-----] and [-----], it is unlikely that recommendations of the Panel will impact the viability of these large firms or his ongoing relationship with them. Therefore, potential concern that Dr. Neaton'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 and 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.

