



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 Clyde W. Yancy, M.D.

I am writing to request a waiver for Clyde W. Yancy, M.D., a member of 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. Yancy 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. Yancy 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. Yancy 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. Yancy has advised the FDA that he has financial interests which could potentially be affected by his participation in this matter. Dr. Yancy serves as [-----], sponsored by [-----] Known as [-----]. He receives expenses and compensation for [-----] in the management of the project, which is unrelated to the matter before the Panel. Total compensation expected for 2007 will be less than \$[---]; the ongoing arrangement is scheduled to end in 2009 or 2010. Relevant to this Panel meeting, [-----] manufactures surgical ablation devices, permanent atrial pacemakers and surgical maze devices to treat atrial fibrillation.

He also reported an unrelated research and limited consulting relationship with [-----], an unaffected subsidiary of parent, [-----]. As part of the arrangement, he served as [-----] and continues to provide consulting services on the issue. Total compensation expected in 2007 is less than \$[---] for time spent on teleconferences and face to face meetings. Relevant to the Panel meeting, [-----], have product lines that include percutaneous catheters and surgical maze devices respectively for the treatment of 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 member of the Circulatory System Devices Panel, Dr. Yancy potentially could become involved in matters that affect [-----]. Under section 208, Dr. Yancy 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. Yancy 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. Yancy's unrelated consulting arrangements with [-----], it is unlikely that recommendations of the Panel will impact the viability of these large firms or his ongoing relationships with them. Therefore, potential concern that Dr. Yancy'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.

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 Agency acknowledges that atrial fibrillation is currently a significant public health problem. Trial design in this area is very challenging for the new percutaneous therapies being discussed. Dr. Yancy is Medical Director of the Baylor Heart and Vascular Institute and Chief of Cardiothoracic Transplantation at Baylor University Medical Center in Dallas, Texas. An expert in clinical trial designs, he brings to the Panel a surgical perspective. As a seasoned panelist, he can assist the Panel in developing recommendations for atrial fibrillation trial design that are rigorous but not overly burdensome. At previous panel meetings he has demonstrated a proclivity in trial design development appropriate for the specific device under discussion. As a heart failure transplant cardiologist, he provides the necessary balance to the Panel, given the significant participation of electrophysiologists, cardiologists, interventional cardiologists, and vascular surgeons. The Agency approached a total of seven cardiologists for this meeting, four were not available. Of the remaining three cardiologists, only Dr. Yancy was considered most suitable to chair the meeting. His critical skills and subject matter knowledge have greatly benefited multiple panel meetings. As a heart failure transplant cardiologist, Dr. Yancy has extensive experience interacting with patients who have undergone major cardiac surgery and is able to speak to the needs and concerns of patients. This perspective will be crucial to a thoughtful discussion of the issues associated with atrial fibrillation and the variety of devices indicated for treatment. As the Panel Chair, Dr. Yancy will provide critical reasoning and clinical trial design expertise to guide the Panel in its challenging discussion.

