



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

DATE: September 19, 2007

TO: Randall W. Lutter, Ph.D.  
Deputy Commissioner for Policy  
Food and Drug Administration

THROUGH: Vincent Tolino       /S/      09/07/07        
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

FROM: Kathleen L. Walker       /S/      08/30/07        
Chief, Integrity, Committee and Conference Management Branch  
Division of Ethics and Management Operations, OMO  
Center for Devices and Radiological Health

SUBJECT: 208(b)(3) 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, he 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 Panel discussions on the following topics:

1. A premarket approval application (PMA) for the *Endeavor Zotarolimus-Eluting Coronary Stent System* submitted by Medtronic Vascular (parent: Medtronic, Inc.). This system is indicated for improving coronary luminal diameter in patients with ischemic heart disease due to de novo lesions of length  $\leq 27$ mm in native coronary arteries with reference vessel diameters of  $\geq 2.5$ mm to  $\leq 3.5$ mm. This matter is coming before the Circulatory System Devices Panel for consideration and is a particular matter involving specific parties.
2. Clinical trial designs for carotid artery stenting in patients not at high risk for adverse events from surgical revascularization. This matter is coming before the Circulatory System Devices Panel for consideration and is a particular matter of general applicability.
3. Several sponsors of clinical trials involving carotid artery revascularization (Abbott Laboratories, Cordis Corp. (J&J), and Boston Scientific Corp.) will individually present and discuss clinical trial design issues for carotid artery stents intended to re-open stenotic carotid arteries in the neck. Each sponsor will present separately in a closed session. This matter is coming before the Circulatory System Devices Panel for consideration and is a particular matter involving specific parties.

The function of the Committee, as stated in its Charter, is 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.

Dr. Yancy has advised the FDA that he has a financial interest which could potentially be affected by his participation in the matter described above. Dr. Yancy serves as [-----] for a [-----], sponsored by Medtronic, Inc. Known as [-----], this [-----]. He receives expenses and compensation for [-----] in the management of the project, which is unrelated to the matters 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, Medtronic is the parent of the PMA sponsor.

He also reported an unrelated research and limited consulting relationship with [-----], an unaffected subsidiary of parent, [-----]. As part of the arrangement, he served as [-----] for a [-----] 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, [-----] subsidiaries, [-----] and [-----], are competing firms for both agenda topics.

In addition, Dr. Yancy’s institute, Baylor Vascular and Heart Institute (BVHI), has been identified as a clinical site for the ENDEAVOR study. He had no direct personal involvement in the trial and has no supervisory oversight over the principal investigator, [-----].

The Office of Device Evaluation within the Center for Devices and Radiological Health provided the following relevant study data:

- Total number of sites involved with ENDEAVOR study: [---]
- Total number of patients enrolled in the trial: [----] (ENDEAVOR: [---]; Control: [---])
- Total number of patients enrolled at BVHI: [---]
- Date of first study enrollment: [-----]
- Date of last study enrollment: [-----]
- Amount to institute: [-----]
- [-----]

As a member of the Circulatory System Devices Panel of FDA's Medical Devices Advisory Committee, Dr. Yancy potentially could become involved in matters that could affect his financial interests. Under section 208, he 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 Dr. Yancy to participate in such matters as you deem appropriate.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Yancy that would allow him to participate fully in the matter described because the need for his services greatly outweighs the conflict of interest created by this financial interest.

First, although Dr. Yancy’s institution was involved in the sponsor’s trial, he had no direct, personal involvement and received no compensation. The fact that this financial interest is imputed to him from his employer should lessen concerns for conflicts of interest in light of the need for his expertise.

Second, there are over twenty firms that manufacture, market or plan to develop competing products or technologies for the same indication as the subject PMA device. The need for this individual’s expertise outweighs the large market availability of similar products being considered.

Third, the issues to be addressed by the Panel, on the second day, 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.

Fourth, given the nature of Dr. Yancy’s unrelated consulting arrangements with Medtronic and [-----], it is unlikely that recommendations of the Panel will impact the viability of these large firms or his ongoing relationships with them.

Moreover, 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 interests and affiliations they may have acquired as a result of their demonstrated abilities.

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. As an experienced member of the panel, Dr. Yancy provides an insightful dimension and critical reasoning to discussions. He was an active member during the December 7 and 8, 2006 Circulatory System Devices Panel meeting discussing general issues of drug eluting stents and is familiar with the history of this important topic. Also, as a non-interventional cardiologist who was in attendance at that critical meeting, he will provide necessary balance to the Panel discussions.

To the discussion regarding appropriate trial designs for evaluation of carotid stents, Dr. Yancy brings expertise in clinical trial design. Further, his experience in assisting the Panel in navigating the issues surrounding this novel technology will be essential in developing recommendations that are rigorous but not overly burdensome. As a heart failure transplant cardiologist, Dr. Yancy has extensive experience interacting with patients who have undergone major cardiac surgery and is in a position to advocate for the needs and concerns of this population. This perspective is crucial to a thoughtful discussion of the issues surrounding both topics at this meeting.

As the Panel Chair, Dr. Yancy is a critical member of this Panel and will provide both clinical trial design expertise, historical perspective on the issues surrounding drug-eluting stents, and the ability to guide the Panel in a meaningful discussion that provides the Agency with the best feedback possible. For the reasons described above, the Center's Division of Cardiovascular Devices believes that Dr. Yancy is best qualified to Chair and, therefore, a search was not done for an alternate Chair. The Center believes the benefits of Dr. Yancy's participation in this meeting will greatly outweigh any potential financial conflicts of interest.

I believe that participation by Dr. Yancy in the committee's deliberations will contribute to the diversity of opinions and expertise represented on the committee.

