



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: October 18, 2007

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

THROUGH: Vincent Tolino /S/ 10/22/07
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

Michael F. Ortwerth, Ph.D. /S/ 10/30/07
Deputy Director, Advisory Committee Oversight and Management Staff
Office of Policy, Planning, and Preparedness

FROM: Kathleen L. Walker /S/ 10/18/07
Chief, Integrity, Committee and Conference Management Branch
Division of Ethics and Management Operations, OMO
Center for Devices and Radiological Health

SUBJECT: 712(c)(2)(B) 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 section 712(c)(2)(A) of the Federal Food, Drug, and Cosmetic Act. Waivers under section 712(c)(2)(B) may be granted by the appointing official where it is "necessary to afford the advisory committee essential expertise" and where the individual has made a disclosure to FDA of the financial interests at issue. We have determined that you are the appointing official for purposes of section 712(c)(2)(B). Therefore, you have the authority to grant Clyde W. Yancy, M.D., a waiver under section 712(c)(2)(B).

Section 712(c)(2)(A) prohibits Federal executive branch employees, including special Government employees, from participating in any particular matter in which the employee or an immediate family member has a financial interest that could be affected by the advice given to the FDA with respect to the matter. Because 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.

The function of the Medical Devices Advisory 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 been asked to participate in the Panel's discussion regarding a premarket approval application (PMA) submitted by Abbott Vascular (a subsidiary of Abbott Laboratories) for the *XIENCE™ V Everolimus Eluting Coronary Stent System*. This system is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to de novo native coronary artery lesions (length \leq 28 mm) with reference vessel diameter of 2.5mm to 4.0mm.

Dr. Yancy has advised the FDA that he has financial interests that could potentially be affected by his participation in the matter described above. Dr. Yancy serves as [-----] for a [-----], sponsored by [-----]. 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, [-----] is a competing firm to 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 to the PMA sponsor.

As a member of the Circulatory System Devices Panel, Dr. Yancy could become involved in matters that could affect his financial interests. Under section 712(c)(2)(A), he is prohibited from participating in such matters. However, as noted above, you have the authority under section 712(c)(2)(B) to grant a waiver permitting Dr. Yancy to participate in such matters if necessary to afford this Panel essential expertise.

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 his voting participation is necessary to afford the Panel essential expertise.

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, he provides an insightful dimension and critical reasoning to Panel discussions. He was an active member during the December, 2006 Circulatory System Devices Panel meeting discussing general issues of drug-eluting stents and is well versed in 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 discussion.

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 this meeting.

For the reasons described above, the Center's Division of Cardiovascular Devices believes that Dr. Yancy is exceptionally qualified to chair what is expected to be a very demanding panel meeting. For a variety of scientific reasons drug-eluting stents are an extremely challenging and complex combination product area where it is critical that historical precedent, clinical trial expertise, and expert cardiovascular disease knowledge, like Dr. Yancy's, are appreciated so that adequate and well founded recommendations are summarized and forwarded to the Agency throughout the meeting by an experienced panel chair. A search was not done for an alternate chair because Dr. Bram Zuckerman, Director of the Division of Cardiovascular Devices, believed when organizing the meeting that no alternate could come close to Dr. Yancy's unique background and perspective. He has proven time and again that he appreciates and understands the Agency public health and scientific missions, and is fully willing as panel chair to use his outstanding background and skill set to provide the Agency with extremely valuable recommendations. This panel meeting, regardless of outcome, is expected to profoundly effect the course of cardiovascular care in the United States over the next few years. It is, therefore, critical that Dr. Yancy chair this meeting as his experience and skills can not be replaced.

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.

Accordingly, I recommend that you grant Dr. Yancy a waiver that would allow him voting participation in all official matters concerning the *XIENCE™ V Everolimus Eluting Coronary Stent System*, PMA sponsored by Abbott Vascular. I believe that such a waiver is appropriate because in this case, Dr. Yancy's voting participation is necessary to afford the Panel essential expertise.

DECISION:

 X Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that voting participation is necessary to afford the Panel essential expertise.

_____ Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that nonvoting participation is necessary to afford the Panel essential expertise

_____ Waiver denied.

 /S/
Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy
Food and Drug Administration

11/09/07
Date