



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/ 09/20/07
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Kathleen L. Walker /S/ 09/19/07
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 JoAnn Lindenfeld, M.D.

I am writing to request a waiver for JoAnn Lindenfeld, M.D., a temporary voting 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 JoAnn Lindenfeld, M.D. 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 her employer has a financial interest. Since JoAnn Lindenfeld, M.D. is a special Government employee, she 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 her or her employer.

Dr. Lindenfeld has been asked to participate in the Panel's discussion regarding 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 ≤ 27 mm in native coronary arteries with reference vessel diameters of ≥ 2.5 mm to ≤ 3.5 mm.

This matter is coming before a meeting of the Circulatory System Devices Panel of FDA's Medical Devices Advisory Committee. This issue 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. Lindenfeld has advised the FDA that she has a financial interest which could potentially be affected by her participation in the matter described above. She reported a consulting arrangement with Medtronic, Inc., parent of the PMA sponsor. She serves on an [-----] for a device unrelated to the agenda topic. Dr. Lindenfeld has only attended one organizational meeting to date; however, she anticipates receiving an annual fee of [-----]. This arrangement began in 2006 and is scheduled to end 2009.

As a temporary voting member of the Circulatory System Devices Panel of FDA's Medical Devices Advisory Committee, Dr. Lindenfeld potentially could become involved in matters that could affect her financial interests. Under section 208, she 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. Lindenfeld 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. Lindenfeld that would allow her to participate fully in the matter described because the need for her services greatly outweighs the conflict of interest created by this financial interest.

First, Medtronic, Inc., is a large, well-established firm with multiple product lines and global presence. Given the nature of the unrelated consulting Dr. Lindenfeld provides to them, it is unlikely that Panel recommendations will significantly impact the economic stability of the company or her continued relationship with them.

Second, there are over 20 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.

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.

The Agency acknowledges that several of the key questions to be addressed at the Panel meeting relate to premarket study design, which new types of trials should be considered and whether there are new noninvasive agents in development that may address some of the concerns at hand. Dr. Lindenfeld brings to the Panel an in-depth knowledge of clinical trial design. Board certified in internal medicine, cardiovascular disease and critical care medicine, she is Professor of Medicine in the Division of Cardiology at the University of Colorado Health Sciences Center. She is also Medical Director of the Cardiac Transplantation Program at the University of Colorado Hospital. Dr. Lindenfeld is universally recognized as an expert noninvasive cardiologist and heart failure expert. She has distinguished herself at device and drug advisory committee meetings, serving as a thoughtful and effective counterweight to the interventional cardiology perspective. Therefore, her participation at this Panel meeting should promote a balanced and productive discussion among cardiologists, interventional cardiologists and vascular surgeons. As a heart failure transplant cardiologist, she shares that credential with only one other Panel participant. The Center's search for other similarly distinguished experts was unsuccessful.

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

