



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: October 5, 2007

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

THROUGH: Vincent Tolino
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Kathleen L. Walker /S/ 10/05/07
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 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 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 JoAnn Lindenfeld, 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 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.

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. 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.

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 712(c)(2)(A), she 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. Lindenfeld 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. Lindenfeld that would allow her to participate fully in the matter described because her voting participation is necessary to afford the Panel essential expertise.

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.

