



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 David C. Naftel, Ph.D.

I am writing to request a waiver for David C. Naftel, Ph.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 David C. Naftel, Ph.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 David C. Naftel, Ph.D. 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. Naftel 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. Naftel has advised the Food and Drug Administration (FDA) that he has a financial interest, which could potentially be affected by his participation in the matter described above. He has an unrelated consulting relationship with [-----], a direct competitor to the PMA sponsor. As a member of [-----], Dr. Naftel provides input on their line of [-----]. He receives [-----] a year for this ongoing arrangement, which began in June 2006. Dr. Naftel is also a member of Medtronic, Inc.'s [-----] for their [-----], a matter unrelated to the agenda topic. Medtronic, Inc. is the parent of the PMA sponsor. He has received [----] for this arrangement which began in November 2005 and is scheduled to conclude November 2007.

As a temporary voting member of the Circulatory System Devices Panel of FDA's Medical Devices Advisory Committee, Dr. Naftel potentially 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. Naftel 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. Naftel that would allow him to participate fully in the matter described because his voting participation is necessary to afford the Panel essential expertise.

The Agency acknowledges there are complex statistical issues regarding drug eluting stent trial designs that require detailed discussion at this Panel meeting. At this time, the Circulatory System Devices Panel is in need of a biostatistician and the Center for Devices and Radiological Health

