



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 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 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. Naftel 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. Naftel 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. 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.

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. 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 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. Naftel 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. Naftel 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, 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.

Second, given the nature of the unrelated consulting Dr. Naftel provides to both [-----] and Medtronic, Inc., it is unlikely that Panel recommendations will significantly impact the economic stability of either company or his continued relationship with them.

