



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 John C. Somberg M.D.

I am writing to request a waiver for John C. Somberg M.D., a 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. Somberg 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. Somberg 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. Somberg 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. Somberg has advised the FDA that his employer has a financial interest which could potentially be affected by his participation in the matter described above. His institute, Rush University Medical Center, has been identified as a clinical site for the ENDEAVOR study. Because Dr. Somberg works in the Pharmacology Department, he was not aware that his institute was involved in the study. He has not discussed the study with anyone at Rush and has no idea of the amount of funding to the institute. The principal investigator, [-----], and Dr. Somberg work in separate and distinct departments.

The Office of Device Evaluation within the Center for Devices and Radiological Health provided the following relevant study data:

- Total number of sites involved with ENDEAVOR study: [---]
- Total number of patients enrolled in the trial: [----] (ENDEAVOR: [---]; Control: [---])
- Total number of patients enrolled at RUMC: [---]
- Date of first study enrollment: [-----]
- Date of last study enrollment: [-----]
- Amount to institute: [-----]
- [-----]

As a member of the Circulatory System Devices Panel of FDA's Medical Devices Advisory Committee, Dr. Somberg 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. Somberg 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. Somberg 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, although Dr. Somberg's institution was involved in the sponsor's trial, he had no direct, personal involvement and received no compensation. The fact that this financial interest is imputed to him from his employer should lessen any potential conflict the interest may present.

Second, Dr. Somberg's institution contributed a statistically insignificant portion of the trial data with only [----] of the total patient enrollment. This limitation should help to mitigate any concern that the SGE's impartiality might be called into question during Panel deliberations.

Third, 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.

Dr. Somberg is the Chief, Division of Clinical Pharmacology and Professor of Medicine and Pharmacology, Rush University Medical College. His unique expertise in cardiovascular pharmacology is unmatched on the Panel and will enhance the discussion of this particular drug-eluting stent (DES) as this product contains a drug not previously approved for any other use. He is also the only participant with this background to have participated in the previous Panel meetings for the currently approved drug eluting stents. He brings to the Panel a distinct pharmacology perspective on potential issues related to this product, which includes a thorough understanding of the mechanisms by which drug eluting stents achieve their intended effect, a critical issue when evaluating a new DES that incorporates an unapproved drug.

He also maintains a practice in clinical cardiovascular medicine where he deals with the concerns of his patients on a daily basis. As a practicing cardiologist, he can speak from the perspective of patients who have received drug eluting stents. One such issue that is expected to arise at this meeting is the topic of antithrombotic drug therapy and the need for patients to be on this therapy for an extended period of time, and to potentially delay or avoid certain invasive surgical procedures. Dr. Somberg's experience in working with patients will allow him to speak directly to this issue.

In addition to his participation in earlier Panel meetings in which DES applications were reviewed, Dr. Somberg was an active member of the December 7 and 8, 2006 Panel meeting that discussed general issues surround DES. His perspective will assist the Panel in determining how to approach not only the data contained in the PMA but also recent data concerning DES. Dr. Somberg's expertise and his status as a voting member support the Center's request for his participation in

