



MEMORANDUM

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

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

Michael F. Ortwerth, Ph.D. _____ /S/
Deputy Director, Advisory Committee Oversight and Management Staff
Office of Policy, Planning, and Preparedness

FROM: Kathleen L. Walker _____ /S/
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 Dale K. Heuer, M.D.

I am writing to request a waiver for Dale K. Heuer, M.D., a member of the Ophthalmic Devices Panel of the 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. Heuer 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. Because Dr. Heuer 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.

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 this 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 the specific issues or problems concerning the safety and effectiveness of devices.

Dr. Heuer has been asked to participate in the April 25, 2008 meeting of the Ophthalmic Devices Panel regarding a general issues discussion of the post market experience with phakic intraocular lenses (IOLs) and laser-assisted *in situ* keratomileusis (LASIK).

This matter is coming before a meeting of the Ophthalmic Devices Panel and is a particular matter of general applicability.

Dr. Heuer has advised the FDA that he has a financial interest that could potentially be affected by his participation in the matters described above. He reported [REDACTED]. For his role on their speaker's bureau, his honoraria totaled [REDACTED] for [REDACTED].

As a member of the Ophthalmic Devices Panel, Dr. Heuer potentially could become involved in matters that could affect his financial interest. 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. Heuer 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. Heuer that would allow him to participate in the matter described because the need for his services greatly outweighs the conflict of interest created by this financial interest.

First, the issues coming before the Panel are of general applicability, involving an entire class of products and granting no advantage to any individual manufacturer. Therefore, Panel recommendations would not be expected to have a significant financial impact on any specific firm.

Second, Dr. Heuer's speaking presentations are unrelated to the Panel topic and addressed no specific manufacturer. Therefore, the potential concern that Dr. Heuer's impartiality might be called into question during this portion of the panel deliberations should be lessened.

