



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: March 11, 2008

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

THROUGH: Vince 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: 712(c)(2)(B) 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, 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 "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 Dr. Heuer 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 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.

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 post market experience with phakic intraocular lenses 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 Food and Drug Administration (FDA) that he has a financial interest that could potentially be affected by his participation in the matters described above. He reported an unrelated consulting arrangement with [REDACTED], a manufacturer of [REDACTED] and [REDACTED]. For his role on their speaker's bureau, his honoraria totaled \$[REDACTED] for [REDACTED] presentations given in 2007.

As a member of the Ophthalmic Devices Panel, Dr. Heuer potentially could become involved in matters that could affect his financial interest. 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. Heuer to participate in such matters if necessary to afford this committee/panel essential expertise.

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 matters described because his participation is necessary to afford the Panel essential expertise.

Dr. Heuer is Professor and Chairman, Department of Ophthalmology at the Medical College of Wisconsin. Although Dr. Heuer is a recognized glaucoma specialist, we believe his insight and clinical judgment will provide a unique perspective on the LASIK and phakic intraocular lens discussions. Furthermore, we believe that all aspects of ophthalmology should be represented at this meeting to promote a balanced and productive discussion and to ensure a thorough and comprehensive consideration of these important postmarket issues. Dr. Heuer is the only glaucoma specialist who is a member of the Ophthalmic Devices Panel.

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.

Accordingly, I recommend that you grant Dr. Heuer a waiver that would allow his participation in all official matters concerning the general issues discussion of post market experience with phakic intraocular lenses and LASIK. I believe that such a waiver is appropriate because in this case, Dr. Heuer's participation is necessary to afford the Ophthalmic Devices Panel essential expertise.

DECISION:

- Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that voting participation is necessary to afford the committee/panel essential expertise.
- Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that nonvoting participation is necessary to afford the committee/panel essential expertise
- Waiver denied.

_____/S/_____
Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy

4/9/2008
Date