DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: May 5, 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: 208(b)(3) Conflict of Interest Waiver for Donald G. Ahearn, Ph.D.

I am writing to request a waiver for Donald G. Ahearn, Ph.D., a temporary 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. Ahearn 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. Ahearn 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. Ahearn has been asked to participate in the June 10, 2008 meeting of the Ophthalmic Devices Panel regarding a general discussion on current issues in contact lenses and contact lens care products, to include keratitis events, pre-clinical and clinical issues, and human factors.

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

Dr. Ahearn has advised the Food and Drug Administration (FDA) that he has a financial interests that could potentially be affected by his participation in the matter described above. Dr. Ahearn reported a consulting arrangement with [redacted], a manufacturer of contact lens care products. For his speaking engagement on [redacted], he received [redacted] in the past year and expects to receive an additional [redacted] over the next three years. [Redacted]. [Redacted].

Dr. Ahearn reported a consulting relationship with [redacted], a manufacturer of contact lenses and contact lens care products. For his consulting services on [redacted], he received [redacted] which started January 1, 2007 and ends December 31, 2008. Dr. Ahearn has a service agreement through his employer and [redacted].

Dr. Ahearn also reported a consulting relationship with [redacted], a manufacturer of contact lenses and contact lens care products. For his consulting services on [redacted], from 2007 to present, he received [redacted]. [Redacted]. Dr. Ahearn has had a 30-year relationship with [redacted]; he does not currently have an active service agreement.

As a temporary member to the Ophthalmic Devices Panel, Dr. Ahearn 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. Ahearn 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. Ahearn 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 and give no advantage to any individual manufacturer, therefore, there is far less risk of a conflict of interest.

Second, there are [redacted] firms that manufacture or market contact lenses and contact lens care products. This existence of multiple products and firms should help mitigate any appearance of bias on the part of the SGE.

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. Ahearn is Research Professor (Emeritus) of Microbiology at Georgia State University, Atlanta, Georgia. He is the author or co-author of over 200 research reports on medically important yeasts and on bacterial and fungal colonization of indoor surfaces and industrial products, including contact lens materials. He has served as a public service consultant to the Centers for Disease Control and Prevention and as a consultant microbiologist for various pharmaceutical and industrial microbiological laboratories with particular emphasis on fungal contamination. Microbial research on contact lenses and contact lens care products is a very narrow area of expertise. Research on this topic is primarily performed by the contact lens industry. Dr. Ahearn’s research on bacterial and fungal colonization of contact lens materials and his work related to the recent keratitis outbreaks is essential for a thorough Panel discussion on microbiological test methods to more accurately predict a product’s “real world” clinical performance.

A search of the SGEs in the Center for Drug Evaluation and Research revealed four microbiologists, however, none of the individuals have ophthalmic or contact lens related experience or expertise, which is considered essential for this Panel meeting. I believe that participation by Dr. Ahearn in the committee's deliberations will contribute to the diversity of opinions and expertise represented on the committee.

Accordingly, I recommend that you grant Dr. Ahearn a waiver that would allow him to participate in all official matters concerning the general discussion on current issues in contact lenses and contact lens care products, to include keratitis events, pre-clinical and clinical issues, and human factors. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Ahearn outweighs the potential for a conflict of interest created by the financial interest attributed to him.

DECISION:

__X__ Waiver granted based on my determination, made in accordance with section 208(b)(3), that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest attributable to the individual.

____ Waiver denied.

_____/S/_____ 5/15/08__
Randall W. Lutter, Ph.D. Date
Deputy Commissioner for Policy