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 Loretta B. Szczotka-Flynn, O.D., M.S., and F.A.A.O.

I am writing to request a waiver for Loretta B. Szczotka-Flynn, O.D., M.S., F.A.A.O., 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. Szczotka-Flynn 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 her employer has a financial interest. Because Dr. Szczotka-Flynn is a special Government employee, she 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 her or her 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. Szczotka-Flynn 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 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. Szczotka-Flynn has advised the Food and Drug Administration (FDA) that she has a financial interest that could potentially be affected by her participation in the matter described above. Dr. Szczotka-Flynn reported a[redacted] with [redacted]. Regarding the [redacted]. [Redacted] is a manufacturer of contact lenses. In her role as a [redacted], she anticipates [redacted] toward salary support; her institution anticipates [redacted]. [redacted]. This [redacted] started in October 2007 and is expected to end September 2008.

As a temporary member to the Ophthalmic Devices Panel, Dr. Szczotka-Flynn potentially could become involved in matters that could affect her financial interest. Under section 208, she 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. Szczotka-Flynn 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. Szczotka-Flynn that would allow her to participate in the matter described because the need for her 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. Szczotka-Flynn is Associate Professor of Ophthalmology, Department of Ophthalmology at Case Western Reserve University, School of Medicine in Cleveland, Ohio. She is a PhD candidate in Epidemiology, with expected completion in 2009, at Case Western Reserve University, Dept. of Epidemiology and Biostatistics. Her research includes contact lens complications, extended wear, and silicone hydrogel-related infiltrative complications. Additionally, she has interests in bacterial adherence and biofilm formation on contact lenses, efficacy of contact lens care solutions against biofilm, and the relationship of bacterial contamination to infiltrative contact lens complications.

Contact lenses are most often prescribed by optometrists, and patients with problems associated with contact lens wear usually first seek help from an optometrist. Therefore, it is critical that this Panel meeting, which concerns contact lens safety, include participants with wide expertise in optometry. Her research experience with contact lenses and contact lens solutions, particularly her studies in silicone hydrogel lenses and in bacterial adherence and contamination, is uniquely suited to the topics for Panel discussion. Her research in silicone hydrogel contact lenses is unmatched by any other prospective Panel member. A search of SGEs in the Center for Drug Evaluation and Research did not yield an optometrist or an ophthalmologist with contact lens expertise. A search of all HHS Advisory Committees did not yield any individual with contact lens expertise in ophthalmology or optometry. I believe that participation by Dr. Szczotka-Flynn in the Panel’s deliberations will contribute to the diversity of opinions and expertise represented on the Panel.

Accordingly, I recommend that you grant Dr. Szczotka-Flynn a waiver that would allow her 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. Szczotka-Flynn outweighs the potential for a conflict of interest created by the financial interest attributed to her.

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/_____ 5/13/08_____
Randall W. Lutter, Ph.D. Date
Deputy Commissioner for Policy