



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: October 14, 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/_____
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 Michael J. Olding, M.D.

I am writing to request a waiver for Michael J. Olding, M.D., a member of the General and Plastic Surgery Devices Panel, 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. Olding 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. Olding 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. Olding has been asked to participate in the November 18, 2008 meeting of the General and Plastic Surgery Devices Panel and the Committee will receive an update on safety information collected on dermal fillers in the commercial setting, discuss current premarket and postmarket approved study designs, and make recommendations on general issues concerning the study of various dermal fillers. In addition, the Committee will discuss the design of clinical trials for future premarket submissions seeking approval of dermal fillers for new intended uses.

This matter is coming before a meeting of the General and Plastic Surgery Devices Panel. This issue is a particular matter of general applicability.

Dr. Olding has advised the Food and Drug Administration he has a financial interest that could potentially be affected by his participation in the matter described above. He reported owning [----] shares in [-----], currently valued at [-----], which represents [--] of his net worth. [-----] is a firm that manufactures dermal fillers.

As a member the General and Plastic Surgery Devices Panel, Dr. Olding 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. Olding 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. Olding 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 – far less risk of a conflict of interest.

Second, there are [--] firms that manufacture, market or plan to develop dermal fillers. The 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. Michael Olding is Chief of Plastic Surgery at The George Washington (GW) University and Director of the Cosmetic Surgery and Laser Center at GW. He is a board certified plastic surgeon with considerable experience in the clinical application of dermal filler products. Dr. Olding has served on the General and Plastic Surgery Devices Advisory Panel since 2002.

The proposed November 18, 2008 Advisory Panel is focused on a general discussion of premarket trial designs and post market performance of the approximately 10 dermal fillers that have been approved in the last 8 years. This discussion will not focus specifically on products produced by [-----] but will instead seek Panel insight on the current general use of dermal filler products. Therefore, any insight provided by Dr. Olding will not have an exclusive effect on the products produced by [-----].

During his tenure as a General and Plastic Surgery Devices Advisory Panel member, Dr. Olding has participated and voted on three Premarket Approval Applications for dermal fillers. Given Dr. Olding's expertise with these products and his participation at previous Advisory Panel meetings on this topic, we believe he is uniquely qualified to contribute to this general topics discussion of dermal fillers. Furthermore, Dr. Olding is the only plastic surgeon on the General and Plastic Surgery Devices Advisory Panel with significant dermal filler experience, which is considered essential for this Panel meeting.

Lastly, a search of the FDA SGE database yielded no plastic surgeons other than those on the General and Plastic Surgery Devices Advisory Panel.

Accordingly, I recommend that you grant Dr. Olding a waiver that would allow him to participate in all official matters concerning general issues concerning dermal fillers. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Olding 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/
Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy

10/23/2008
Date