



**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: 712(c)(2)(B) 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 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. Olding 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. 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.

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 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 of the General and Plastic Surgery Devices Panel, Dr. Olding could become involved in matters that could affect his financial interests. 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. Olding 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. Olding that would allow him to participate without voting in the matter described because his nonvoting participation is necessary to afford the committee/panel essential expertise.

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 [-----].

