



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: October 27, 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 Hollis G. Potter, M.D.

I am writing to request a waiver for Hollis G. Potter, M.D. a temporary member of the Orthopaedic and Rehabilitation Devices Panel of FDA's Medical Devices Advisory Committee, 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. Potter 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. Potter 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.

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. Potter has been asked to participate in the November 14, 2008 meeting of the Orthopaedic and Rehabilitation Panel. The Panel will discuss and make recommendations on a premarket notification application for the ReGen Collagen Scaffold (CS), sponsored by ReGen Biologics, Inc. The ReGen Collagen Scaffold is a resorbable collagen matrix comprised primarily of bovine Type I collagen. The device is intended for use in surgical procedures for the reinforcement and repair of chronic soft tissue injuries of the meniscus (one to three prior surgeries to the involved meniscus) where weakness exists. The surgeon assesses the meniscus defect and trims the device to the size necessary for repair of the damaged or weakened soft tissue. In repairing and reinforcing meniscal defects, the patient must have an intact meniscal rim and anterior and posterior horns for attachment of the mesh.

This matter is coming before a meeting of the Orthopaedic and Rehabilitation Devices Panel of FDA's Medical Devices Advisory Committee. This issue is a particular matter involving specific parties. There will be no voting on this matter.

Dr. Potter 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. She reported a potentially related consulting agreement with [-----], parent of [-----], a firm whose preliminary research may lead to a future meniscal repair device. [-----]. This relationship commenced in 2007 and she anticipates receiving [-----] for her services in 2008. Although the work is completed, the final report has not been submitted. She will attend an upcoming conference to present the imaging data.

As a temporary member of the Orthopaedic and Rehabilitation Devices Panel, Dr. Potter could become involved in matters that could affect her financial interests. Under section 712(c)(2)(A), she 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. Potter to participate in such matters if necessary to afford this Panel essential expertise.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Potter that would allow her to participate in the matter described because her participation is necessary to afford the Panel essential expertise.

Dr. Potter is Chief of the Division of Magnetic Resonance Imaging /Director of Research in the Department of radiology & Imaging at the Hospital for Special Surgery, New York, New York and Professor of Radiology at Weill Medical College of Cornell University. Dr. Potter's participation in the discussion of a meniscal repair device is considered critical because radiographic evaluation of the knee is necessary to assess the effectiveness of this device for its intended use. She is a board-certified radiologist with clinical interests related to sports medicine and meniscal and cartilage imaging. In addition to Dr. Potter, we considered 41 academic and clinical radiologists including those on the Radiological Devices Panel as well as one other radiologist from the Orthopaedic and Rehabilitation Devices Panel. None of the other Special Government Employees possessed the same relevant expertise to the Panel topic, particularly, the experience that Dr. Potter has with radiographic evaluation and imaging of the knee. Her clinical interests of sports medicine and cartilage imaging are also unique among the candidates considered, and directly relevant to the knee meniscal repair product to be discussed at the Panel meeting. I believe that participation by Dr. Potter in the Panel's deliberations will contribute to the diversity of opinions and expertise represented on the 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. Potter a waiver that would allow her nonvoting participation in all official matters concerning the ReGen Collagen Scaffold 510(k), sponsored by ReGen Biologics, Inc. I believe that such a waiver is appropriate because in this case, Dr. Potter's nonvoting participation is necessary to afford the 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

10/30/08
Date