



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: 208(b)(3) 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 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. Potter 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. 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 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. Potter has been asked to participate in the November 14, 2008 meeting of the Orthopaedic and Rehabilitation Devices Panel. The Panel will discuss and make recommendations on a premarket notification application (510(k)) 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.

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 potentially could become involved in matters that could affect her financial interests. 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. Potter 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. Potter 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, although her consulting agreement with [-----] is potentially related to the 510(k) under discussion, the Agency can only speculate on the direction that [-----] may pursue with this data, including the intended use. Therefore, we believe it is highly unlikely that her participation in the matters coming before the Panel will have an impact on [-----] or her continuing relationship with the firm.

Second, there are more than [-] firms actively pursuing development or marketing of meniscal repair products. The existence of multiple 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. 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.

Accordingly, I recommend that you grant Dr. Potter a waiver that would allow her to participate 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, the need for the services of Dr. Potter outweighs the potential for a conflict of interest created by the financial interest attributed to her.

