



MEMORANDUM

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

THROUGH: Vince Tolino
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Kathleen L. Walker /S/ 01/08/07
Chief, Integrity, Committee and Conference Management Branch
Division of Ethics and Management Operations, OMO
Center for Devices and Radiological Health

SUBJECT: Conflict of Interest Waiver for Michael B. Mayor, M.D.

I am writing to request a waiver for Michael B. Mayor, M.D., serving on the Orthopaedic and Rehabilitation Devices Panel of FDA's Medical Devices Advisory Committee as a consultant, 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. Mayor 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. Since Dr. Mayor is a special Government employee, this individual 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.

Dr. Mayor has been asked to participate in the Panel discussion of a premarket approval application (PMA) for the *Cormet 2000 Hip Resurfacing System*, sponsored by Corin U.S.A. This metal-on-metal hip resurfacing prosthesis is intended for use in resurfacing hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients experiencing the following conditions:

- Non-inflammatory degenerative arthritis such as osteoarthritis, and avascular necrosis; or
- Inflammatory arthritis such as rheumatoid arthritis.

These matters are coming before the Orthopaedic and Rehabilitation Devices Panel for consideration and are particular matters involving specific parties.

Dr. Mayor has advised the FDA that he has a financial interest, which could potentially be affected by his participation in this matter. Dr. Mayor receives royalties for a patent on an [-----], licensed by [-----]; its sister company, [-----], is a competitor to the PMA sponsor. He received [-----] in royalties for 2006 and previously reported [-----] for 2005. These royalties are considerably less than the [-----] he reported in 2004. Dr. Mayor has advised the FDA that [-----] and expects royalties to continue to diminish. Dr. Mayor receives no other compensation from [-----] or its parent, [-----].

The functions of the committee, as stated in its Charter, are 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 the premarket approval 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 specific issues or problems concerning the safety and effectiveness of devices. As a consultant to the Orthopaedic and Rehabilitation Devices Panel, Dr. Mayor potentially could become involved in matters that affect [-----] and its parent, [-----]. Under section 208, Dr. Mayor 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 this individual 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. Mayor allowing him to participate fully in all matters identified below.

First, the royalties Dr. Mayor received have significantly decreased over the last two years. Since [-----] and royalties will continue to diminish, any decision reached would have little impact on the value of the patent.

Second, there are [---] firms manufacturing or developing other types of total hip replacement prostheses. Additionally, [---] other firms are marketing or currently developing a hip resurfacing system similar to the PMA system. The existence of multiple competitors' products should help to mitigate any appearance of bias on the part of the SGE.

Third, [-----] and its parent, [-----], are very large, well-established organizations. Thus, the recommendation of the Panel would not be expected to impact the stability of these firms.

Lastly, 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 interest and affiliations they may have acquired as a result of their demonstrated abilities.

Dr. Mayor is William and Bessie Allyn Professor of Surgery in Orthopaedics, Dartmouth Medical School and Adjunct Professor of Engineering, Thayer School of Engineering, Dartmouth College, Lebanon, New Hampshire. In the Center's attempt to find other qualified individuals with expertise in the area of joint replacement, we conducted a search of the 18 NIH groups listed in the Federal Advisory Committee Act (FACA) database and the NIH employee listing. The FACA search identified SGEs with dental research focus and the NIH employee search found employees with orthopaedic research at the cellular level. These areas of research are not relevant to the Panel discussion. Therefore, we request to use the services of Dr. Mayor because he has the knowledge and expertise on the subject matter being discussed. Dr. Mayor's clinical experience with joint replacement, particularly femoral prostheses, and research interests related to implant retrieval analysis makes him especially qualified for the issues related to the hip resurfacing prosthesis to be brought before the Panel. We believe Dr. Mayor's participation in this meeting will ensure the level of expertise required to provide advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Dr. Mayor a waiver that would allow this individual to participate fully in all official matters before the Panel related to the *Cormet 2000 Hip Resurfacing System* PMA, sponsored by Corin U.S.A. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Mayor outweighs the potential for a conflict of interest created by the financial interest involved.

CONCURRENCE:

_____/S/_____
Vince Tolino
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

Date 01/31/07

DECISION:

_____ 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 conflict of interest created by the financial interest attributable to the individual.

_____ Waiver denied.

_____/S/_____
Randall Lutter, Ph.D.
Associate Commissioner for Policy
and Planning

Date 02/01/07