



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: March 11, 2008

TO: Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy
Food and Drug Administration

THROUGH: Vincent Tolino _____/S/
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

Michael F. Ortwerth, Ph.D. _____/S/
Deputy 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 David C. Musch, Ph.D., M.P.H.

I am writing to request a waiver for David C. Musch, Ph.D., M.P.H., a temporary member of the Ophthalmic Devices Panel of the 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. Musch 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. Musch 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. Musch has been asked to participate in the Panel's discussion regarding a premarket approval application (PMA) for the *IMT™ Implantable Miniature Telescope*, sponsored by VisionCare Technologies, Inc. The IMT™, a visual prosthetic device, is indicated for monocular implant in patients with stable, moderate to profound central vision impairment due to bilateral central scotomas associated with end-stage macular degeneration with geographic atrophy or disciform scar, foveal involvement and cataract.

This matter is coming before a meeting of the Ophthalmic Devices Panel of FDA's Medical Devices Advisory Committee. This issue is a particular matter involving a specific party.

Dr. Musch has advised the FDA that he has an imputed financial interest that could potentially be affected by his participation in the matter described above. His institute, the University of Michigan, is a clinical site for the IMT study; he had no involvement nor did he receive any compensation. He reports the principal investigator, Dr. Paul R. Lichtor, is his supervisor.

VisionCare Technologies, Inc. provided the following information:

Total enrollment: [REDACTED]

IMT001 pilot investigation trial: [REDACTED]

IMT002 pivotal investigation trial: [REDACTED]

Ongoing activities and Payment: Long Term Monitoring (LTM), a trial in which [REDACTED]

At University of Michigan

IMT001: [REDACTED]

IMT002: [REDACTED]

Enrollment: [REDACTED]

Treated/Followed: [REDACTED]

First Study Enrollment Date: [REDACTED]

Date of Last Study Enrollment: [REDACTED]

Trial Follow-up Requirements: [REDACTED]

Payments to date: \$ [REDACTED]

Ongoing Activities and Payments: [REDACTED]

LTM related services: Projected additional payments are estimated [REDACTED]

As a temporary member to the Ophthalmic Devices Panel, Dr. Musch potentially could become involved in matters that could affect his imputed financial interest. 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. Musch 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. Musch 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, although Dr. Musch's employer was involved in the IMT trial, he had no direct personal involvement nor did he receive compensation. The fact that this financial interest is imputed to him from his employer should lessen any potential conflict the interest may present.

Second, Dr. Musch's institute contributed a statistically insignificant portion [REDACTED] of the trial data. This limitation should help mitigate any concern that Dr. Bressler's impartiality might be called into question during Panel deliberations.

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. Musch currently holds joint appointments in the University of Michigan Medical School as Professor in the Dept. of Ophthalmology and Visual Sciences and in the School of Public Health as an Associate Research Scientist in the Dept. of Epidemiology. Trained as an epidemiologist, Dr. Musch addresses treatment effectiveness, variation in measurement and diagnostic abilities, and medical outcomes in his research programs. He is involved as a consultant to several multicenter clinical trials of laser treatments for age-related macular degeneration, and serves on the Data and Safety Monitoring Committees for both NIH and industry-sponsored clinical trials. Another of his research interests is the development of validated questionnaires for measuring vision-related quality of life. His expertise, particularly with regard to vision-related quality of life, is considered essential to ensure an in-depth discussion of the IMT, a device that is intended for some patients with end-stage macular degeneration. An alternate SGE with expertise in quality of life issues was considered; however that SGE is employed by the same institution as one of the voting members who will attend this meeting. I believe that participation by Dr. Musch in the Panel's deliberations will contribute to the diversity of opinions and expertise represented on the Panel.

