

MEMORANDUM

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

THROUGH: Jenny Slaughter /S/ 06/08/06
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Kathleen L. Walker /S/ 06/02/06
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 Neil M. Bressler, M.D.

I am writing to request a waiver for Neil M. Bressler, M.D., a member of the Ophthalmic 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. Bressler 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. Bressler 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. Bressler has been asked to participate in the Panel's deliberations on a premarket approval application (PMA) submitted by [-----] for their Implantable Miniature Telescope (IMT™). The IMT™ is a visual prosthetic device which, when combined with the optics of the cornea, constitutes a telephoto lens and is indicated for use in patients with bilateral, stable macular degeneration and other bilateral, stable untreatable central vision disorders.

Dr. Bressler's employer has a financial interest that could potentially be affected by his participation in this matter. His employing institute, the Johns Hopkins University School of Medicine (Wilmer Eye Institute), was a clinical site for the IMT study. Dr. Bressler had no personal or financial involvement with this trial, and no knowledge of the study funding.

He is a Professor of Ophthalmology within the Department of Ophthalmology. The principal investigator, [-----], does not serve in a supervisory role with regard to Dr. Bressler. He and [-----] are within the Department of Ophthalmology but in separate divisions . Dr. Bressler is in the Retina Division and [-----] is in the Cataract Division.

The Office of Device Evaluation within the Center for Devices and Radiological Health provided the following relevant study data:

- Total number of sites involved: [-----]
- Total number of patients enrolled in the trial: [---]
- Total number of patients treated at Johns Hopkins: [-]
- Date of first study enrollment: [-----]
- Date of last study enrollment: [-----]
- Amount to institute: \$[-----]

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 member of the Ophthalmic Devices Panel, Dr. Bressler potentially could become involved in matters that affect [-----]. Under section 208, Dr. Bressler 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. Bressler that would allow this individual to participate in matters identified below.

First, although Dr. Bressler’s institution was involved in the sponsor’s trial, he had no knowledge of the study, had no direct, personal involvement and received no compensation. The fact that this financial interest is imputed to him from his employer should lessen any potential concern for bias.

