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 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 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. 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. Because Dr. Bressler 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 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.

Dr. Bressler has been asked to participate in the April 24, 2008 meeting of the Ophthalmic Devices Panel 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.

The 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. Bressler 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 employing institute, The Johns Hopkins Hospital (JHH), is a clinical site for the IMT study. He had no personal involvement nor did he receive any compensation. The principal investigator, Dr. Oliver Schein, and Dr. Bressler both work in the Department of Ophthalmology, but in different divisions. Dr. Bressler has no professional or managerial relationship with Dr. Schein.

The Sponsor reported the following trial 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] patients from the [REDACTED] patient IMT002 trials are currently enrolled and will be followed for up to [REDACTED] from date of enrollment in the IMT002 trial.

At JHU:
IMT001: [REDACTED].
IMT002:
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 to be [REDACTED]

As a member of the Ophthalmic Devices Panel, Dr. Bressler 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. Bressler 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 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. Bressler'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. Bressler'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. Bressler has an international referral practice as Chief of the Retina Division of the Wilmer Eye Institute of The Johns Hopkins University School of Medicine. His main research interests have been collaborative efforts in clinical trials, with specific emphasis on the treatment of choroidal neovascularization in age-related macular degeneration and diabetic retinopathy, as well as designing and evaluating reliable classification schemes of imaging in retinal diseases. His expertise is considered essential for this meeting to assure an in-depth discussion of the IMT, a device that is intended for some patients with end-stage macular degeneration. This meeting represents the second time the IMT is under discussion and voting by the Ophthalmic Devices Panel. At the July 14, 2006 meeting the Panel members recommended additional data collection to address complex safety issues. It is important, insofar as it is possible, that members who participated in the July 2006 meeting attend the April 24, 2008 meeting to provide necessary continuity and permit a thorough and fair evaluation of this device. Because Dr. Bressler actively participated in the July 14, 2006 meeting, has a thorough understanding of the complex safety issues, and has focused his research on age-related macular degeneration, we believe he will provide an invaluable perspective during the IMT discussions. For these reasons, a search was not conducted to find an alternate individual. I believe that participation by Dr. Bressler 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. Bressler a waiver that will allow him to participate in all official matters concerning VisionCare Technologies, Inc.'s PMA for the *IMT™ Implantable Miniature Telescope.* I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Bressler outweighs the potential for a conflict of interest created by the financial interest attributed to him.

DECISION:

_____X____ 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/_____ 4/7/2008
Randall W. Lutter, Ph.D. Date
Deputy Commissioner for Policy