



Waiver to Allow Participation in a Food and Drug Administration  
Advisory Committee

DATE: February 13, 2009

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

Name of Advisory Committee Member: Karen Bandeen-Roche, Ph.D.

Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee

Meeting date: March 27, 2009

Description of the Facts on Which the Waiver is Based:

Type, Nature, and Magnitude of the Financial Interest(s):

Dr. Bandeen-Roche, Ph.D., currently serves on the Ophthalmic Devices Panel, which reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in the eye and makes appropriate recommendations to the Commissioner of Food and Drugs. Dr. Bandeen-Roche's institute, the Johns Hopkins University (JHU), is a clinical site for the premarket approval application (PMA) study coming before the panel for discussion. She has no involvement nor receives any compensation. Her employer received less than \$100,000 toward this study over the course of 6 years. Dr. Bandeen-Roche reported past, unrelated collaborations with Dr. Oliver

Schein (the study principal investigator (PI)), including shared grant funding and publications. Her most recent association with him was in 2001. SGE has no managerial responsibilities over Dr. Schein. They work in two different departments; Dr. Bandeen-Roche works in the Department of Biostatistics and Dr. Schein carries joint appointments in the Department of Ophthalmology and Epidemiology.

Description of the Particular Matter to Which the Waiver Applies:

Dr. Bandeen-Roche has been asked to participate in the meeting to discuss, make recommendations, and vote on a PMA for the *IMT™ Implantable Miniature Telescope* sponsored by VisionCare Technologies, Inc. The IMT™ is a visual prosthetic device which, when combined with the optics of the cornea, constitutes a telephoto lens. The IMT™ is indicated to improve vision by monocular implantation in patients 65 or older with stable moderate (distance BCVA of  $\leq 20/80$ ) to profound (distance BCVA  $\geq 20/800$ ) vision impairment caused by bilateral central scotomas associated with end-stage age-related macular degeneration.

Additional Facts: None

Basis for Granting the Waiver:

Dr. Bandeen-Roche is an Associate Professor of Biostatistics in the School of Hygiene and Public Health at Johns Hopkins University, in Baltimore. She is well published and has contributed extensively to many publications including the American Journal of Epidemiology, Investigative Ophthalmology and Vision Science, and the Journal of American Statistical Association, Biometrika, and Statistics in Medicine. The Panel has a strong need for a biostatistician who has expertise in the area of multiple-variate and longitudinal data analysis, quality of life assessment and clinical study issues that directly relate to the PMA. Dr. Bandeen-Roche comes highly qualified and nationally recognized in these areas. She is also uniquely qualified for this particular PMA meeting due to the fact that she has authored journal articles and conducted research related to ophthalmic issues, particularly in the area of non-invasive assessment of the visual system. Currently she is the only statistician available for this meeting, after searching the CDRH panel databases and rosters and finding none of the other statisticians with ophthalmic experience. The importance of Dr. Bandeen-Roche's presence at this panel meeting cannot be understated, as the application going to panel contains critical statistical issues and analysis that must be explained and analyzed from an outside expert in order to have a thorough and fair deliberation of this PMA. The clinical physicians will defer to her expertise to breakdown the complicated statistical modeling used by the sponsor. The Ophthalmic Devices Panel is in need of a statistician for this panel and Dr. Bandeen-Roche brings with her a necessary and unique perspective from her extensive experience in dealing with ophthalmic devices and clinical data.

Thus we are requesting a waiver for Dr. Bandeen-Roche, a temporary voting member of the Ophthalmic Devices Panel, from the conflict of interest prohibitions of 18 U.S.C. § 208(a).

Certification:

The individual may participate – The Regular Government Employee’s financial Interest is not so substantial as to be deemed likely to affect the integrity of the services provided by that individual.

The individual may participate – The need for the Special Government Employee’s services outweighs the potential for a conflict of interest.

Limitations on the Regular Government Employee’s or Special Government Employee’s Ability to Act:

Non-voting

Other (specify):

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Denied – The individual may not participate.

/S/

03/02/2009

\_\_\_\_\_  
Randall W. Lutter, Ph.D.  
Deputy Commissioner for Policy

\_\_\_\_\_  
Date