



Food and Drug Administration  
Rockville MD 20857

MEMORANDUM

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

THROUGH: Jenny Slaughter /S/ 9/6/06  
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

FROM: Kathleen L. Walker /S/ 9/5/06  
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 Mark B. Williams, Ph.D.

I am writing to request a waiver for Mark B. Williams, Ph.D., a member on the National Mammography Quality Assurance 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. Williams 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. Williams 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. Williams has been asked to participate in the Committee's general issue discussions on (1) amendments to the current Mammography Quality Standards Act (MQSA) regulations; (2) all guidance documents issued since the last meeting; and (3) updates on recently approved alternative standards and the radiological health programs.

Dr. Williams has advised the FDA that he has a financial interest which could potentially be affected by his participation in this matter. Dr. Israel reported a pending grant with the National Cancer Institute of the National Institutes of Health and Avon on Dual Modality Image-Guidance for Surgery of Non-palpable Breast Lesions. His employer, the University of Virginia, expects to receive [-----] for the first year and [-----] for the second year for direct costs. For his role as the principal investigator he expects to receive [-----] in compensation. This grant started September 11, 2006 and is expected to end August 31, 2008.

The function of the Committee, as stated in its Charter, is to provide advice to the Food and Drug Administration on the following tasks: developing appropriate quality standards and regulations for mammography facilities, developing appropriate standards and regulations for bodies accrediting mammography facilities, developing regulations on sanctions, developing procedures to monitor compliance with standards, establishing a mechanism to investigate consumer complaints, reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities, determining whether there is a shortage of mammography facilities in rural and health professional shortage areas, determining whether there will be a sufficient number of medical physicists after October 1, 1999, and determining the costs and benefits of compliance with these requirements. As a member of the National Mammography Quality Assurance Advisory Committee, Dr. Williams potentially could become involved in matters that affect the National Institutes of Health and Avon. Under section 208, Dr. Williams 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 it would be appropriate for you to grant a waiver to Dr. Williams allowing him to participate in matters identified below.

First, the Committee discussion is a matter of general applicability, involving an entire class of mammography related products and granting no advantage to any individual manufacturer. The subject matter of his employer's grant is not a topic for discussion at this meeting. Therefore, the potential concern that Dr. Williams' impartiality might be called into question during Committee deliberations should be minimized.

Second, the Committee's role is advisory in nature and the Agency officials making the decisions are not bound by the recommendations of the Committee. Therefore, the Agency will take into consideration the involvement of the SGE when making a final decision.

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. Williams is Associate Professor of Radiology and Biomedical Engineering and Physics at the University of Virginia. His areas of expertise include medical physics, instrumentation, diagnosis or early detection of cancer and digital mammography/ diagnostic radiology. He is a nationally recognized expert in the field of digitally acquired x-ray images. He has extensive experience evaluating full field digital mammographic systems. We believe that Dr. Williams' participation in these Committee deliberations is invaluable and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

