



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 Julie E. Timins, M.D.

I am writing to request a waiver for Julie E. Timins, M.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. Timins 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 her employer has a financial interest. Since Dr. Timins 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 her or her employer.

Dr. Timins 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. Timins has advised the FDA that she has financial interests which could potentially be affected by her participation in these matters. She reported owning [---] shares of [-----] stock, currently valued at [----], which represents [-----] of her net worth. [-----] is a manufacturer of mammography equipment. She also reported [----] shares of [-----] stock, currently valued at [----] and representing [-----] of her net worth. [-----] is the parent of a subsidiary that manufactures a breast biopsy system.

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. Timins potentially could become involved in matters that affect [-----] and [-----]. Under section 208, Dr. Timins 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. Timins allowing her 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. Therefore, the potential concern that Dr. Timins' impartiality might be called into question during Committee deliberations should be minimized.

Second, the values of Dr. Timins' stocks represent [-----] of her total net worth. Therefore it is unlikely that her interests would be considered so significant as to affect the integrity of the services the Government may expect from her.

Third, the Committee recommendations would not be expected to affect the viability of [-----] and [-----] or significantly alter their stock value since they are both very large, well-established organizations with highly diversified product lines and global presence.

Fourth, 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. Timins is one of only three radiologists who serve this Committee. She is a staff radiologist at Christ Hospital, Jersey City, New Jersey and a MQSA-qualified interpreting physician who serves an indigent population. Her unique background positions her to advise the Agency on the effects of MQSA regulations and their impact on a general radiology practice that also provides mammography services.

