



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

DATE: September 21, 2007

TO: Randall W. Lutter, Ph.D.  
Deputy Commissioner for Policy

THROUGH: Vincent Tolino  
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

FROM: Kathleen L. Walker /S/ 9/21/07  
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 Carol J. Mount, R.T.

I am writing to request a waiver for Carol J. Mount, R.T., a member of 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 Ms. Mount 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 Ms. Mount is a special Government employee, she 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.

The function of the National Mammography Quality Assurance Advisory 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.

Ms. Mount has been asked to participate in the Committee's discussion of issues related to the possible regulation of interventional mammography and receive input from professional organizations.

Ms. Mount has advised the FDA that she has a financial interest that could potentially be affected by her participation in the matter described above. She reported a consulting relationship with [-----] -----, on an unrelated topic, [-----]. Relevant to this meeting, [-----] is a manufacturer of interventional mammography devices. Although she does not receive any personal compensation for her role as [-----], [-----] has paid directly for her hotel and airfare in 2006 and is likely to pay again for her trip in November 2007.

This matter is coming before a meeting of the National Mammography Quality Assurance Advisory Committee. This issue is a particular matter of general applicability.

As a member of the National Mammography Quality Assurance Advisory Committee, Ms. Mount potentially could become involved in matters that could affect her financial interests. Under section 208, she 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 Ms. Mount 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 Ms. Mount that would allow her to participate fully in the matter described because the need for her services greatly outweighs the conflict of interest created by this financial interest.

First, Ms. Mount receives no personal compensation for her consulting relationship. The hotel and travel expenses paid directly by the firm are not so significant that the amount would outweigh the need for her services.

Second, the discussion before the committee is a particular matter of general applicability, granting no advantage to any individual or manufacturer.

Third, 25 firms have been identified as marketing or pursuing development of interventional mammography devices, therefore, the need for this individual's expertise outweighs the large market availability of the devices being considered.

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 interest and affiliations they may have acquired as a result of their demonstrated abilities.

