



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

DATE: October 15, 2007

TO: Randall W. Lutter, Ph.D.  
Deputy Commissioner for Policy  
Food and Drug Administration

THROUGH: Vincent Tolino /S/ 10/16/07  
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

Michael F. Ortwerth, Ph.D. /S/ 10/16/07  
Deputy Director, Advisory Committee Oversight and Management Staff  
Office of Policy, Planning, and Preparedness

FROM: Kathleen L. Walker /S/ 10/16/07  
Chief, Integrity, Committee and Conference Management Branch  
Division of Ethics and Management Operations, OMO  
Center for Devices and Radiological Health

SUBJECT: 712(c)(2)(B) 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 FDA's National Mammography Quality Assurance Advisory Committee, from the conflict of interest prohibitions of section 712(c)(2)(A) of the Federal Food, Drug, and Cosmetic Act. Waivers under section 712(c)(2)(B) may be granted by the appointing official where "it is necessary to afford the advisory committee essential expertise" and where the individual has made a disclosure to FDA of the financial interests at issue. We have determined that you are the appointing official for purposes of section 712(c)(2)(B). Therefore, you have the authority to grant Carol J. Mount, R.T., a waiver under section 712(c)(2)(B).

Section 712(c)(2)(A) prohibits Federal executive branch employees, including special Government employees, from participating in any particular matter in which the employee or an immediate family member has a financial interest that could be affected by the advice given to the FDA with respect to the matter. Because Carol J. Mount, R.T. 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.

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.

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

Ms. Mount has advised the FDA that she has a financial interest which 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.

As a voting 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 712(c)(2)(A), she is prohibited from participating in such matters. However, as noted above, you have the authority under section 712(c)(2)(B) to grant a waiver permitting Ms. Mount to participate in such matters if necessary to afford this Committee essential expertise.

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 her voting participation is necessary to afford the Committee essential expertise.

Ms. Mount is Assistant Professor of Radiology, Mayo Clinic College of Medicine, Rochester, Minnesota. Her distinguished career in mammography spans a period of three decades. When she began performing mammograms at Mayo Clinic, she also became an active participant in research involving computed tomography of the breast using the first dedicated body scanner. Ms. Mount is recognized on a national level for her technical expertise in mammography quality control and has developed five licensed inventions for use in mammography quality control testing. In her current position as Supervisor for the Division of Breast Imaging and Intervention

