



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: February 6, 2008

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

THROUGH: Vincent Tolino /S/ 2/7/08
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

Michael F. Ortwerth, Ph.D. /S/ 2/11/08
Deputy Director, Advisory Committee Oversight and Management Staff
Office of Policy, Planning, and Preparedness

FROM: Kathleen L. Walker /S/ 2/6/08
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 John A. Carrino, M.D., M.P.H.

I am writing to request a waiver for John A. Carrino, M.D., M.P.H., a temporary member of the Radiological Devices Panel of FDA's Medical Devices 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 John A. Carrino, M.D., M.P.H. 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 Dr. Carrino is a special Government employee, he 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.

The function of the Medical Devices Advisory Committee, as stated in its Charter, is to review and evaluate available data concerning the safety and effectiveness of marketed and investigational devices and advise the Commissioner of Food and Drugs regarding recommended classification of these devices into one of three regulatory categories; recommend the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advise on any possible risks to health associated with the use of devices; advise on formulation of product development protocols and review premarket approval applications for those devices classified in the premarket approval category; review classification as appropriate; recommend exemption to certain devices from the application of portions of the Act; advise on the necessity to ban a device; and respond to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

Dr. Carrino has been asked to participate in the Panel's discussion on general issues relating to Computer Aided Detection (CAD) devices for breast, colon, and lung images. Currently, these devices are used to analyze digital image information and mark areas of interest that a radiologist might overlook as an aid to prevent observational oversights. The CADs are not considered stand-alone devices. These matters are coming before the Radiological Devices Panel for consideration and are particular matters of general applicability.

Dr. Carrino has advised the FDA that he has financial interests that could potentially be affected by his participation in the matter described above. He has requested his employer's approval of consulting activities, which he performed during his previous employment. The consulting contract involves serving on [-----], a matter unrelated to the agenda topic. If the request is approved, Dr. Carrino anticipates working with [-----] in the latter part of 2008 with expected earnings of [-----]. No work has been performed in 2007 for this consulting arrangement. Relevant to this Panel meeting, [-----] is identified as having an agreement with [-----] for a CAD device to analyze breast images.

As a temporary member of the Radiological Devices Panel, Dr. Carrino could become involved in matters that could affect his financial interests. Under section 712(c)(2)(A), he 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 Dr. Carrino to participate in such matters if necessary to afford this Panel essential expertise. For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Carrino that would allow him to participate fully in the matter described because his participation is necessary to afford the Panel essential expertise.

Dr. Carrino is an Associate Professor of Radiology and Orthopedic Surgery at Johns Hopkins University School of Medicine. He is also Section Chief, Musculoskeletal Radiology at The Russell H. Morgan Department of Radiology and Radiological Science, Johns Hopkins Hospital. One of the important topics to be discussed is CAD use with chest computed tomography (CT) images. It is vital that the Panel consists of physicians experienced in chest CT. Dr. Carrino is a renowned radiologist with considerable experience with clinical issues regarding chest CT. His participation is considered essential as he will be the only chest radiologist participating. Over the last three months, the Center's Division of Abdominal, Reproductive and Radiological Devices (DARRD) has contacted over 20 radiologists experienced in chest CT and they were not available. The Center encountered schedule conflicts in its recruitment of chest radiologists because a Thoracic Society Conference is being held during the week of March 3. For the reasons described above, the Center's DARRD believes that Dr. Carrino's participation in the deliberations will contribute to the diversity of opinions and expertise represented on the Panel.

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

Accordingly, I recommend that you grant Dr. Carrino a waiver that would allow his participation in all official matters concerning general issues regarding CAD devices for breast, lung and colon images. I believe that such a waiver is appropriate because in this case, Dr. Carrino's participation is necessary to afford the Panel essential expertise.

DECISION:

Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that voting participation is necessary to afford the Panel essential expertise.

Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that nonvoting participation is necessary to afford the Panel essential expertise.

Waiver denied.

/S/
Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy
Food and Drug Administration

2/12/08
Date