



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: 208(b)(3) 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 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. Carrino 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. 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 or his employer.

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 Radiology 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 potentially could become involved in matters that could affect his financial interests. Under section 208, he 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 Dr. Carrino 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 Dr. Carrino that would allow him to participate fully in the matter described because the need for his services greatly outweighs the conflict of interest created by this financial interest.

First, the issues to be addressed by the Panel are particular matters of general applicability, involving an entire class of products and granting no advantage to any individual manufacturer. Therefore, the Panel recommendations would not be expected to have a significant financial impact on any specific firm.

Second, given the nature of Dr. Carrino's unrelated pending consulting arrangement with [-----], it is unlikely that recommendations of the Panel will impact the viability of this large firm or his ongoing relationship with them.

Third, there are over 20 firms actively pursuing development or marketing of various CAD devices to analyze breast, lung and colon images. The existence of multiple products and firms should help mitigate any appearance of bias on the part of the SGE.

