



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: June 12, 2008

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

THROUGH: Vince Tolino _____ / S /
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

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

FROM: Kathleen L. Walker _____ / S /
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 Dorothy M. Adcock, M.D.

I am writing to request a waiver for Dorothy M. Adcock, M.D., a member of the Hematology and Pathology Devices Panel of the 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 Dorothy M. Adcock, M.D., 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. Because Dr. Adcock 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 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 this 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 the specific issues or problems concerning the safety and effectiveness of devices.

Dr. Adcock has been asked to participate in the July 18, 2008 meeting of the Hematology and Pathology Devices Panel regarding a general discussion of issues relevant to the potential for automated differential cell counters (ADCC's) being waived under the Clinical Laboratory Improvement Amendments. The discussion will include pre-analytical, analytical, and post-analytical issues associated with performing automated hematology complete blood counts and differentials in a waived setting (may include laboratories and point-of-care sites, e.g., nursing home, pharmacy.) Traditionally, ADCC's have limited regulatory clearance for *in-vitro* diagnostic use by the laboratory professional, who has a professional level of education and certification. Manufacturers are requesting that the ADCC be granted waiver status even though the operators at these sites will not have the same professional level of education and certification.

This matter is coming before a meeting of the Hematology and Pathology Devices Panel. This issue is a particular matter of general applicability.

Dr. Adcock has advised the Food and Drug Administration (FDA) that she has a financial interest that could potentially be affected by her participation in the matter described above. She reported an unrelated speaking engagement funded by { redacted }, a manufacturer of differential cell counter devices. For her April 2008 presentation, she received an honorarium of { redacted }. Although she participates on { redacted } speaker's bureau and speaks once a year, she has no contract with the firm.

As a member of the Hematology and Pathology Devices Panel, Dr. Adcock potentially could become involved in matters that could affect her financial interest. 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 Dr. Adcock 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. Adcock that would allow her to participate in the matter described because the need for her 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, there are more than { redacted } firms that manufacture, market or plan to develop the types of cell counter devices to be discussed. The existence of multiple products and firms should help mitigate any appearance of bias on the part of the SGE.

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.

Dr. Adcock is the Laboratory Director and Medical Director at Esoterix Coagulation Laboratory in Englewood, Colorado. Board certified in Anatomic and Clinical Pathology, she has a strong background in both hematology and pathology and is considered a leading expert in coagulation. As a current voting member and chair of the Panel and one who served as a member in the past, Dr. Adcock brings regulatory knowledge and critical reasoning to the discussion. As a laboratory director, Dr. Adcock is responsible for determining laboratory instrument testing performance and knows the importance of correct test results as well as the significance of incorrect results. She is knowledgeable regarding all laboratory instruments and particularly the automated differential cell counter. She will add an insightful dimension to the Panel discussion on the appropriateness of granting a waiver application to automated differential cell counters. There are two other hematologists selected for this panel meeting, however, unlike Dr. Adcock, they do not have the valuable experience of a laboratory director. A search was done of the SGEs on all of the diagnostic device panels but no one with Dr. Adcock's experience was found. The search was limited to the *in vitro* diagnostic device panels because of the uniqueness of the devices under discussion. In that search only two other SGEs were reviewed for participation, however, they were not sufficiently qualified. I believe that participation by Dr. Adcock in the Panel's deliberations will contribute to the diversity of opinions and expertise represented on the Panel.

Accordingly, I recommend that you grant Dr. Adcock a waiver that would allow her to participate in all official matters concerning issues relevant to the potential for automated differential cell counters being waived under the Clinical Laboratory Improvement Amendments. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Adcock outweighs the potential for a conflict of interest created by the financial interest attributed to her.

