



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: February 22, 2008

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

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

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

FROM: William Freas, Ph.D. _____
Director, Division of Scientific Advisors and Consultants
Center for Biologics Evaluation and Research

SUBJECT: 208(b)(3) Conflict of Interest Waiver for Mark Ballow, M.D.

I am writing to request a waiver for Dr. Mark Ballow, a member of the Blood Products 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. Mark Ballow 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. Ballow 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 Blood Products Advisory Committee, as stated in its Charter, is to advise the Commissioner of the Food and Drug Administration in discharging responsibilities as they relate to assuring safe and effective biological products for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

Dr. Ballow has been asked to participate in the May 1-2, 2008 Blood Products Advisory Committee meeting. For Topic 2, the Committee will discuss, review and make recommendations on Lev Pharmaceutical's plasma derived C1 Esterase inhibitor for use in hereditary angioedema.

This matter is coming before a meeting of the Blood Products Advisory Committee. Topic 2 is a particular matter involving specific parties (product discussion).

Dr. Ballow has advised the Food and Drug Administration (FDA) that he has a financial interest that could potentially be affected by his participation in the matter described above. Dr. Ballow is a consultant for [REDACTED]. He is a member of their Advisory Council. Dr. Ballow received [REDACTED] for his service as a consultant from March 2007 to present. Dr. Ballow indicated that his services are unrelated to the discussion of Lev Pharmaceutical's plasma derived C1 esterase inhibitor for use in hereditary angioedema.

As a member of the Blood Products Advisory Committee, Dr. Ballow 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. Ballow 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. Ballow that would allow him to participate in the matter described because the need for his services greatly outweighs the conflict of interest created by this financial interest.

First, Dr. Ballow is a standing member of the Blood Products Advisory Committee (BPAC), whose membership began February 2, 2006. His presence at this meeting will provide continuity and will add historical relevance for future BPAC meetings on similar topics.

Second, the waiver is also justified because the Committee has a special need for Dr. Ballow's service because of his unique expertise, experience, and viewpoints with respect to the issue before the Committee. Dr. Ballow is Chief of the Division of Allergy and Immunology, Department of Pediatrics, State University of New York. He is board certified in pediatrics, allergy, immunology and clinical laboratory immunology. He is the only standing member with this combination of specialized expertise. His clinical immunology expertise will contribute to the BPAC discussion. Additionally, since he is a standing member of the Blood Products Advisory Committee, his participation is vital to the continuity of discussions within all of the advisory committee meetings.

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.

