



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: 712(c)(2)(B) 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 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 "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 Dr. Ballow 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. 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.

The function of the Blood Products Advisory Committee is, 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 use of blood and products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human disease.

Dr. Ballow has been asked to participate in the May 2, 2008 meeting of the Blood Products Advisory Committee meeting. Topic 2, the Committee will discuss, review, and make recommendations on Lev Pharmaceuticals' plasma derived C1 esterase inhibitor.

This matter is coming before a meeting of the Blood Products Committee. This issue is a particular matter involving specific parties.

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 reported he is a consultant for [REDACTED]. He 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.

As a member of the Blood Products Advisory Committee, Dr. Ballow 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. Ballow 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 Dr. Ballow that would allow him to participate fully in the matter described because his voting participation is necessary to afford the committee essential expertise.

First, the waiver is 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. His clinical immunology expertise will contribute to the Blood Products Advisory Committee discussion. Additionally, since he is a standing member of the BPAC, his participation is vital to the continuity of discussions within all of the advisory committee meetings.

As indicated above, Dr. Ballow's credentials are substantial in the field of clinical immunology and allergy. It is his unique knowledge in hereditary angioedema (HAE) that will be especially important in the discussion of Lev Pharmaceutical's C1 esterase inhibitor product that will be used in treatment of this indication.

Besides the importance of having Dr. Ballow attend the May 2, 2008 Blood Products Advisory Committee meeting as a seated member of the Committee, the Office of Blood Research and Review needed additional expertise in the field of hereditary angioedema. They, therefore sought

