



DATE: August 11, 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 /
Director, Advisory Committee Oversight and Management Staff
Office of Policy, Planning, and Preparedness

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

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

I am writing to request a waiver for Dr. John Modlin, a member of the Vaccines and Related Biological 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. John Modlin, 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. Modlin 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 Vaccines and Related Biological 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. Modlin has been asked to participate in the September 25, 2008 Vaccines and Related Biological Products Advisory Committee meeting. The Committee will discuss the use of MDCK Cells for manufacture of Live Influenza Vaccines.

This matter is coming before a meeting of the Vaccines and Related Biological Products Advisory Committee. This is a particular matter involving specific parties.

Dr. Modlin has advised the Food and Drug Administration (FDA) that he has financial interests that could potentially be affected by his participation in the matters described above. Dr. Modlin is a member of the Data Safety Monitoring Board with [REDACTED]. He received [REDACTED] in August 2007.

As a member of the Vaccines and Related Biological Products Advisory Committee, Dr. Modlin 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. Modlin 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. Modlin 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. Modlin is a standing member of the Vaccines and Related Biological Products Advisory Committee (VRBPAC), whose membership began in November 2005. He is a committed VRBPAC committee member. His presence at this meeting will provide continuity and will add historical relevance for future VRBPAC meetings on similar topics.

Second, the waiver is also justified because the Committee has a special need for Dr. Modlin's service because of his unique expertise, experience, and viewpoints with respect to the issue before the Committee. Dr. Modlin is Professor of Pediatrics, Dartmouth-Hitchcock Medical Center. He is a pediatrician and virologist, with expertise in pediatric virology, and is a leading childhood infectious diseases expert. Dr. Modlin has participated in past VRBPAC meetings on similar topics and will add historical perspective regarding committee viewpoints. Additionally, the manufacture of a Live Influenza Vaccine using MDCK cells would have a significant impact on the pediatric population. Dr. Modlin's expertise in pediatric virology will add relevant discussion to the topic.

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

