



DATE: January 2, 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: 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 February 20-21, 2008 Vaccines and Related Biological Products Advisory Committee meeting. Topic 1, the Committee will discuss and make recommendations on the safety and efficacy of a Rotavirus vaccine, manufactured by GlaxoSmithKline. Topic 2, the Committee will discuss strain selection for influenza virus vaccine for the 2008 - 2009 season. Topic 3, the Committee will discuss clinical development of influenza vaccines for pre-pandemic uses.

These matters are coming before an advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee. Topic 1 is a particular matter involving specific parties. Topic 2 and Topic 3 are particular matters of general applicability.

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 consultant for [REDACTED]. He is Chair of the Data Safety Monitoring Board on Human Papillomavirus on Clinical Trials. He has received no remuneration. The consulting is unrelated to the topics. Dr. Modlin is also a member of the Data Safety Monitoring Board with [REDACTED] on [REDACTED]. He received [REDACTED] on 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 would bring important perspective to the Committee discussions.

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. Modlin is a pediatrician with expertise focusing on viral vaccines and virology. Since the topics before the Committee include an influenza vaccine that will be administered to the pediatric population and a pediatric rotavirus vaccine, I believe Dr. Modlin's participation will contribute to the diversity of expertise and viewpoints represented and will help provide a foundation for developing advice and recommendations that are fair and comprehensive. In addition, Dr. Modlin has experience chairing the VRBPAC Advisory Committee, and has been asked to Chair the February 20-21, 2008 meeting because of the current vacancy of the VRBPAC Chair. Current additional VRBPAC Committee members are either new to the Committee or have no experience in the Chair role. Because Dr. Modlin is an appointed standing member of this Committee providing required expertise and contributing to the balance of points of view, equitable geographic distribution and diversity of the Committee in accordance with FACA, a replacement for Dr. Modlin was not sought.

For these reasons, I believe that participation by Dr. Modlin in the committee's deliberations will contribute to the diversity of opinions and expertise represented on the committee.

Accordingly, I recommend that you grant Dr. John Modlin, a waiver that would allow him to participate in all official matters concerning the safety and efficacy of Rotarix, the 2008 - 2009 influenza virus vaccine strain selection, and influenza vaccines for pre-pandemic uses. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Modlin outweighs the potential for a conflict of interest created by the financial interest attributed to him.

DECISION:

Waiver granted based on my determination, made in accordance with section 208(b)(3), that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest attributable to the individual.

Waiver denied.

1/5/
Randall W. Luter, Ph.D.
Deputy Commissioner for Policy
Food and Drug Administration

1/24/08
Date