



MEMORANDUM DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE : January 9, 2007

FROM : William Freas, Ph.D. William Freas
Director, Division of Scientific Advisors and
Consultants

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

TO : Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

Through: Vince Tolino
Director, Ethics and Integrity Staff
Office of Management Programs, OM

I am writing to request a waiver for John Modlin, M.D., a member of the Vaccines and Related Biological Products Advisory Committee at the February 27-28, 2007 meeting, from conflict of interest prohibitions of 18 U.S.C. 208(a). The Committee will hear and make recommendations on the safety and immunogenicity of an H5N1 Inactivated Influenza Vaccine, manufactured by Sanofi Pasteur. This is a particular matter involving specific parties. Topic 2, the Committee will discuss pandemic influenza vaccine strategies/clinical development of pandemic influenza vaccines. This is a particular matter of general applicability. Topic 3, the Committee will discuss and make recommendations on the selection of strains to be included in the influenza virus vaccine for the 2007 - 2008 season. This is a particular matter of general applicability. Topic 4, the Committee will discuss influenza B Strain - discussion on circulating lineages. This is a particular matter of general applicability. 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. Because you are the appointing official, you have the authority to grant Dr. 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, to his knowledge, the employee, his spouse, minor children, or general partner; an organization in which he is serving as officer, director, trustee, general partner, or employee, or a person or organization with which he is negotiating for or has arrangement concerning prospective employment has a financial interest. Dr. Modlin is a special Government employee and 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 to his employer.

The function of the 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.

The Committee is scheduled to meet on February 27-28, 2007. The Committee will hear and make recommendations on the safety and immunogenicity of an H5N1 Inactivated Influenza Vaccine. Topic 2, the Committee will discuss pandemic influenza vaccine strategies/ clinical development of pandemic influenza vaccines. Topic 3, the Committee will discuss and make recommendations on the selection of strains to be included in the influenza virus vaccine for the 2007 - 2008 season. Topic 4, the Committee will discuss influenza B Strain - discussion on circulating lineages.

Dr. John Modlin has advised the FDA that he has a financial interest related to the above topics that could potentially be affected by his participation in the matter at issue. Dr. Modlin has reported that he consults with [REDACTED]. He is a member of the Data Safety Monitoring Board for [REDACTED]. According to Dr. Modlin, his consulting is unrelated to the matter coming before the Committee. He reported in the past he received [REDACTED] in consulting fees between 2002 and 2005. No payments were received in 2006.

Under 18 U.S.C. 208, Dr. Modlin is prohibited from participating in any matter affecting this interest, unless he receives a waiver. However, as noted above, you have the authority under 18 U.S.C. 208(b)(3) to grant a waiver.

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 discussions before the Committee.

First, Dr. Modlin is a standing member of the Vaccines and Related Biological Products Advisory Committee (VRBPAC), whose membership began in November 2005. He has attended one previous VRBPAC meeting on influenza. 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 an esteemed pediatrician, virologist, and has research interests in viral vaccines and immunizations. Dr. Modlin would bring important perspective to the Committee discussions.

Further, 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 various advisory committee members and Dr. Modlin's participation will contribute to the balance of views represented and the diversity of opinions and expertise. 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's research focuses on viral vaccines and immunizations. Since the topics before the Committee include influenza vaccines and influenza strains, 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.

For these reasons, I believe that Dr. Modlin's participation in the deliberations of the advisory committee will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant John Modlin, M.D., a waiver that would allow him to participate in the discussions before the February 27-28, 2007 meeting. I believe that such a waiver is

