



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

DATE : December 1, 2006

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 January 25, 2007 meeting, from conflict of interest prohibitions of 18 U.S.C. 208(a). The Committee will hear and discuss the safety and immunogenicity of a DTaP-IPV-Hib Vaccine, Pentacel, manufactured by Sanofi Pasteur Canada. This is a particular matter involving specific parties. 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 January 25, 2007. The Committee will hear and discuss the safety and immunogenicity of a DTaP-IPV-Hib Vaccine, Pentacel. The vaccine will protect infants and young children against Diphtheria, Tetanus, Pertussis, and Hib.

Dr. John Modlin has advised the FDA that he has a financial interest related to Pentacel 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] vaccine. 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 a member of numerous professional societies such as the American Pediatric Society.

Dr. Modlin has participated in several national research committees and policy conferences concerning pediatric infectious diseases. Dr.





