



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

DATE : March 23, 2007

FROM : William Freas, Ph.D. /s/
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 May 16-17, 2007 meeting, from conflict of interest prohibitions of 18 U.S.C. 208(a). The Committee will discuss and make recommendations on the safety and effectiveness of FluMist in a pediatric population less than 59 months of age. Topic 2, Overview of Laboratory of Bacterial Polysaccharides and Laboratory of Enteric and Sexually Transmitted Diseases, Division of Bacterial Parasitic and Allergenic Products, Office of Vaccines Research and Review. This discussion does not require conflict of interest screening. Topic 3, the Committee will discuss and make recommendations on the safety and effectiveness on ACAM2000 (live vaccinia virus smallpox vaccine) percutaneous scarification. 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 May 16-17, 2007. The Committee will discuss and make recommendations on the safety and effectiveness of FluMist in a pediatric population less than 59 months of age. This is a particular matter involving specific parties. Topic 3, the Committee will discuss and make recommendations on the safety and effectiveness on ACAM2000 (live vaccinia virus smallpox vaccine) percutaneous scarification. This is a particular matter involving specific parties.

Dr. John Modlin has advised the FDA that he has a financial interest related to Topic 1 that could potentially be affected by his participation in the matter at issue. Dr. Modlin has reported that he is a member [REDACTED] Data Safety Monitoring Board for [REDACTED]. According to Dr. Modlin, his consulting is unrelated to the matter coming before the Committee. He receives no remuneration in 2006. Dr. Modlin has also reported he is a member of [REDACTED] Data Safety Monitoring Board is for [REDACTED]. This is also unrelated to the matter before the Committee. He received no remuneration in 2006.

Under 18 U.S.C. 208, Dr. Modlin is prohibited from participating in any matter affecting these interests, 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 an 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. 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.

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.

