



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 Lisa Jackson, M.D., M.P.H.

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 Lisa Jackson, M.D., M.P.H., 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. Jackson 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 her knowledge, the employee, her spouse, minor children, or general partner; an organization in which she is serving as officer, director, trustee, general partner, or employee, or a person or organization with which she is negotiating for or has arrangement concerning prospective employment has a financial interest. Dr. Jackson 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 her or to her employer.

The function of the Committee, as stated in its Charter, is to advise the Commissioner of the Food and Drug Administration in

Associate Commissioner for Policy and Planning

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. Jackson has advised the FDA that she has a financial interest related to Pentacel that could potentially be affected by her participation in the matter at issue. Dr. Jackson has reported that she could possibly consult for [REDACTED] vaccine. According to Dr. Jackson, her consulting is unrelated to the matter coming before the Committee. The consulting is under negotiation for January 1, 2007 to January 31, 2007. Dr. Jackson also reported that, through her employer, the Center for Health Studies Group Health Cooperative, she has a contract with [REDACTED] on Influenza Vaccine. The Center receives [REDACTED] from August 2006 to July 2007. The contract is unrelated to the topics before the Committee. Arguably, Dr. Jackson's current contract activities do not constitute financial interests in the particular matter within the meaning of 18 U.S.C. § 208(a), because this contract is unrelated to Pentacel and its competing products. Nevertheless, in the utmost of caution, I have included this financial interest in this waiver.

Under 18 U.S.C. 208, Dr. Jackson is prohibited from participating in any matter affecting this interest, unless she 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. Jackson that would allow her to participate in the discussions before the Committee.

First, Dr. Jackson is a standing member of the Vaccines and Related Biological Products Advisory Committee (VRBPAC), whose membership began in May 2006. She has attended one previous VRBPAC meeting. Her 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. Jackson's service because of her unique expertise, experience, and viewpoints with respect to the issue before the Committee. Dr. Jackson is Senior Scientific Investigator, Center for Health Studies at Group Health Cooperative. She is an established investigator and specialist in epidemiology and infectious diseases. Dr. Jackson is an internist and infectious

Associate Commissioner for Policy and Planning

disease epidemiologist with research interests in evaluations of vaccine safety and effectiveness and the epidemiology of vaccine preventable diseases.

Dr. Jackson has participated in several national research committees and policy conferences concerning pediatric infectious diseases and has consulted previously on the VRBPAC Committee. Dr. Jackson 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. Jackson'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. Jackson's research focuses on the evaluation of vaccine safety and effectiveness and the epidemiology of vaccine preventable diseases. Since Pentacel is a vaccine intended for use in infants and young children, I believe Dr. Jackson'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. Jackson'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 Lisa Jackson, M.D., M.P.H., a waiver that would allow her to participate in the discussions before the January 25, 2007 meeting. I believe that such a waiver is appropriate because, in this case, the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest attributable to the individual.

Associate Commissioner for Policy and Planning

CONCURRENCE:

/s/
Vince Tolino
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

12/27/06
Date

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.

/s/
Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

12/27/06
Date

