



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 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 May 16-17, 2007 meeting, from conflict of interest prohibitions of 18 U.S.C. 208(a). For Topic 1, the Committee will discuss and make recommendations on the safety and effectiveness of FluMist in a pediatric population less than 59 months of age, manufactured by MedImmune. This is a particular matter involving specific parties. 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, manufactured by Acambis, Inc. 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 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. For Topic 1, 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. For Topic 3, the Committee will discuss and make recommendations on the safety and effectiveness of ACAM2000 (live vaccinia virus smallpox vaccine) percutaneous scarification, manufactured by Acambis, Inc. This is a particular matter involving specific parties.

Dr. Jackson has advised the FDA that she has a financial interest related to the above topics that could potentially be affected by her participation in the matter at issue. Dr. Jackson has reported that she could possibly consult for [REDACTED] on [REDACTED]. According to Dr. Jackson, her consulting is unrelated to the matter coming before the Committee. The consulting is scheduled for 5/23/07-5/24/07 and is still being negotiated. She expects to receive [REDACTED] for her services. Dr. Jackson is a member of the Data Safety Monitoring Board for [REDACTED] on [REDACTED]. To date she has received [REDACTED]. In addition, Dr. Jackson has a research contract with [REDACTED] on seasonal influenza flu vaccine. Her institution receives [REDACTED] per year. Dr. Jackson does not receive any personal remuneration.

In addition, Dr. Jackson reported that she is the Site PI on an unrelated research contract awarded by [REDACTED] to study [REDACTED]. Her institution receives [REDACTED] per year from January 2007 to December 2008. She receives no personal remuneration. Also, Dr. Jackson is the Site PI on an unrelated research contract awarded by [REDACTED] to study [REDACTED]. Her institution receives [REDACTED] per year from March 2007 to July 2008. She receives no personal remuneration. Arguably, these interests do not constitute a financial interest in the matter under 18 U.S.C. §208(a). Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

Under 18 U.S.C. 208, Dr. Jackson is prohibited from participating in any matter affecting these interests, 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 three previous VRBPAC meetings. Her presence at this meeting will provide continuity and will add historical relevance for future VRBPAC meetings on similar topics. Because Dr. Jackson 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. Jackson was not sought.

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 infectious diseases. Dr. Jackson is an internist and infectious 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. 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.

Acknowledgment and Consent for Disclosure of Potential Conflict(s) of Interest and Waivers under 18 U.S.C. §208(b)(3) and 21 U.S.C. §355(n)(4)

Name of Participant: Lisa Jackson, M.D., M.P.H.

Committee: Vaccines and Related Biological Products Advisory Committee

Meeting Date: May 16-17, 2007

I acknowledge that contingent upon public disclosure of the following financial interest listed below related to the review of the safety and effectiveness of FluMist in a pediatric population less than 59 months of age, manufactured by MedImmune, also the safety and effectiveness of ACAM2000 (live vaccinia virus smallpox vaccine) percutaneous scarification, manufactured by Acambis. I am eligible to receive waivers under 18 U.S.C. §208(b)(3) and 21 U.S.C. §355(n)(4).

<u>Type of Interest</u>	<u>Nature</u>	<u>Magnitude</u>
Pending Consulting (unrelated)	Competing Firm	Less than \$10,000
Research Contract (related)	Competing Firm	More than \$300,000
Consulting (related)	Competing Firm	Less than \$10,000

I hereby request that FDA make this information publicly available on my behalf. I understand that without public disclosure of the interests the waiver is not valid.

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

4/15/07
Date