



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 Lawrence Moulton, Ph.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 Lawrence Moulton, Ph.D., a consultant of the Vaccines and Related Biological Products Advisory Committee at the May 16, 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. 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. 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. Moulton 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. Moulton 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.

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Associate Commissioner for Policy and Planning

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, 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.

Dr. Lawrence Moulton has advised the FDA that he has a financial interest related to the above topic that could potentially be affected by his participation in the matter at issue. Dr. Moulton is a member of NIAID's Data Safety Monitoring Board on infectious diseases and new vaccines. He received approximately [REDACTED] in 2005 and [REDACTED] in 2006. In addition, Dr. Moulton reported that he is a statistician on an unrelated research contract supported by [REDACTED] to study [REDACTED]. His institution receives [REDACTED] per year from 2004-2007. Dr. Moulton receives [REDACTED] of his salary from this research contract. Arguably, this interest does 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. Moulton 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. Moulton that would allow him to participate in the discussions before the Committee.

The waiver is justified because the Committee has a special need for Dr. Moulton's service because of his unique expertise, experience, and viewpoints with respect to the issue before the Committee. Dr. Moulton is Professor, Department of International Health, Johns Hopkins University School of Public Health. He is a biostatistician working primarily on infectious diseases around the world with vaccines as a major area of application. Dr. Moulton would bring important perspective to the Committee discussions. In an effort to have sufficient expertise and balance for topic discussion, a decision was made to invite an additional statistician. Two biostatisticians were discussed as possibilities. Dr. Moulton's work focuses primarily on vaccines as a major portion of his worldwide infectious disease background. Additionally, Dr. Moulton was available to attend the meeting. Therefore, a decision was made to invite Dr. Moulton over another possible attendee.

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. Moulton's participation will

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: Lawrence Moulton, Ph.D.

Committee: Vaccines and Related Biological Products Advisory Committee

Meeting Date: May 16, 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, 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>
Consulting (unrelated)	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.

/s/
Lawrence Moulton, Ph.D.

4/23/07
Date