

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. Stapleton 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 of ACAM2000 (live vaccinia virus smallpox vaccine) percutaneous scarification, manufactured by Acambis, Inc. This is a particular matter involving specific parties.

Dr. Stapleton has advised the FDA that he has a financial interest related to Topic 3 that could potentially be affected by his participation in the matter at issue. Dr. Stapleton has reported that he has a research grant with [REDACTED] on [REDACTED]. The grant is from 2006 - present. The Institution receives [REDACTED] per year. Dr. Stapleton received no salary support from this grant.

In addition for Topic 1, Dr. Stapleton reported unrelated speaking with [REDACTED] on 3 occasions in 2006 regarding [REDACTED]. He received [REDACTED] for his services. Also for Topic 1, Dr. Stapleton reported a research subcontract award by Baylor through the Vaccine and Treatment Evaluation Unit for a Clinical Trial on H5N1. The Vaccine and Treatment Evaluation Unit funds were awarded by NIAID to Baylor. Dr. Stapleton is the co-investigator for this research subcontract for 187,465 per year from 9/15/05-5/31/07. 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. Stapleton 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. Stapleton that would allow him to participate in the discussions before the Committee.

First, Dr. Stapleton is Professor and Division Director of Infectious Diseases, University of Iowa Hospital Clinic. Dr. Stapleton is a member of the Vaccines and Related Biological Products Advisory Committee (VRBPAC), whose membership began in May 2006. He has attended three previous VRBPAC meetings. His presence at this meeting will provide continuity and will add historical relevance for future VRBPAC meetings on similar topics. Because Dr. Stapleton 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. Stapleton was not sought.

Second, the waiver is also justified because the Committee has a special need for Dr. Stapleton's service because of his unique expertise, experience, and viewpoints with respect to the issue before the Committee. Dr. Stapleton is a leader in virology research with expertise in infectious diseases.

Dr. Stapleton has participated in several national research committees and policy conferences concerning infectious diseases. Dr. Stapleton 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. Stapleton'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. Stapleton's research focuses on the evaluation of virology and infectious diseases. Dr. Stapleton'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. Stapleton's participation in the deliberations of the advisory committee 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: Jack Stapleton, M.D.

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, and the safety and effectiveness of ACAM2000 (live vaccinia virus smallpox vaccine) percutaneous scarification, manufactured by Acambis, Inc., 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>
Grant (related)	Competing Firm	less than \$100,000

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.

JS

Jack Stapleton, M.D.

4/7/07

Date