



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. WJ
Director, Division of Scientific Advisors and
Consultants

SUBJECT: 208(b)(1) Waiver for John Teerlink, 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 Teerlink, M.D., a Center for Drugs Evaluation advisory committee member to participate in the Vaccines and Related Biological Products Advisory Committee at the May 17, 2007 meeting, from conflict of interest prohibitions of 18 U.S.C. 208(a). For Topic 3, the Committee will discuss and make recommendations on the safety and effectiveness of ACAM2000 (live vaccinia virus smallpox vaccine) percutaneous scarification. This is a particular matter involving specific parties. Waivers under Section 208(b)(1) may be granted by the appointing official where "the employee's interest is not so substantial as to be deemed likely to affect the integrity of the services which the government may expect from him, and where the individual has made a disclosure of the financial interests at issue. We have determined that you are the appointing official for purposes of section 208 and have the authority to grant Dr. Teerlink a waiver under Section 208(b)(1).

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, or employee, or a person or organization with which he is negotiating for or has arrangement concerning prospective employment has a financial interest. Dr. Teerlink is under 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 to 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 17, 2007. Topic 3, the Committee will discuss and make recommendations on the safety and effectiveness of ACAM2000 (live vaccinia virus smallpox vaccine) percutaneous scarification. Dr. Teerlink has a financial interest that may be affected by the Committee discussions. Dr. Teerlink is a member of the [REDACTED] for [REDACTED]. Dr. Teerlink is a blinded endpoint reviewer. He receives [REDACTED] per case reviewed and [REDACTED] per face-to-face meeting. In 2006, he received [REDACTED]. He expects to receive [REDACTED] in 2007, and in 2008 he expects to receive [REDACTED]. [REDACTED] is a firm that could be affected by the Committee discussions.

As a consultant to the Vaccines and Related Biological Products Advisory Committee, Dr. Teerlink potentially could become involved in matters that could affect him or his employer's financial interests. Under section 208, he is prohibited from participating in such matters. However, as noted above, you have the authority under 18 U.S.C. 208(b)(1) to grant a waiver permitting him to participate in the Committee proceedings as set out below.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Teerlink that would allow him to participate in the discussions before the Committee on the safety and effectiveness of ACAM2000 (live vaccinia virus smallpox vaccine) percutaneous scarification manufactured by Acambis, Inc.

First, although Dr. Teerlink has a financial interest associated with the Committee discussions on ACAM2000, the interest is unrelated to the topic.

Second, 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 advisory committee. Also, the Committee's intended purposes 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. Teerlink is Director, Heart Failure Clinic, and Director, University of California, San Francisco, San Francisco Veteran's Affairs Medical Center. He is a cardiologist and a current member of CDER's Cardiovascular and Renal Drugs Advisory Committee. He is familiar with advisory committee procedures and his presence at this meeting would add relevant data and objectivity to the topic discussions because of his cardiology expertise. Additionally, there were five other cardiologists invited who were unable to attend.

Acknowledgment and Consent for Disclosure of Potential Conflict(s) of Interest and Waivers
under 18 U.S.C. §208(b)(1) and 21 U.S.C. §355(n)(4)

Name of Participant: John Teerlink, M.D.

Committee: Vaccines and Related Biological Products Advisory Committee

Meeting Date: May 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 ACAM2000 (live vaccinia virus smallpox vaccine) percutaneous scarification, manufactured by Acambis, I am eligible to receive waivers under 18 U.S.C. §208(b)(1) 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.

JS
John Teerlink, M.D.

4/23/07
Date