



**FOOD AND DRUG ADMINISTRATION**  
**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH**

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MEMORANDUM

**DATE:** October 2, 2002

**FROM:** William Freas, Ph.D. Willie Freas  
Chief, Scientific Advisors and Consultants Staff, CBER

**SUBJECT:** Conflict of Interest Waiver for Anastasios A. Tsiatis, Ph.D.

**TO:** Linda Arey Skladany, Esq.  
Senior Associate Commissioner for External Relations  
Food and Drug Administration

**Through:** Jenny Slaughter  
Chief, Ethics and Integrity Branch  
Division of Management Programs, OHRMS

I am writing to request a waiver for Anastasio Tsiatis, Ph.D., a member of the Biological Response Modifiers Advisory Committee at the October 10, 2002 meeting, from conflict of interest prohibitions of 18 U.S.C. 208(a). 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. Tsiatis 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. Tsiatis 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.

2006-42070-06-Tsiatis-208

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Senior Associate Commissioner for External Relations  
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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 October 10, 2002. During the meeting the Committee will be asked to discuss retrovirus vectors in gene therapies for the treatment of patients with severe combined immune deficiency disease.

Dr. Tsiatis consults with [REDACTED] an associate [REDACTED], occasionally on the review of protocols regarding statistical methods. He receives compensation for his consulting. [REDACTED] could be affected by the Committee discussions. In addition, Dr. Tsiatis is the Principal Investigator on an unrelated grant from NCI, is the Principal Investigator on an unrelated grant from NIAID, and serves on the Data Safety Monitoring Board for the AIDS Clinical Trials Group for NIAID. He receives salary support from the NCI and NIAID grants.

Under Section 208, Dr. Tsiatis is prohibited from participating in any matter affecting this interest, 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. Tsiatis that would allow him to participate in the discussions before the Committee. The discussions could affect classes of products and biologics manufacturers. The discussions of the Committee do not involve any product approvals. There are no licensed retrovirus vector gene therapy products for the treatment of severe combined immune deficiency disease. In addition, there is no known direct and predictable effect on Dr. Tsiatis's interest.

The waiver is also justified because the Committee has a special need for Dr. Tsiatis's services because of his unique expertise, experience, and viewpoints with respect to the issue before the Committee. Dr. Tsiatis is Professor in the Department of Statistics, North Carolina State University. Dr. Tsiatis is an expert in statistical methods and biostatistics. He has received numerous awards and honors, and is a member of many professional organizations.

For these reasons, I believe that Dr. Tsiatis's participation in the deliberations of the advisory committee will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

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Senior Associate Commissioner for External Relations  
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According, I recommend that you grant Anastasios Tsiatis, Ph.D., a waiver that would allow him to participate in the discussions before the October 10, 2002, meeting and any other meeting where his interests in NCI, NIAID, and [REDACTED] are unrelated. I believe that such a waiver is appropriate because, in this case, the interests of Dr. Tsiatis are not likely to affect the integrity of the services which the Government may expect from him.

CONCURRENCE: Jenny Slaughter  
Jenny Slaughter  
Chief, Ethics and Integrity Branch  
Division of Management Programs, OHRMS

10/4/02  
Date

DECISION:

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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.  
Linda Arey Skladany  
Linda Arey Skladany, Esq.  
Senior Associate Committee for External Relations  
Food and Drug Administration

10/8/02  
Date