



DEPARTMENT OF HEALTH & HUMAN SERVICES

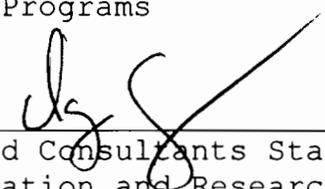
Food and Drug Administration  
Rockville MD 20857

**MEMORANDUM**

**DATE:** March 20, 2006

**TO:** Jason D. Brodsky  
Acting Associate Commissioner  
Office of External Relations  
Food and Drug Administration

**THROUGH:** Jenny Slaughter  
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

**FROM:** Igor Cerny, Pharm.D.   
Director, Advisors and Consultants Staff  
Center for Drug Evaluation and Research

**SUBJECT:** Conflict of Interest Waiver for John R.  
Teerlink, M.D.

I am writing to request a waiver for John R. Teerlink, M.D., a member of Cardiovascular and Renal Drugs Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a). Waivers under section 208(b)(1) may be granted by the appointing official where "the [financial] interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such employee" 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. Therefore, you have the authority to grant John R. Teerlink, M.D., 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 the employee, or any other person whose interests are imputed to the employee under 18 U.S.C. §208, has a financial interest. Since Dr. Teerlink is a full-time Government employee, he is under a statutory obligation to refrain from participating in an official capacity in any particular matter having a direct and predictable effect on a financial interest attributable to him, his spouse, minor child, or general partner; an organization or entity for which he serves as an officer, director, trustee, general partner, or employee; and, a person with whom he is negotiating for, or has an arrangement concerning, prospective employment.

The function of the Cardiovascular and Renal Drugs Advisory Committee, as stated in its Charter, is to review and evaluate available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders and to make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Teerlink has been asked to participate in the discussion of the Agency's draft recommendations for re-labeling of anti-hypertensive drugs for outcome claims, as a follow-up to the committee's meeting on June 15, 2005, where the committee discussed class labeling of antihypertensive drugs based on the proximity of their data to outcome trials. The discussion will not focus on any particular product or firm and is a particular matter of general applicability.

Dr. Teerlink has advised the Food and Drug Administration that he has financial interests which could potentially be affected by his participation in the matter described above. **Dr. Teerlink provides independent and blinded adjudication of cardiovascular events and information to the Data Safety Monitoring Board for \_\_\_\_\_ in prostate cancer study. He also assists \_\_\_\_\_ in a product development program for \_\_\_\_\_, a \_\_\_\_\_, for the treatment of heart failure. \_\_\_\_\_ and \_\_\_\_\_ are both unrelated to the issue coming before the committee.**

**In addition, Dr. Teerlink serves as an Endpoint Reviewer for the \_\_\_\_\_ clinical trial, sponsored by \_\_\_\_\_ to evaluate the efficacy of \_\_\_\_\_, an affected antihypertensive drug, for an unrelated indication, \_\_\_\_\_.**

As a member of Cardiovascular and Renal Drugs Advisory Committee, Dr. Teerlink potentially could become involved in matters that could affect his financial interests. Under 18 U.S.C. §208(a), 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 Dr. Teerlink to participate in such matters as you deem appropriate.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Teerlink that would permit him to participate in the matter described above.

**First, arguably, Dr. Teerlink's interests do not constitute financial interests in the particular matter within the meaning of 18 U.S.C. §208(a). I nevertheless recommend that this waiver be granted.**

**Second, considering that Dr. Teerlink is one of the experts in the area of endothelin receptor antagonists and treatment of heart failure and his advice is sought by regulated industry and government alike, it seems unlikely that \_\_\_\_\_ would terminate their consulting contracts or be less likely, in the future, to retain the services of an expert such as Dr. Teerlink.**

Lastly, 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 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. Teerlink is Director of the Heart Failure Clinic and Director of Clinical echocardiography at the San Francisco Veterans Administration Medical Center. He is also Associate Professor of Medicine at the University of California, San Francisco. He is board certified in internal medicine and cardiovascular medicine. Dr. Teerlink's clinical research interests include the study of the pathogenesis and therapy of heart failure on both an experimental and clinical level. Dr. Teerlink has served as a principal investigator for a multi-center international acute heart failure trial and is active in multiple chronic heart failure therapeutics development programs. He is a member of several prestigious medical societies including the American College of Physicians, the American Heart Association and the American College of Cardiology. He has given numerous national and international presentations,

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and has published extensively on various cardiology issues, such as acute heart failure and acute coronary syndrome. I believe that Dr. Teerlink will bring an enormous amount of experience and knowledge that is essential to the committee's discussions and his participation will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant John R. Teerlink, M.D., a waiver that will permit him to participate in all official matters concerning class labeling of antihypertensive drugs based on the proximity of their data to outcome trials. I believe that in this case, Dr. Teerlink's financial interests are not so substantial as to be deemed likely to affect the integrity of the services that the Government may expect from him.

CONCURRENCE:

  
\_\_\_\_\_  
Jenny Slaughter  
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

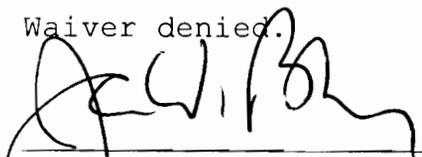
3/1/06  
Date

DECISION:

  
\_\_\_\_\_

Waiver granted based on my determination, made in accordance with section 18 U.S.C. §208(b)(1), that the interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such employee.

\_\_\_\_\_ Waiver denied.

  
\_\_\_\_\_  
Jason D. Brodsky  
Acting Associate Commissioner  
Office of External Relations  
Food and Drug Administration

3.28.06  
Date