



**MEMORANDUM**  
**DEPARTMENT OF HEALTH & HUMAN SERVICES**  
**Public Health Service**  
**Food and Drug Administration**  
**Center for Biologics Evaluation and Research**

**DATE** : December 14, 2005

**FROM** : William Freas, Ph.D. 2/17  
Director, Scientific Advisors & Consultants, CBER

**SUBJECT** : Conflict of Interest Waiver for  
Jeffrey S. Chamberlain, Ph.D.

**TO** : Sheila Dearybury Walcoff, Esq.  
Associate Commissioner for External Relations  
Food and Drug Administration

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

I am writing to request a waiver for Jeffrey S. Chamberlain, Ph.D., a member of the Cellular, Tissue and Gene Therapies Advisory Committee, from the 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. Chamberlain 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. Because Dr. Chamberlain is a special Government employee, he 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.

2006-4207W-01-chamberlain-208

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 will meet to discuss the following issues: 1) Potency for Cellular, Tissue and Gene Transfer Products; 2) National Toxicology Program on Retroviral Mutagenesis; and 3) the Report of the Review of Research Programs in the Office of Cellular, Tissue and Gene Therapies.

Dr. Chamberlain reported that he has [REDACTED] patents [REDACTED] for adenoviral vectors and for mini-dystrophy clones. He also reported that he has a patent [REDACTED] for a multiplex PCR a technique to diagnose muscular dystrophy. Dr. Chamberlain receives no remuneration. These patents are unrelated to the discussions.

Under section 208, Dr. Chamberlain 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. Chamberlain 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. Chamberlain's services because of his unique expertise, experience and viewpoint with respect to the issue before the Committee. Dr. Chamberlain is a Professor, Department of Neurobiology, Medicine and Biochemistry, Health Sciences Center, University of Washington School of Medicine, Seattle, Washington.

Dr. Chamberlain's areas of interest are in gene therapy, especially vector modification for delivery to muscle, muscle disease therapy, and muscular dystrophy. His research is focused on understanding and developing treatments for muscular dystrophies, specifically Duchenne dystrophy (DMD). Dr. Chamberlain's other areas of interest involves the development of viral vectors to deliver dystrophic genes to human muscle for gene therapy of DMD and adenoviral vectors. He serves on several scientific boards as an ad hoc reviewer. He has also published numerous articles, reviews, book chapters, and books. The Committee discussions will benefit from Dr. Chamberlain's unique experience and viewpoints with respect to the issues before the Committee. Dr. Chamberlain's expertise is

sequence characterization of gene transfer products and potential long-term effects of vector classes in gene therapy trials will be invaluable to the Committee discussions.

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

Accordingly, I recommend that you grant Jeffrey S. Chamberlain, Ph.D. a waiver that would allow him to participate in any Committee discussions where these interests are waivable. I believe that such a waiver is appropriate because, in this case, the need for the services of Dr. Chamberlain outweighs the potential for a conflict of interest created by his financial interests.

CONCURRENCE:

1/5/06  
Jenny Slaughter  
Director, Ethics and Integrity Staff  
Division of Management Programs, OM

1/10/06  
Date

DECISION:

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.

1/5/06  
Sheila Dearybury Walcoff, Esq.  
Associate Commissioner for External  
Relations, FDA

1-17-06  
Date