



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

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MEMORANDUM

DATE: February 12, 2007

FROM: William Freas, Ph.D. 5  
Director, Division of Scientific Advisors and Consultants, CBER

SUBJECT: 208(b)(3) Conflict of Interest Waiver for Mary M. Horowitz, M.D.

TO: Randall Lutter, Ph.D.  
Associate Commissioner for Policy and Planning

Through: Vince Tolino  
Director, Ethics and Integrity Staff  
Division of Management Programs, OM

I am writing to request a waiver for Mary M. Horowitz, M.D., a consultant of the Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAC) at the March 30, 2007 CTGTAC meeting, from conflict of interest prohibitions of 18 U.S.C. 208(a). The Committee will discuss: (1) Guidance to Industry for licensure of minimally manipulated unrelated placental/umbilical cord blood products (Topic 3), and (2) scientific issues regarding minimally manipulated unrelated allogeneic peripheral blood stem cells (Topic 4). Both topics are a particular matter of general applicability. 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. Horowitz 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 her knowledge, the employee, her spouse, minor children, or general partner; an organization in which she is serving as officer, director, trustee, general partner, or employee, or a person or organization with which she is negotiating for or has arrangement concerning prospective employment has a financial interest. Dr. Horowitz 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 her or to her 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.

Dr. Horowitz advised the FDA that she has a financial interest related to the above stated topics that could potentially be affected by her participation in the matters at issue. Dr. Horowitz reported that she consults with three affected firms: [REDACTED], [REDACTED], as part of her official duties with the Center for International Blood and Marrow Transplant Research (IBMTR), Data Coordinating Center. Her consulting is unrelated to the topics. She receives [REDACTED] per year from October 1, 2006-September 30, 2007 from [REDACTED]; [REDACTED] per year from April 1, 2006-March 31, 2007 from [REDACTED] and [REDACTED] from February 1, 2007-January 1, 2008 from [REDACTED].

Under Section 208, Dr. Horowitz is prohibited from participating in any matter affecting these interests, unless she 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. Horowitz that would allow her to participate in the discussions before the Committee:

Dr. Mary H. Horowitz is Scientific Director of the International Bone Marrow Transplant Registry and Professor of Medicine, Medical College of Wisconsin. She is a central figure in both national and international transplant circles. The IBMTR enjoys wide respect as an impartial source of data on both autologous and allogeneic cord blood transplants. Transplant and processing centers all over the U.S. participate in the data collection efforts. Due to her position with the IBMTR, Dr. Horowitz is an invaluable and unique source of up to date data and activity in the field of cord blood transplantation and her participation is critical for the committee discussion of processing standards for cord blood establishments. The pool of other individuals with expertise in the IBMTR related to cord blood transplantation is very small. One other individual with comparable expertise from the National Marrow Donor Program was identified and determined to have a greater conflict of interest.

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

