FOOD AND DRUG ADMINISTRATION

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

MEMORANDUM

DATE: February 5, 2007

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

SUBJECT: 208(b)(3) Conflict of Interest Waiver for Howard I. Scher, 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 from conflict of interest prohibitions of 18 U.S.C. 208(a) for Howard I. Scher, M.D., a special Government employee for the Center for Drug Evaluation and Research. Dr. Scher was invited to participate as a consultant at the Cellular, Tissue and Gene Therapies Advisory Committee meeting on March 29, 2007. The Committee will discuss and make recommendations on issues related to Sipuleucel-T, Dendreon Corp., indicated for the treatment of men with asymptomatic metastatic hormone refractory prostate cancer. This is a particular matter involving specific parties. 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. Scher 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. Scher 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.

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. Scher advised the FDA that he has a financial interest related to the above topic that could potentially be affected by his participation in the matter at issue. Dr. Scher reported that he has joint stock in [redacted] at a current value of [redacted] Additionally he reported that his institution has a grant from [redacted] (competing firm). The grant is current and his institution receives [redacted] per year from 2006-2007. Dr. Scher receives no salary from the grant. The grant is to study a licensed, approved drug ([redacted]) in prostate cancer trials. [redacted] is a licensed drug currently used in other cancer therapies. Dr. Scher also reported that his institution has a grant from [redacted] (competing firm). The grant is current and his institution receives [redacted] per year from 2006-2008. Dr. Scher receives no salary from the grant. The grant is to study an investigational drug ([redacted]) that is also being studied in several types of cancer. It is unlikely that Dr. Scher's participation in the discussions on March 29 of a cellular therapy for prostate cancer will have a direct and predictable effect on his financial interest.

Under Section 208, Dr. Scher 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. Scher that would allow him to participate in the discussions before the Committee.

The Committee has a special need for Dr. Scher's services because of his expertise as a practicing clinician with extensive experience in prostate cancer clinical trials. Dr. Scher is the D. Wayne Calloway Chair in Urologic Oncology, Chief, Genitourinary Oncology Services, Department of Medicine, Sidney Kimmel Center for Prostate Cancer Center, Memorial Sloan-Kettering Cancer Center. The committee has a critical need for prostate cancer clinical trial expertise to assist the committee in the evaluation of appropriate clinical trial end points for a novel prostate cancer cellular therapy. Dr. Scher has been involved in a national effort to define guidelines for patient participation in studies for the treatment of prostate cancer patients who have relapsed. His experience in evaluating patient eligibility and outcome criteria are crucial to the committee discussions of product efficacy. Additionally, Dr. Scher has prior FDA advisory committee experience as a consultant of the Oncology Drugs Advisory Committee and understands the FDA mission to move new therapies forward at the same time protecting the welfare of patients. His expertise and perspective are critical. Nine other special Government employees and members of the Oncology Drugs Advisory Committee with related oncology expertise were considered. Five did not have equivalent expertise, two were determined to have equal or greater conflicts of interest and two were unavailable.

Accordingly, I recommend that you grant Howard I. Scher, M.D., a waiver that would allow him to participate in the discussions before the Committee on March 29, 2007. I believe that such a waiver is appropriate because, in this case, the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest attributable to the individual.

CONCURRENCE: /s/ 2/26/07

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

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.

/s/ 3/8/07

Randall Lutter, Ph.D.
Associate Committee for Policy and Planning

Date

Acknowledgment and Consent for Disclosure of Potential Conflict(s) of Interest and Waivers under 18 U.S.C. §208(b)(3) and 21 U.S.C. §355(n)(4)

Name of Participant: Howard I. Scher, M.D.

Committee: Cellular, Tissue and Gene Therapies Advisory Committee

Meeting Date: March 29, 2007

I acknowledge that contingent upon public disclosure of the following financial interest listed below related to the review of Sipuleucel-T, Dendreon Corp., for the treatment of men with asymptomatic metastatic hormone refractory prostrate cancer, I am eligible to receive waivers under 18 U.S.C. §208(b)(3) and 21 U.S.C. §355(n)(4).

Type of Interest	Nature	Magnitude
Grant (related)	Competing Firm	$100,000-$300,000
Grant (related)	Competing Firm	$100,000-$300,000
Stock	Competing Firm	$5,000-$100,000

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.

Howard I. Scher, M.D.

2/26/07
Date