



FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

MEMORANDUM

DATE: February 1, 2007

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

SUBJECT: 208(b)(3) Conflict of Interest Waiver for Derek Raghavan, M.D., Ph.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 Derek Raghavan, M.D., Ph.D., a special Government employee for the Center for Drug Evaluation and Research. Dr. Raghavan 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. Raghavan 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. Raghavan 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.

Page 2 -- Randall Lutter, Ph.D.

Associate Commissioner for Policy and Planning

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. Raghavan 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. Raghavan reported that he has a grant from [REDACTED]. The grant is current and awarded to his institution. His institution receives [REDACTED] from 2006-2007. Dr. Raghavan receives no direct support 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. It is unlikely the committee discussions on March 29 of a cellular therapy for prostate cancer will affect Dr. Raghavan's financial interests.

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

The Committee has a special need for Dr. Raghavan's services because of his expertise as a prostate oncologist with clinical and laboratory research experience. Dr. Raghavan is the Director of the Cleveland Clinic Cancer Center and widely recognized as an expert in the treatment of genitourinary cancers. The committee has a critical need for prostate oncology expertise to evaluate clinical and manufacturing data from trials of a novel therapy for prostate cancer. Dr. Raghavan's medical and research background provide him with unique qualifications to evaluate both clinical and product characterization data. Additionally, Dr. Raghavan has prior FDA advisory committee experience as a past member 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.

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: Derek Raghavan, M.D., Ph.D..

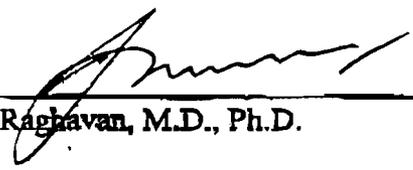
Committee: Cellular, Tissue and Gene Therapies Advisory Committee

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., indicated for the treatment of men with asymptomatic metastatic hormone refractory prostate cancer, I am eligible to receive waivers under 18 U.S.C. §208(b)(3) and 21 U.S.C. §355(n)(4).

<u>Type of Interest</u>	<u>Nature</u>	<u>Magnitude</u>
Grant (related)	Competing Firm	\$100,000-\$300,000

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.



Derek Raghavan, M.D., Ph.D.

3/6/07

Date