



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

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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 Savio L. C. Woo, 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 for Savio L. C. Woo, Ph.D., a member of the Cellular, Tissue and Gene Therapies Advisory Committee at the March 29-30, 2007 meeting, from conflict of interest prohibitions of 18 U.S.C. 208(a). The Committee will discuss and make recommendations 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 (Topic 1, Day 1). 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. Woo 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. Woo 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. Woo has advised the FDA that he has a financial interest related to the above stated topic that could potentially be affected by his participation in the matter at issue. Dr. Woo reported that he consults with an affected firm – [REDACTED]. The consulting is unrelated to the topic. He receives [REDACTED] per year for his consulting with the [REDACTED]. Dr. Woo also reported a patent licensed by an affected firm – [REDACTED] for gene transfer technology he invented. He received [REDACTED] from 2005. The technology is available and used for other indications. In addition, Dr. Woo is the principal investigator on five unrelated grants from the National Cancer Institute (NCI). He receives [REDACTED] in salary and fringe benefits from these grants. Dr. Woo's institution receives a combined total for all five grants of approximately \$790,000 per year from April 2002- present from NCI. These grants do not entail a direct and predictable affect on the interests.

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

Dr. Woo's consulting with an affected firm is unrelated to the topic, as a member of the [REDACTED] he provides an independent appraisal of the educational program of the School, encompassing the approach, quality and content of the curriculum, instructional methods and supporting facilities. His consulting on the [REDACTED] will not be affected by his participation in the meeting and the chance is extremely remote that his position on the [REDACTED] will affect his viewpoints on the topic. The technology he invented and that was licensed to an affected firm is related to a gene transfer technology that is being studied in prostate cancer but has also been studied in other types of cancer as well as liver transplantation. This is a gene transfer technology and the likelihood is low that the committee discussion of the topic, which is a cellular therapy, will impact the studies the affected firm is conducting with the technology invented by Dr. Woo. The chance is remote that the committee discussion of the topic will have a direct and predictable effect on Dr. Woo's financial interest.

Further, Dr. Woo is a standing member of the Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAC). The Federal Advisory Committee Act requires that committee membership be fairly balanced in terms of the points of view represented and the functions to be performed by the various advisory committee members. Dr. Woo's participation will contribute to the balance of views represented and the diversity of opinions and expertise and will help provide a foundation for developing advice and recommendations that are fair and comprehensive. The Committee's intended purpose would be significantly impaired if the



**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: **Savio L. C. Woo, Ph.D.**

Committee: **Cellular, Tissue and Gene Therapies Advisory Committee**

Meeting Date: **March 29-30, 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 symptomatic metastatic hormone refractory prostate cancer, sponsor, 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
Consulting (unrelated)	Competing Firm	Less than \$10,000 <i>in last 12 months</i>
Patent (related)	Competing Firm	Less than \$15,000 <i>in last 12 months</i>

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.

  
Savio L. C. Woo, Ph.D.

March 5, 2007  
Date