



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

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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 Maha Hussain, M.D., FACP

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 Maha Hussain, M.D., a special Government employee for the Center for Drug Evaluation and Research. Dr. Hussain 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. Hussain 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. Hussain 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. Hussain advised the FDA that she has a financial interest related to the above topic that could potentially be affected by her participation in the matter at issue. Dr. Hussain reported that her husband owns stock in the following competing firms: [REDACTED]

[REDACTED] Dr. Hussain does not hold control in the purchase or sale of the stocks. Dr. Hussain also is the principal investigator on an unrelated research contract awarded by a competing firm. Dr. Hussain's institution receives approximately [REDACTED] per year from May 2006 to September 2009. She does not receive any personal remuneration. This research contract does not entail a direct and predictable affect on the interest.

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

Dr. Hussain has a national reputation in the fields of cancer research and clinical care for advanced genitourinary cancers. She is a member of the FDA Oncology Drugs Advisory Committee (ODAC). Dr. Hussain has extensive experience in clinical trials of drug therapies for prostate cancer. There is a critical need on the Committee for clinical care expertise in the treatment of advanced, metastatic prostate cancer patients who don't respond to standard treatment. Dr. Hussain will provide this expertise which will assist the Committee in evaluating the efficacy of a cellular therapy for prostate cancer.

Additionally, Dr. Hussain's clinical trial expertise will contribute to the Committee's discussion of appropriate patient populations and study end points. Dr. Hussain's experience, a member of the ODAC, advising the FDA on the safety and efficacy of new cancer therapies, will be invaluable to the Committee discussions. The benefit to FDA of Dr. Hussain's clinical, research and advisory committee expertise outweighs the risk of a direct and predictable affect on Dr. Hussain's imputed financial interests.



**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:** Maha Hussain, M.D., FACP

**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>
Stock	Competing Firm	\$5,000-\$100,000
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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.

  
Maha Hussain, M.D., FACP

2/26/07  
Date