



FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

MEMORANDUM

DATE: January 29, 2007

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

SUBJECT: 208(b)(3) Conflict of Interest Waiver for Glenn Dranoff, 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 limited waiver for Glenn Dranoff, M.D., a consultant of the Cellular, Tissue and Gene Therapies Advisory Committee at the March 29, 2007 meeting, from conflict of interest prohibitions of 18 U.S.C. 208(a). The Committee will hear 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. Dranoff 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. Dranoff 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.

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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.

The Committee is scheduled to meet on March 29, 2007. The Committee will hear and make recommendations on issues related to a cellular immunotherapy for the treatment of men with asymptomatic metastatic hormone refractory prostate cancer.

Dr. Dranoff has 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. Dranoff has reported that he is consulting with the following affected firms: [REDACTED]. He also reported a patent licensed by [REDACTED] for technology that he developed. Dr. Dranoff's consulting with [REDACTED] which is an unrelated topic. He received [REDACTED] per year for this consulting. His consulting with [REDACTED] is informal and sporadic. He does not receive remuneration from [REDACTED] for his consulting. His consulting with [REDACTED] is based on his expertise of a tumor vaccine technology that he invented, that was subsequently patented by the [REDACTED] and licensed by [REDACTED]. The vaccine technology is available and may be used by other firms for other indications. [REDACTED] is currently using this technology in their studies of prostate and lung cancers. Dr. Dranoff does not receive remuneration for this technology.

Under Section 208, Dr. Dranoff 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 limited waiver to Dr. Dranoff that would allow him to participate in the discussions before the Committee but not vote.

The Committee has a special need for Dr. Dranoff's services because of his unique expertise, experience, and viewpoints with respect to the issue before the Committee. Dr. Dranoff is Director, Human Gene Transfer Laboratory Core at Dana-Farber Cancer Institute. Dr. Dranoff is a highly respected scientist in the field of cancer vaccines with expertise in immunotherapy clinical trials. His expertise and perspective are critical, providing specific genitourinary immunotherapy expertise for the Committee's evaluation of the efficacy of a novel cellular therapy for prostate cancer. The area of cellular vaccines for genitourinary cancers is fairly narrow. Two other equally qualified experts were considered and invited. One individual was unavailable, the other was determined to have greater potential conflicts of interest. Four other experts from the Oncology Drugs Advisory Committee with related expertise were invited, all were unavailable.

