



Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

M E M O R A N D U M

DATE: September 13, 2005

FROM: William Freas, Ph.D. *William Freas*
Director, Division of Scientific Advisors and
Consultants

TO: Sheila Dearybury Walcoff, Esq.
Associate Commissioner for External Relations
Food and Drug Administration

SUBJECT: General Matters Waiver Under 18 U.S.C. 208(b)(3)
for James J. Mulé, Ph.D.

THROUGH: Jenny Slaughter
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

James J. Mulé, Ph.D. has been appointed as a special Government employee to the Center for Biologics Evaluation and Research (CBER). He has been asked to participate in the September 29, 2005, meeting of the Cellular, Tissue and Gene Therapies Advisory Committee. This memorandum constitutes a determination that the need for Dr. Mulé's services on the Committee outweighs the potential for a conflict of interest created by any personal or imputed financial interest that he may have in matters of general applicability in which he is expected to participate on the Committee. 18 U.S.C. 208(b)(3).

The Committee will listen to presentations about the research program at the Office of Cellular, Tissue and Gene Therapies (OCTGT). They will also discuss the program and make recommendations that will be publicly discussed at a future meeting of the Cellular, Tissue and Gene Therapies Advisory Committee. It is expected that the Committee will focus largely, if not exclusively, on matters of general applicability, as opposed to matters involving specific parties or matters that uniquely and distinctly affect any particular person or organization.

These matters may affect certain financial interests of Dr. Mulé's or of persons and organizations with which he may have certain relationships. This would include:

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Financial investments in medical product companies, food related companies, drug related companies, health care industry, and any other industry that might be affected by the recommendations of the Committee (no interests currently reported);

Employment with research institutions, state and local governments, medical product manufacturers, food related companies, drug related companies, health care industry or other organizations that may be affected by the Committee's recommendations, for example, the H. Lee Moffitt Cancer Center and Research Center where he is employed, [REDACTED] where he consults [REDACTED] and the [REDACTED] where he speaks;

Grants, contracts or other funding for research or other services received from the federal government that might be affected by the Committee's recommendations, for example, grants with the National Institute of Health's National Cancer Institute (NCI) and the Department of Health and Human Service's Health Resources and Services Administration (HRSA) where he is the principal investigator;

Grants, contracts or other funding for research or other services received from non-federal sources, including industry and foundations, that might be affected by the Committee's recommendations, (no interests currently reported);

Expert witness, litigation or advocacy services in matters that might be affected by the recommendations of the Committee, (no interests currently reported);

Any interest of a group or other organization in which Dr. Mulé is appointed as an officer, director, trustee, employee or general partner that might be affected by the Committee's recommendations, (no interests currently reported).

Under 18 U.S.C. 208, Dr. Mulé may not participate in any particular matter affecting these interests, unless he receives a waiver. However, pursuant to my authority to grant waivers under 18 U.S.C. 208(b)(3), I have determined that the need for the services of James J. Mulé on this Committee, with respect to matters of general applicability, outweighs any concern that these types of interests might create a potential for a conflict of interest. Consequently, Dr. Mulé may participate in matters of general applicability affecting any current and future financial interests of the types described above. This determination is based on the following considerations

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The Food and Drug Administration has a particularly strong need for Dr. Mulé's services. Dr. Mulé is the Associate Center Director for Translational Research and Technology Development at the H. Lee Moffitt Cancer Center and Research Institute. He is an internationally recognized expert in the field of tumor immunology and immunotherapy. He provides critical expertise on the Subcommittee to address research in the Office of Cellular, Tissue and Gene Therapies related to tumor vaccine development. He is familiar with FDA regulatory and research responsibilities and his participation is invaluable to the Subcommittee discussions of critical pathways for the development of cancer vaccines.

Furthermore, the Committee Charter requires the appointment of individuals who are authorities knowledgeable in the fields of cellular therapies, tissue transplantation, gene transfer therapies and xenotransplantation including biostatistics, bioethics, hematology/oncology, human tissues and transplantation, reproductive medicine, general medicine and various medical specialties including surgery and oncology, immunology, virology, molecular biology, cell biology, developmental biology, tumor biology, biochemistry, rDNA technology, nuclear medicine, gene therapy, infectious diseases, and cellular kinetics. The Committee will also include representatives of consumer organizations, product recipients, and healthcare providers. Consequently, it is expected that persons qualified to serve on the Committee will have interests, financial and otherwise, in the work of the Committee. This includes not only employment interests, but also investment and pension interests, as experience has shown that persons employed in the biomedical area frequently acquire investment and pension interests in organizations related to their expertise. In short, financial interests simply are unavoidable in view of the work and membership requirements of this Committee.

Likewise, the very diversity of interests required by the Charter will ensure that no one member is in a position to determine policy in favor of any one affected interest. In addition to the specific requirements of the Charter, the Federal Advisory Committee Act requires fair balance and openness, which serve as important checks against real or apparent threats to the objectivity of Committee action.

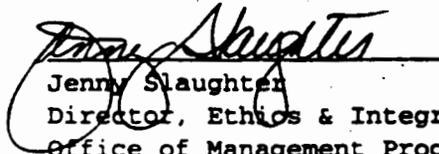
Finally, the Committee is expected to focus mainly on matters of general applicability, rather than matters involving specific parties. It is well-recognized that such general matters pose less risk of a conflict of interest. Matters of general applicability include regulations, legislation, and policies governing classes of organizations, individuals, and products

However, this does not include matters involving specific parties, such as specific grants (as opposed to general recommendations for increased funding in a given area), contracts, product approval applications, or enforcement matters involving known parties.

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Please note that this waiver is limited to general matters. It will not allow Dr. Mulé to participate in any matters involving specific parties that may affect his financial interests, or any person or organization described above. If the work of the Committee turns from matters of general applicability to more specific matters (e.g., recommendations regarding a specific product), participants will seek additional advice.

CONCURRENCE:

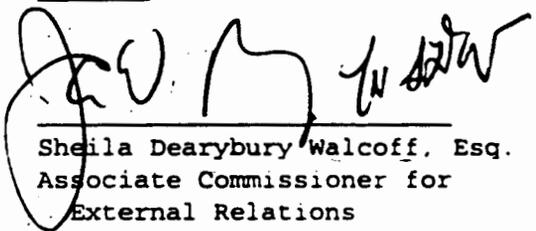

Jenny Slaughter
Director, Ethics & Integrity Staff
Office of Management Programs
Office of Management

9/16/05
Date

DECISION:

General matters 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.


Sheila Dearybury Walcoff, Esq.
Associate Commissioner for
External Relations
Food and Drug Administration

9/27/05
Date