



MEMORANDUM
DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE : December 13, 2005

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

SUBJECT: Conflict of Interest Waiver for
Richard C. Mulligan, Ph.D.

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

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

I am writing to request a limited waiver for Richard C. Mulligan, M.D., a consultant to the Cellular, Tissue and Gene Therapies Advisory Committee from the conflict of interest prohibitions of 18 U.S.C. 208(a). 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. Mulligan a limited-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 an arrangement concerning prospective employment has a financial interest. Because Dr. Mulligan is a special Government employee, he 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.

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The Committee will discuss the National Toxicology Program (NTP) in Retroviral Mutagenesis.

Dr. Mulligan reported that he has a patent [REDACTED] for general gene transfer technology. He receives royalties for this patent.

Under section 208, Dr. Mulligan 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 limited waiver.

For the following reason, I believe that it is appropriate for you to grant a limited waiver to Dr. Mulligan that allows him to participate in the discussions by sharing his expertise and experiences. Dr. Mulligan's patent is for a cell packaging line that will not be used in the proposed NTP study. Dr. Mulligan will not be permitted to vote on any of the questions related to NTP studies proposed related to vector design for retroviral gene transfer products. The discussions could affect classes of products and biologics manufacturers. There are no licensed retroviral vector gene transfer products. In addition, there is no known direct and predictable effect on Dr. Mulligan's interest.

The limited waiver is also justified because the Committee has a special need for Dr. Mulligan's services because of his unique expertise, experience, and viewpoints with respect to the issues before the Committee. Dr. Mulligan is the Mallinckrodt Professor of Genetics at Harvard Medical School, and the Director of Gene Therapy at Children's Hospital, and Director of the Harvard Gene Therapy Initiative. He is an internationally recognized pioneer in the development of new technologies for transferring genes into mammalian cells. His areas of expertise include pre-clinical and clinical evaluation of novel gene-based therapies for the treatment of both inherited and acquired diseases. Dr. Mulligan has 20 years of unparalleled experience in the field. Dr. Mulligan's expertise in sequence characterization of gene transfer products and potential long-term effects of vectors classes in gene therapy trials will be invaluable to the Committee discussions.

For these reasons, I believe that Dr. Mulligan's participation in the discussions of the National Toxicology Program in Retroviral Mutagenesis will help the Committee provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Richard C. Mulligan, Ph.D. a limited waiver that allows him to participate in the Committee discussions. Dr. Mulligan will not be permitted to vote on any questions posed to the Committee. I believe that a limited waiver

