



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

M E M O R A N D U M

DATE: August 24, 2006

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

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

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

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

James A. Mastrianni, M.D., Ph.D. has been appointed as a special Government employee and a member of the Transmissible Spongiform Encephalopathies Advisory Committee. This memorandum constitutes a determination that the need for Dr. Mastrianni'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 review and evaluate available scientific data concerning the safety of products which may be at risk for transmission of spongiform encephalopathies having an impact on the public health as determined by the Commissioner of Food and Drugs. The Committee will also make recommendations to the Commissioner regarding the regulation of such products. 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. Mastrianni's or of persons and organizations with which he may have certain relationships. This would include:

Associate Commissioner for Policy and Planning

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, his employment with the University of Chicago which operates a blood bank and conducts research activities that may be affected by the FDA decisions based on the advice received from the Committee. He also consults with the [REDACTED] where he received an honorarium. This entity could be affected by the FDA decisions based on the advice received from the Committee.

Under 18 U.S.C. 208, Dr. Mastrianni 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 A. Mastrianni, M.D., Ph.D., 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. Mastrianni 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:

The Food and Drug Administration has a particularly strong need for Dr. Mastrianni's services. Dr. Mastrianni is an Assistant Professor of Neurology at The University of Chicago. Dr. Mastrianni is an expert in chemistry, pharmacology, and neurology. His specialties include the study of human prion diseases, genetics, and clinical aspects of TSEs in humans. His research studies currently are focused exclusively on prion biology and the transmissible nature of blood in patients with prion diseases. His knowledge in prion diseases and prion transmission in blood will assist the Committee with a broader understanding of the issues before the Committee in assessing risks of Transmissible Spongiform Encephalopathies in foods and other animal derived FDA regulated products.

Furthermore, the Committee Charter requires the appointment of individuals who are authorities knowledgeable in the fields of clinical and administrative medicine, hematology, virology, neurovirology, neurology, infectious diseases, immunology, transfusion medicine, surgery, internal medicine, biochemistry, biostatistics, epidemiology, biological and physical sciences, sociology/ethics, and other related professions. 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.

Please note that this waiver is limited to general matters. It will not allow Dr. Mastrianni 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:

 |S|
Jenny Slaughter
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

 8/24/06
Date

DECISION:

 X 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.

 |S|
Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

 8/24/06
Date