



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

MEMORANDUM

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 Michael Geschwind, M.D., Ph.D.

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

Michael Geschwind, 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. Geschwind'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. Geschwind's or of persons and organizations with which he may have certain relationships. This would include:

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 California, San Francisco 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 [REDACTED]

[REDACTED] where he receives an honorarium. These entities could also be affected by the FDA decisions based on the advice received from the Committee.

Under 18 U.S.C. 208, Dr. Geschwind 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 Michael Geschwind, 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. Geschwind 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. Geschwind's services. Dr. Geschwind is Assistant Adjunct Professor of Neurology in the Department of Neurology, Memory and Aging Center at the San Francisco Medical Center, University of California, San Francisco, California. He is a neurologist who treats and performs clinical research involving progressive dementia diseases, including Creutzfeldt-Jakob disease. Dr. Geschwind's knowledge and experience will significantly contribute to the clinical implications for the committee discussions.

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.

