

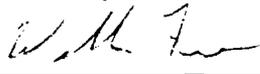


DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DATE: August 24, 2006

FROM: William Freas, Ph.D.   
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 Laura K. Manuelidis, M.D.

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

Laura K. Manuelidis, M.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. Manuelidis' services on the Committee outweighs the potential for a conflict of interest created by any personal or imputed financial interest that she may have in matters of general applicability in which she 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. Manuelidis' or of persons and organizations with which she 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, her employment with Yale University School of Medicine 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.

Under 18 U.S.C. 208, Dr. Manuelidis may not participate in any particular matter affecting these interests, unless she 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 Laura K. Manuelidis, M.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. Manuelidis 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. Manuelidis' services. Dr. Manuelidis is a Professor and Head of Neuropathology, Yale University School of Medicine. She is an expert in neuropathology with specific expertise in CDJ and the transmission of Creutzfeldt-Jacob disease with scrapie-like syndrome including clinical and morphological aspects of transmissible CDJ disease. She will provide expertise that is important to 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.

