DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: January 6, 2006

TO: Jason D. Brodsky
Acting Associate Commissioner for External Relations
Food and Drug Administration

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

FROM: Igor Cerny, Pharm.D.
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for Terry Davis, Ph.D.

I am writing to request a waiver for Terry Davis, Ph.D., a consultant to the Center for Drug Evaluation and Research, from the conflict of interest prohibitions of 18 U.S.C. §208(a). The appointing official may grant waivers under section 208(b)(3) 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. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant Terry Davis, Ph.D., a waiver under 18 U.S.C. §208(b)(3).

Section 208(a) prohibits Federal executive branch employees, including special Government employees, from participating personally and substantially in matters in which the employee, or any other person whose interests are imputed to the employee under 18 U.S.C. §208, has a financial interest. Since Dr. Davis is a special Government employee, she is under a statutory obligation to refrain from participating in an official capacity in any particular matter having a direct and predictable effect on a financial interest attributable to her, her spouse, minor child, or general partner; an organization or entity for which she serves as an officer, director, trustee,

general partner,or employee; and, a person with whom she is negotiating for, or has an arrangement concerning, prospective employment.

Terry Davis, Ph.D., has been asked to participate in all official matters concerning (1) discussion of approaches that could be used to study whether Attentions Deficit Hyperactivity Disorder (ADHD) products increase the risk of adverse cardiovascular outcomes; and, (2) The Agency's actions for the COX-2 selective Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). These matters are coming before the Drug Safety and Risk Management Advisory Committee for consideration.

The function of the of the Drug Safety and Risk Management Advisory Committee, as stated in its Charter, is to advise the Commissioner of Food and Drugs on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which the Food and Drug Administration has regulatory responsibility. The committee also advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of all information gathered by the Department of Health and Human Services and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by the Department of Health and Human Services with regard to the marketing, investigation, and control of such drugs or other substances.

Dr. Davis has advised the Food and Drug Administration (FDA) that she has financial interests that could potentially be affected by her participation in the matters described above. Dr. Davis owns modest amounts of stock in [redacted] distributes products that could be affected by the committee's discussions of COX-2 selective Nonsteroidal Anti-Inflammatory Drugs. [redacted] divisions of [redacted] is a subsidiary of [redacted]

[redacted] is an ADHD product that could be affected by the committee's discussions of approaches that could be used to study whether ADHD drugs increase the risk of cardiovascular outcomes.

As a consultant advising the Drug Safety and Risk Management Advisory Committee, Dr. Davis potentially could become involved in matters that could affect her financial interests. Under 18 U.S.C. §208(a), she is prohibited from participating in such matters. However, as noted above, you have the authority under 18 U.S.C. §208(b)(3) to grant a waiver permitting Dr. Davis to participate in such matters as you deem appropriate.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Davis, which would permit her to participate in the matter previous described above.

First, the stocks represent only a small percentage of Dr. Davis total net worth and are not so substantial as to preclude her participation in these matters.

Second, the matters before the committee are particular matters of general applicability and will not focus on any particular product or company.

Further, the Federal Advisory Committee Act requires that committee memberships be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee. Also, the committee's intended purpose would be significantly impaired if the Agency could not call upon experts who have become eminent in their fields, notwithstanding the financial interests and affiliations they may have acquired as a result of their demonstrated abilities.

Dr. Davis is Professor of Medicine and Pediatrics, Louisiana State University Health Sciences Center and, Director of Behavioral Science Section, Feist-Weiller Cancer Center. Dr. Davis' research interest is in work centered education materials and methods, e.g. pamphlets, posters, video tapes, peer educators. She works with providers, federal health agencies, and professional organizations to develop best practices for continuing education for practicing physicians, e.g. office based in-services, computer based CME, train-the-trainer models. She works with key stakeholders to design primary care clinics that are user-friendly for patients with limited literacy and test the efficacy in regard to health care quality and outcomes. I believe her participation will contribute to the diversity of opinions and expertise represented on the committee and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Dr. Davis a waiver that would allow her to participate in all official matters concerning (1) discussion of approaches that could be used to study whether Attention Deficit Hyperactivity Disorder (ADHD) products increase the risk of adverse cardiovascular outcomes; and, (2) The Agency actions for the COX-2 selective Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). I believe that such a waiver is appropriate because in this case, the need for the services

of Dr. Davis outweighs the potential for a conflict of interest created by the financial interests attributable to her.

CONCURRENCE:

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

1/10/06
Date

DECISION:

✓ 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

Jason D. Brodsky
Acting Associate Commissioner for External Relations
Food and Drug Administration

1.12.06
Date