



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: June 16, 2006

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

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

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

SUBJECT: Conflict of Interest Waiver for Sandra Olson, M.D.

I am writing to request a waiver for Sandra Olson, M.D., a member of the Peripheral and Central Nervous System Drugs Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a). The appointing official may grant waivers under 18 U.S.C. §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 Sandra Olson, M.D., a 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 the employee or his employer has a financial interest. Since Sandra Olson, M.D., is a special Government employee, she 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 her or her employer.

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The functions of the Peripheral and Central Nervous System Drugs Advisory Committee, as stated in its Charter, is to review and evaluate data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases and make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Olson has been asked to participate in the Joint Meeting of the Dental Products Panel of the Medical Devices Advisory Committee of the Center for Devices and Radiological Health and the Peripheral and Central Nervous System Drugs Advisory Committee of the Center for Drug Evaluation and Research to review and discuss peer-reviewed scientific literature on dental amalgam devices and its potential mercury toxicity, specifically as it relates to neurotoxic effects.

Dr. Olson has advised the Food and Drug Administration (FDA) that she has a financial interest that could potentially be affected by her participation in this matter. She owns stock in _____ . _____ makes a _____ that could be affected by the committee's discussions.

As a member of the Peripheral and Central Nervous System Drugs Advisory Committee, Dr. Olson could potentially become involved in matters that could affect her financial interest. Under section 208, 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. Olson 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. Olson that would allow her to participate fully in the matter described above.

First, Dr. Olson's stock interest represents a minimal percentage of her total net worth and is not so substantial as to preclude her participation in this matter.

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 various advisory committee members and Dr. Olson's participation will contribute to the balance of views represented and the diversity of opinions and expertise. 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. Sandra Olson is the Professor of Clinical Neurology at Feinberg Medical School of Northwestern University. She is board certified in Psychiatry and Neurology. Dr. Olson also serves as the President of the American Academy of Neurology (AAN), a position she assumed during the groups annual meeting in March 2003. The first woman to hold the office of the AAN president. Dr. Olson hopes during her term to expand the benefits of the organization's key programs in science, education, and member support, while emphasizing through lifelong learning, ethics, and patient care initiatives. She is active in many other organizations including the Accreditation Council for Graduate Medical Education, the American Medical Association Council on Medical Education, the Illinois State Medical Society, and is a current board member of the State of Illinois' Department of Professional Regulation. Dr. Olson also serves on the board of governors of the Illinois State Medical Inter-Insurance Exchange Mutual Insurance Co. I believe that Dr. Olson's participation will contribute to the diversity of expertise and viewpoints represented and will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Sandra Olson, M.D., a waiver that would allow her to participate in the Joint Meeting of the Dental Products Panel of the Medical Devices Advisory Committee of the Center for Devices and Radiological Health and the Peripheral and Central Nervous System Drugs Advisory Committee of the Center for Drug Evaluation and Research to review and discuss peer-reviewed scientific literature on dental amalgam devices and its potential mercury toxicity, specifically as it relates to neurotoxic effects.

