



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: June 30, 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 Larry Goldstein, M.D.

I am writing to request a waiver for Larry Goldstein, 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 Larry Goldstein, 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 Larry Goldstein, M.D., is a special Government employee, he 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 him or his 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. Goldstein 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. Goldstein has advised the Food and Drug Administration (FDA) that he has a financial interest that could potentially be affected by his participation in this matter. Dr. Goldstein is a consultant for _____ . _____

_____, a subsidiary of _____ 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. Goldstein could potentially become involved in matters that could affect his financial interest. Under section 208, he 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. Goldstein 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. Goldstein that would allow him to participate fully in the matter described above.

First, arguably Dr. Goldstein's interest in _____ does not constitute a financial interest in the particular matter within the meaning of 18 U.S.C. §208(b)(3), since his consulting is unrelated to the issue or the affected firms. Nevertheless, I recommend that this waiver be granted.

Second, it is unlikely that Dr. Goldstein's interest will affect his impartiality. Even if _____ would be more or less likely, in the future, to continue their consulting relationship with Dr. Goldstein, the financial impact on him would probably be minimal since this is not a substantial financial interest.

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. Goldstein's participation in 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. Goldstein is Director, Duke Center Cerebrovascular Disease; Associate Research Professor, Center for Health Policy Research and Education, Duke University Medical Center; Professor of Medicine, Duke University School of Medicine. His research efforts have involved several aspects of cerebrovascular disease. In the laboratory, his work has centered on developing an understanding of the mechanisms underlying pharmacological modulation of motor recovery after injury to the cerebral cortex and has led to several clinical studies in patients with stroke and traumatic brain injury. His specific areas of expertise include; effects of drugs on recovery after stroke and brain injury, stroke prevention, trial design and outcomes measures, carotid endarterectomy, neuroplasticity and behavioral recovery after brain injury. His memberships in professional societies include the Society of Neurosciences, International Behavioral Neurosciences Society, the National Stroke Association and the American Neurological Association. He has published over 100 original articles on stroke and other brain disorders. I believe his participation will contribute to the diversity of opinions and expertise

