



DEPARTMENT OF HEALTH & HUMAN SERVICES

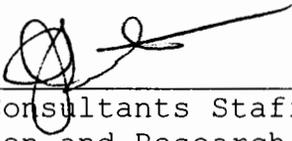
Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: January 26, 2005

TO: Jason D. Brodsky
Acting Associate Commissioner
Office of External Relations

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 Larry Goldstein,
M.D.

I am writing to request a waiver for Larry Goldstein, M.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 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 Dr. Goldstein 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 any other person whose interests are imputed to the employee under 18 U.S.C. §208, has a financial interest. Since Dr. Goldstein is a special Government employee, he 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 him, his spouse, minor child, or general partner; an organization or entity for which he serves as an

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

Dr. Goldstein has been asked to participate in all official matters concerning Biologic License Application (BLA) 125104/15, Tysabri (Natalizumab) injection, sponsored by Biogen Idec, Inc. and Elan Pharmaceuticals, a subsidiary of Elan Corporation, plc. Issues on the agenda for this meeting include (1) the risks (including progressive multifocal leukoencephalopathy (PML)) associated with Tysabri administration, (2) the efficacy of Tysabri for the treatment of patients with relapsing forms of multiple sclerosis to delay the progression of physical disability and to reduce the frequency of clinical exacerbations, (3) the possible return of Tysabri to the market place, and (4) the proposed risk management plan(s) for Tysabri. These matters are coming before the Peripheral and Central Nervous System Drugs Advisory Committee for consideration.

The function of 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 advised the Food and Drug Administration (FDA) that he has financial interests that could potentially be affected by his participation in this matter. Dr. Goldstein serves on _____ advisory board and is a member of its _____ Steering Committees. In addition, Dr. Goldstein serves as a consultant to _____. According to Dr. Goldstein, these activities are unrelated to the product coming before the committee for consideration, or the competing products. _____ make competing products to Tysabri.

As a consultant advising the Peripheral and Central Nervous System Drugs Advisory Committee, Dr. Goldstein could potentially become involved in matters that could affect his financial interests. 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. Larry 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, Dr. Goldstein's financial interests are not so substantial as to preclude his participation in the matter. He receives minimal compensation from these firms for these activities.

Second, arguably, Dr. Goldstein's financial interests in these firms do not constitute financial interests in the particular matter within the meaning of 18 U.S.C. §208(a), since these are on unrelated issues. Nevertheless, I recommend that this waiver be granted.

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. 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 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. Goldstein a waiver that would allow him to participate in all official matters concerning the committee's discussions of Biologic License Application (BLA) 125104/15, Tysabri (Natalizumab) injection, sponsored by Biogen Idec, Inc. and Elan Pharmaceuticals, a subsidiary of Elan Corporation, plc.

**APPEARS THIS WAY
ON ORIGINAL**

I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Goldstein outweighs the potential for a conflict of interest created by the financial interests attributable to him.

CONCURRENCE:



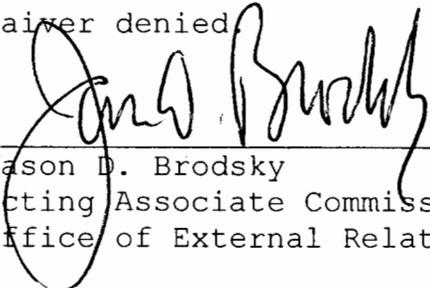
Jenny Slaughter
Director, Ethics and
Integrity Staff
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2/1/06

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
Office of External Relations

7.6.06

Date