



DEPARTMENT OF HEALTH & HUMAN SERVICES

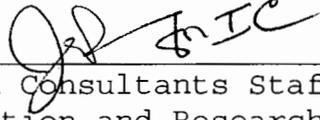
MEMORANDUM

Food and Drug Administration
Rockville MD 20857

DATE: January 31, 2006

TO: Jason D. Brodsky
Acting Associate Commissioner
Office of 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 Lily Jung, M.D.,
M.M.M.

I am writing to request a waiver for Lily Jung M.D., M.M.M., the consumer representative 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. you are the appointing official for purposes of section 208; therefore, you have the authority to grant Dr. Jung 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. Jung 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.

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. Jung has been asked to participate in all official matters regarding 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.

Dr. Jung has advised the Food and Drug Administration (FDA) that she has financial interests that could potentially be affected by her participation in the matter described above. Dr. Jung lectures for

on the management of specific impairments (including fatigue, bladder and bowel problems, spasticity, pain, visual problems, depression and anxiety, speech difficulties and sexual dysfunction) which can continue throughout the life of a person with multiple sclerosis. Dr. Jung's lectures are general in nature and are not product specific.

As the consumer representative member of the Peripheral and Central Nervous System Advisory Committee, Dr. Jung could potentially become involved in matters that

could affect her financial interests. 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. Jung 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. Jung that would permit her to participate in the matters previously described.

First, although Dr. Jung's lectures on issues related to the management of specific impairments that can occur throughout the life of a person with MS, she does not lecture on products used to treat or prevent relapse in patients with MS.

Second, Dr. Jung's financial interests in _____ are not so substantial as to preclude her participation in this meeting. She receives nominal compensation for her speaking.

Third, Dr. Jung is the consumer representative for the committee and her participation is essential to providing the committee with input from consumers on medical and scientific issues. As the consumer representative, Dr. Jung's role is to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and, facilitate dialogue with the advisory committee on scientific issues that affect consumers. To qualify, a consumer representative must be able to analyze scientific data, understand research design, discuss benefits and risks, and evaluate the safety and efficacy of products under review. It is also essential that the representative have an affiliation with and/or active participation in consumer or community-based organizations. Dr. Jung's expertise as a practicing neurologist, researcher, and advocate on behalf of people with MS, makes her uniquely qualified to serve in this capacity.

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. Jung'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. Lily Jung is the Medical Director of the neurology clinic at the Seattle Neuroscience Institute, clinical assistant professor in the Department of Neurology at the University of Washington Medical School, and an adjunct assistant professor in Health System Management at Tulane University School of Public Health. She is a board-certified Psychiatry and Neurology, with an impassioned interest in Multiple Sclerosis. Dr. Jung is a member of numerous societies, such as, the American Academy of Neurology's Legislative Affairs Committee, Puget Sound Neurological Society and Physicians Review Network. She was inducted into the National Multiple Sclerosis Society Hall of Fame for her advocacy on behalf of people with the disease. Dr. Jung is a co-author for a book, "*Living Beyond Multiple Sclerosis: A Woman's Guide*". I believe that Dr. Jung's participation will provide the committee and Agency with the consumer perspective and will contribute the diversity of opinions and expertise represented.

Accordingly, I recommend that you grant Lily Jung, M.D., M.M.M., a waiver that will permit her 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. I believe that such a waiver is appropriate because in this

**APPEARS THIS WAY
ON ORIGINAL**

case, the need for the services of Dr. Jung outweighs the potential for a conflict of interest created by the financial interests attributable to her.

CONCURRENCE: Jenny Slaughter 2/1/06
Date
Jenny Slaughter
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

DECISION:

Waiver granted based on my determination, made in accordance with section 18 U.S.C. §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 2.6.06
Date
Jason D. Brodsky
Acting Associate Commissioner
Office for External Relations
Food and Drug Administration