



DEPARTMENT OF HEALTH & HUMAN SERVICES

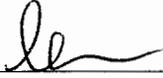
MEMORANDUM

Food and Drug Administration  
Rockville MD 20857

**DATE:** January 26, 2006

**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 Karl Kieburtz,  
M.D.

I am writing to request a waiver for Karl Kieburtz, 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). Waivers under section 208(b)(3) may be granted by the appointing official when it is determined that "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. Kieburtz 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. Kieburtz 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 as an arrangement concerning, prospective employment.

Dr. Kiebertz 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. 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. This matter is 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 neurological diseases and make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Kiebertz has advised the Food and Drug Administration (FDA) that he has financial interests that could potentially be affected by his participation in the matter described previously. Dr. Kiebertz is a consultant for \_\_\_\_\_ on matters unrelated to \_\_\_\_\_ and its competing products. \_\_\_\_\_ is the \_\_\_\_\_ and is currently studying \_\_\_\_\_

**APPEARS THIS WAY  
ON ORIGINAL**

He is also a consultant for \_\_\_\_\_ on matters unrelated to the product at issue and the competing products. \_\_\_\_\_ make competing products to Tysabri and are currently studying investigational drugs for use in the treatment of \_\_\_\_\_ makes a competing product to Tysabri.

As a member of the Peripheral and Central Nervous System Drugs Advisory Committee, Dr. Kieburtz potentially could become involved in matters that could affect his financial interests. Under 18 U.S.C. §208(a), 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. Kieburtz 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. Karl Kieburtz that would permit him 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.

First and foremost, this waiver is justified because arguably, Dr. Kieburtz's interests do not constitute financial interests in the particular matter within the meaning of 18 U.S.C. §208(a), since his consulting is unrelated to the particular matter in which he is being asked to participate. Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

Second, Dr. Kieburtz's financial interests are not so substantial as to preclude his participation in this matter. He receives nominal compensation for his consulting.

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. Kieburtz'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. Kieburtz is Professor of Neurology and Community and Preventive Medicine and Chief, Movement and Inherited Neurological Disorders Unit, Department of Neurology, at the University of Rochester School of Medicine and Dentistry. His primary clinical and research interests are in the treatment of neurodegenerative diseases affecting the basal ganglia, particularly Parkinson's disease, Huntington's disease, and HIV related neurological disorders. He has been an active participant in the research activities of the Parkinson Study Group since 1989, and directs the Coordination Center for this and other multi-center academic consortia, including the Huntington Study Group. He is the principal investigator for the National Institutes of Neurological Disorders & Stroke sponsored trials of neuroprotective agents for Parkinson's disease. His publications and presentations have focused on experimental therapeutics and clinical research design strategies. I believe that Dr. Kieburtz's participation in the committee's discussions and deliberations will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Dr. Karl Kieburtz a waiver that will permit him to participate in all official matters concerning Biologic License Application (BLA) 125104/15, Tysabri (Natalizumab) injection, sponsored by Biogen Idec, Inc. and Elan

**APPEARS THIS WAY  
ON ORIGINAL**

Pharmaceuticals, a subsidiary of Elan Corporation. I believe that such a waiver is appropriate because in this case, the need for Dr. Kieburz's services outweighs the potential for a conflict of interest created by the financial interests attributable to him.

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 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 of External Relations