



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
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 Steven DeKosky,
M.D.

I am writing to request a waiver for Steven DeKosky, M.D., a member of the Peripheral and Central Nervous System 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. DeKosky 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 Dr. DeKosky 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.

The function 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. DeKosky 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. DeKosky has advised the Food and Drug Administration (FDA) that he has a financial interest that could potentially be affected by his participation in the matter described above. Dr. DeKosky lectures and consults for _____ on unrelated issues. _____ a competing product to Tysabri, is _____ by _____

As a member of the Peripheral and Central Nervous System Advisory Committee, Dr. DeKosky 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. Steven DeKosky 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 Steven DeKosky, M.D., that would permit him to participate in the matters previously described.

First, arguably, Dr. DeKosky's interest in [REDACTED] does not constitute a financial interest in the particular matter within the meaning of 18 U.S.C. §208(b)(3), since his lecturing and consulting are unrelated to the issues and product at issue, and the competing products. Dr. DeKosky lectures on the pathology and treatment of dementia, and he has been asked by [REDACTED] to consult at another meeting regarding research studies. In addition, he will be participating in the [REDACTED] Visiting Professor program where for 3 days he will teach and interact with the faculty, students, residents, research fellows and physicians at another University.

Second, Dr. DeKosky's financial interest is not so substantial as to preclude his participation in this meeting. He receives minimal compensation for his consulting services. Dr. DeKosky has advised that he does not accept more than [REDACTED] from any one company in a year.

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. DeKosky'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. Steven T. DeKosky, M.D., is a neurologist and Director of the NIA (National Institute on Aging)-funded Alzheimer's Disease Research Center (ADRC) and Director of the Division of Geriatrics and Neuropsychiatry at the University of Pittsburgh. His clinical research includes differential diagnosis, neuroimaging and genetic risks of Alzheimer's disease and trials of new medications. His

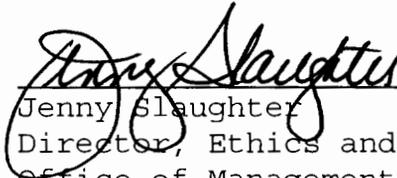
basic research centers on structural and neurochemical changes in human brains in dementia. Dr. DeKosky has served as Chair of the Section on Geriatrics of the American Academy of Neurology. He has been an Examiner in Neurology for the American Board of Psychiatry and Neurology (ABPN) for more than 15 years and serves as a member of the ABPN Part I (Written) Examination Committee as well. He has received a Teacher Investigator Development Award from the NINDS, as well as the Presidential Award of the American Neurological Association, and is listed in *The Best Doctors in America*. He has published more than 100 peer-reviewed articles and chapters. Dr. DeKosky chairs the National Medical and Scientific Advisory Council for, and is Vice Chairman of, the Board of Directors of the Alzheimer's Association. He also chairs the Professional Advisory Board of the Greater Pittsburgh Chapter of the Alzheimer's Association and was a Founding Member of the Lexington-Blue Grass Chapter of the Alzheimer's Association. Dr. DeKosky's participation will contribute to the diversity of expertise and opinions represented on the committee.

Accordingly, I recommend that you grant Steven DeKosky, M.D., 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 Pharmaceuticals, a subsidiary of Elan Corporation, plc. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. DeKosky outweighs

**APPEARS THIS WAY
ON ORIGINAL**

the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE:



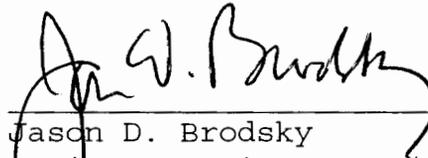
Jenny Slaughter
Director, Ethics and Integrity Staff
Office of Management Programs
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Date

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
Acting Associate Commissioner
Office for External Relations
Food and Drug Administration

2.6.06
Date