

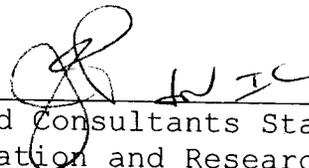


MEMORANDUM

DATE: January 6, 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 Steve Nissen, M.D.

I am writing to request a waiver for Steve Nissen, 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). Waivers under section 208(b)(3) may be granted by the appointing official 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 Steve Nissen, M.D., 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. Nissen 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.

The function of the Drug Safety and Risk Management Advisory Committee, as stated in its Charter, is to advise the Commissioner of Food and Drugs on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which the Food and Drug Administration has regulatory responsibility. The committee also advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of all information gathered by the Department of Health and Human Services and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by the Department of Health and Human Services with regard to the marketing, investigation, and control of such drugs or other substances.

Dr. Nissen has been asked to participate in all official matters concerning approaches that could be used to study whether Attention Deficit Hyperactivity Disorder (ADHD) products increase the risk of adverse cardiovascular outcomes. This matter is coming before the Drug Safety and Risk Management Advisory Committee on February 9, 2005.

Dr. Nissen 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. Nissen serves as a consultant to _____ on an unrelated matter. He receives minimal compensation for his consulting which he donates to charity. _____ is the manufacturer of one of the products which could potentially be affected by the committee's discussions.

As a consultant advising the Drug Safety and Risk Management Advisory Committee, Dr. Nissen potentially could become involved in matters that could affect his financial interest. 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. Nissen 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 Steve Nissen, M.D., that would permit him to participation in the matter previously described.

First, and foremost, this waiver is justified because Dr. Nissen's interest arguably does not constitute a financial interest in the particular matter within the meaning of 18 U.S.C. §208(a) since his consulting activity is unrelated to the issue coming before the committee for consideration. Nevertheless, I recommend that this waiver be granted.

Second, Dr. Nissen's interest is not so substantial as to preclude his participation in this matter. He receives minimal compensation for consulting which he donates to charity.

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. Nissen'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. Steven Nissen is the Director of the Cleveland Clinic Cardiovascular Coordinating Center. Dr. Nissen is board certified in internal medicine and cardiovascular medicine and is a professor of medicine at the Ohio State University. Dr. Nissen is an elected member of the American College of Cardiology Board of Trustees and several other ACC committees. He also serves on the editorial board of nine scientific publications, including the International Journal of Cardiac Imaging, Cardiology Today and Clinical Cardiology. Dr. Nissen has played an important role in numerous clinical trials, and he lectures frequently on the use of intravascular ultrasound and has authored several dozen book chapters and more than 100 articles in scientific journals such as Circulation, the Journal of the American College of

Cardiology and the American Journal of Cardiology, demonstrating his vast clinical and research expertise in acute myocardial infarction, unstable angina, and atherosclerosis. I believe that Dr. Nissen's broad professional abilities will contribute to the diversity of opinions and expertise foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Steve Nissen, M.D., a waiver that will permit him to participate in all official matter concerning discussion of approaches that could be used to study whether Attention Deficit Hyperactivity Disorder (ADHD) products increase the risk of adverse cardiovascular outcomes. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Nissen outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE: Jenny Slaughter _____ Date 1/10/06
Jenny Slaughter
Director, Ethics and
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 _____ Date 1.12.06
Jason D. Brodsky
Acting Associate Commissioner
Office of External Relations
Food and Drug Administration