



DEPARTMENT OF HEALTH & HUMAN SERVICES

MEMORANDUM

Food and Drug Administration  
Rockville MD 20857

**DATE:** February 10, 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 Wayne K. Goodman,  
M.D.

I am writing to request a waiver for Wayne K. Goodman, M.D., Chairman of the Psychopharmacologic 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 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 Wayne K. Goodman, 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. Goodman 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.

The function of the Psychopharmacologic 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 practice of psychiatry and related fields and make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Goodman has been asked to participate in all official matters concerning New Drug Application (NDA) 20-717/S-019, Provigil (modafinil tablets), sponsored by Cephalon, Inc., for the proposed indication for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). This matter is coming before the March 23, 2006, meeting of Psychopharmacologic Drugs Advisory Committee for consideration.

Dr. Goodman has advised the Food and Drug Administration that his employer, the University of Florida College of Medicine, has financial interests that could potentially be affected by his participation in the matters described above. Dr. Goodman is the Chairman of the Department of Psychiatry at the University of Florida. The Department of Psychiatry at the University of Florida currently has sixty faculty members on staff. **One of these faculty members is the Principal Investigator (PI) for two [redacted] sponsored trials involving [redacted] and another faculty member is the PI for [redacted] -sponsored open-label trials of [redacted] and an investigational agent, [redacted], in children and adolescents with ADHD. [redacted] and [redacted] are competing products to Provigil.** Dr. Goodman has no direct involvement in these trials. His only involvement is administrative as Chairman of the Department. He does not receive any personal remuneration or salary support from the funds received.

As a member of the Psychopharmacologic Drugs Advisory Committee, Dr. Goodman potentially could become involved in matters that could affect his employer's 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. Goodman 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 Wayne K. Goodman,

M.D., that would permit him to participate in all official matters concerning New Drug Application (NDA) 20-717/S-019, Provigil (modafinil tablets), sponsored by Cephalon, Inc., for the proposed indication for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

**First, although Dr. Goodman's employer has financial interests in \_\_\_\_\_ and \_\_\_\_\_ he himself has no current personal financial interest in either company. Although the financial interests of an employer impute to the individual under 18 U.S.C. §208, generally there is less likelihood that the judgment of the individual will be affected by an imputed interest of an employer than by a personal financial interest.**

Second, it is important to note that Dr. Goodman is not an investigator in these trials. His only involvement is administrative, as Chairman of the Department of Psychiatry.

**Moreover, it is significant to consider that two of three products under study, \_\_\_\_\_ and \_\_\_\_\_, are already approved and marketed for use in the treatment of ADHD, the indication being considered for Provigil. The third product, \_\_\_\_\_ under study in the \_\_\_\_\_ sponsored trial is an investigational agent that has numerous stages of study to go through to demonstrate that it is safe and effective for its intended use. Of 100 drugs for which investigational new drug applications are submitted to FDA, about 70 will successfully complete Phase 1 trials and go on to Phase 2; approximately 33 of the original 100 will complete Phase 2 and proceed to Phase 3; and, 25 to 30 of the original 100 will clear Phase 3. On average, about 20 of the original 100 investigational drugs will ultimately be approved for marketing. Given these considerations, it is unlikely that Dr. Goodman's participation in matters concerning Provigil will have an immediate and distinct impact upon his employer's interest.**

Further, it is difficult to predict what impact, if any, that Dr. Goodman's participation in this matter will have upon the clinical trials currently underway within the Department of Psychiatry. It is unlikely that any action, short of a "clinical hold," would effect these studies or cause the sponsors to prematurely terminate the trials. Even if it were possible that these firms would be more or less likely to continue to provide financial support to the University of Florida in the future as a result of the committee's deliberations, the financial impact would probably be

relatively insignificant since these are not significant financial interests. The University of Florida is a large, diverse, research institution which receives funding from a variety of public, private, and governmental agencies in support of its' research activities. It does not depend upon one or two sources for its funding. For the period 2002-2003, the University of Florida faculty attracted more than \$458 million in research and training grants.

Finally, 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 advisory committee. Also, 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. Goodman is the Chairman of the Department of Psychiatry at the University of Florida College of Medicine, Psychiatrist-in-Chief, Shands Healthcare, Chief, Obsessive-Compulsive and Tourette's Disorders Clinic, and Professor (Tenured), Department of Psychiatry. Dr. Goodman completed his internship, residency, and a research fellowship at Yale University School of Medicine where he founded and served as chief of the Obsessive Compulsive Disorders (OCD) Clinic at Yale's prestigious Clinical Neuroscience Research Unit. While on faculty at Yale, Dr. Goodman conducted research on the phenomenology, neurobiology, and treatment of obsessive-compulsive disorder and related disorders and he is the principal developer of the Y-BOCS, the gold standard for rating OCD. Dr. Goodman was the founder of the Obsessive Compulsive Foundation and served as Chair of its Scientific Advisory Board from 1987-1995. Dr. Goodman is a member of the American College of Neuropharmacology, Society for Neuroscience, and Society for Biological Psychiatry. He has conducted pioneering research on obsessions, compulsions, and chronic tics and has brought state-of-the-art biopsychiatry to Florida. Dr. Goodman has also done seminal work on the use of Selective Serotonin Reuptake Inhibitors (SSRIs) in the treatment of OCD, depression, and panic disorder. Dr. Goodman's research focuses on Obsessive Compulsive Disorder, Tourette's Syndrome and related disorders and on improving treatment of OCD, particularly resistant cases. Dr. Goodman has published over 150 scientific articles on such topics as "Obsessive-compulsive disorder: diagnosis and treatment," "Genetics of childhood disorders," and, "Pharmacological challenges in anxiety disorders." Dr. Goodman is listed among

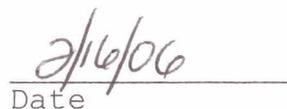
the top 20 Most Highly Cited Researchers in Psychiatry/Psychology and was listed as one of the "Best Doctors" in 2003-2004. I believe that Dr. Goodman's participation will bring an enormous amount of experience, knowledge, and expertise that is essential to the committee's discussions of the data submitted in support of the safety and efficacy of Provigil for use in the treatment of Attention Deficit Hyperactivity Disorder, and will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Wayne K. Goodman, M.D., a waiver that will permit him to participate in all official matters concerning New Drug Application (NDA) 20-717/S-019, Provigil (modafinil tablets), sponsored by Cephalon, Inc., for the proposed indication for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Goodman outweighs the potential for a conflict of interest created by the financial interests attributable to him.

CONCURRENCE:



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

  
Date

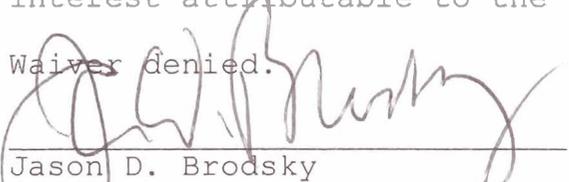
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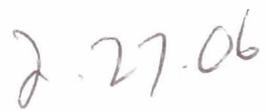


Waiver granted based on my determination, made in accordance with section 208(b)(3) that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest attributable to the individual.

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Waiver denied.

  
Jason D. Brodsky  
Acting Associate Commissioner  
Office of External Relations  
Food and Drug Administration

  
Date