



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: November 8, 2006

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning
Food and Drug Administration

THROUGH: Vince Tolino
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Igor Cerny, Pharm.D. 151
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for Dennis Turk, Ph.D.

I am writing to request a waiver for Dennis Turk, Ph.D., a member of the Arthritis Drugs Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a). The appointing official may grant waivers under section 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. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant Dr. Turk 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. Turk 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.

Dr. Turk has been asked to participate in all official matters concerning the safety and efficacy of New Drug Application NDA 20-998, supplement 021, trade name, Celebrex (celecoxib), a non-steroidal anti-inflammatory drug (COX-2 inhibitor), manufactured by Searle Ltd. for G.D. Searle LLC, subsidiaries of Pfizer, for the proposed indication of the relief of the signs and symptoms of juvenile rheumatoid arthritis (JRA) in patients two years and older. This matter is a particular matter involving specific parties.

The function of the Arthritis Advisory Committee, as stated in its Charter is to review and evaluate available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases, and to make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Turk has advised the Food and Drug Administration that he has financial interests that could potentially be affected by his participation in the matter at issue. Dr. Turk serves on the advisory board for _____ on issues unrelated to the matter coming before the committee or the competing products. Dr. Turk also serves as a consultant to _____ on treatments with opioids. Dr. Turk receives minimal compensation for these activities. _____, a competing product to Celebrex is _____ by _____, and _____ makes two of the many competing products to Celebrex.

As a member of the Arthritis Drugs Advisory Committee, Dr. Turk 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. Turk 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. Turk, which would permit him to participate in the matter previously described.

First, Dr. Turk's interests are not so substantial as to preclude his participation in this matter. He receives minimal compensation from _____ and _____.

Second, with respect to Dr. Turk's interests in _____ it is important to consider that this interest is unrelated to the product coming before the committee, or the competing products. Narcotic pain relievers do not decrease the inflammation that occurs with arthritic diseases. Narcotic drugs work on pain receptors on nerve cells to relieve pain associated with arthritis/JRA and are generally used as adjunct to first line therapies.

Third, the uniqueness of Dr. Turk's qualification justifies granting this waiver. Dr. Turk is a standing member of the Arthritis Advisory Committee. His background is in pain management with expertise in behavioral therapy, interdisciplinary rehabilitation and clinical trials. As a founding member of both the International Association for the Study of Pain and the American Pain Society, Dr. Turk possesses the clinical and trial design expertise to be able to appropriately evaluate the studies on which the sponsor seeks to approval of this product for the treatment of signs and symptoms of juvenile rheumatoid arthritis. Dr. Turk has been nationally recognized by the Academy of Behavioral Medicine Research, and the Society of Behavioral Medicine as an expert in the field of pain management and was identified as one of the "Top 10 leaders in pain research and treatment development." Specializing in the psychology of chronic pain and analgesics, Dr. Turk has taken several initiatives to disperse his knowledge about chronic pain and how to deal with it. His opinion and expertise would be of significant contribution to the meeting in which the committee will deliberate the approval of a product intended to alleviate pain and other symptoms in a pediatric population.

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. Dennis Turk is a professor of anesthesiology and Pain Research and Director of the Fibromyalgia Research Center at the University of Washington, School of Medicine in Seattle. He has presented numerous educational courses and workshops on the subjects of Assessment and Treatment of Chronic Pain, and Cognitive-Behavioral Therapy of Chronic Pain, and has published extensively in numerous book chapters, journals, abstracts in these areas. Dr. Turk is a member of numerous professional societies, such as the American Psychological Association, the Academy of Behavioral Medicine Research, the American Pain Society, and Fellow, the Society of Behavioral Medicine. I believe his participation will contribute to the diversity of opinions and expertise represented on the committee and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Dennis Turk, Ph.D., a waiver that will permit him to participate in all official matters concerning the safety and efficacy of New Drug Application NDA 20-998, supplement 021, trade name, Celebrex (celecoxib), a non-steroidal anti-inflammatory drug (COX-2 inhibitor), manufactured by Searle Ltd. for G.D. Searle LLC, subsidiaries of Pfizer, for the proposed indication of the relief of the signs and symptoms of juvenile rheumatoid arthritis (JRA) in patients two years and older. I believe that such a waiver is

appropriate because in this case, the need for the services of Dennis Turk, Ph.D., outweighs the potential for a conflict of interest created by the financial interests attributable to him.

CONCURRENCE:

15/ 11/8/06
Vince Tolino Date
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.

15/ 11/8/06
Randall Lutter, Ph.D. Date
Associate Commissioner for Policy
and Planning
Food and Drug Administration