DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: October 20, 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. /S/
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for Thomas J.A. Lehman, M.D.

I am writing to request a waiver for Thomas J.A. Lehman, 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). 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. Lehman 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 any other person whose interests are imputed to the employee under 18 U.S.C. §208. Since Dr. Lehman 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. Lehman 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 coming before the Arthritis Drugs Advisory Committee for consideration and is a particular matter involving specific parties.

The function of the Arthritis Drugs Advisory Committee 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. Lehman 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. Lehman is on Speaker's Bureaus for ——— and ———. He speaks on the care of children with rheumatic diseases. ——— ———, and ——— makes ——— and ———, competing products.**

As a voting consultant advising the Arthritis Drugs Advisory Committee, Dr. Lehman could potentially become involved in matters that could affect his financial interests. 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. Lehman 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. Lehman that would permit him to participate in the matter previously described.

First, and foremost, it is important to note that Dr. Lehman's interests in ——— and ——— are unrelated to the particular matter in which he is being asked to participate, or to the competing products.

Second, his interests are not so substantial as to preclude his participation in this matter. He receives minimal compensation for his Speaker's Bureau activities.

Third, the uniqueness of Dr. Lehman's qualification justifies granting this waiver. Dr. Lehman has been involved in the field of rheumatology for nearly 30 years, including serving on the committees for the Section on Rheumatology of the American Academy of Pediatrics and with the Pediatric Rheumatology Executive Council of the American College of Rheumatology. He has extensive experience with pediatric rheumatology clinical trial development and design through years of working with the Pediatric Rheumatology Collaborative Study Group and the Childhood Arthritis and Rheumatology Research Alliance). These organizations are the key pediatric rheumatology organizations for academic clinicians to collaborate on the identification of clinical conditions in pediatric rheumatology for investigation and the development of clinical trial design for patients with rheumatic diseases. Dr. Lehman's involvement in the conduct of these clinical trials has provided him the opportunity to gain experience with the evaluation of safety data in clinical trials. His contribution to the committee's discussion of the potential safety concerns associated with the use of Celebrex will be invaluable.

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. Lehman'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. Lehman is Chief of the Division of Pediatric Rheumatology at the Hospital for Special Surgery in New York City, and Professor of Clinical Pediatrics, Cornell University Medical College. He is a recognized expert in the rheumatic diseases of childhood and under his direction, the

Division of Pediatric Rheumatology has become one of the preeminent Pediatric Rheumatology programs for both patient care and physician education. He is a Fellow of the American College of Rheumatology, the American Academy of Pediatrics, and the Western Society for Pediatric Research. Dr. Lehman is the author of more than 40 peer-reviewed publications in pediatric rheumatology as well as over 25 invited manuscripts and textbook chapters. Many of these publications are devoted to animal models of rheumatic diseases, including juvenile rheumatoid arthritis. Dr. Lehman's participation is essential to the committee's discussion of whether the data submitted in support of the supplemental New Drug Application for Celebrex demonstrates that the product is safe and effective for use in pediatric patients with juvenile rheumatoid arthritis.

Accordingly, I recommend that you grant Dr. Thomas J.A. Lehman 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

Dr. Lehman outweighs the potential for a conflict of interest created by the financial interests attributed to him.

CONCURRENCE: /s/ 11/2/06

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.

/s/ 11/2/06

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