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 Patricia Chesney, M.D.

I am writing to request a waiver for Patricia Chesney, 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. Patricia Chesney 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. Chesney is a special Government employee, she 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 her, her spouse, minor child, or general partner; an organization or entity for which she serves as an officer, director, trustee, general partner, or employee; and, a person with whom she is negotiating for, or has an arrangement concerning, prospective employment.

Dr. Chesney 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. Patricia Chesney has advised the Food and Drug Administration that she has a financial interest that could potentially be affected by her participation in the matter at issue. **Dr. Chesney's ——— owns stock in——— and ———. Subsidiaries of ———, ——————— and ————————, manufacture ————.. ——— manufactures ———————— and ———, which are competing products to Celebrex.**

As a voting Consultant advising the Arthritis Drugs Advisory Committee, Dr. Chesney could potentially become involved in matters that could affect her financial interests. Under section 208, she 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. Patricia Chesney 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 Patricia Chesney, M.D., that would permit her to participate in the matter previously described.

First, Dr. Chesney's ———————— stock interests represent less than 5% percentage of ——— total net worth.

Second, the uniqueness of Dr. Chesney's qualification justifies granting this waiver. Dr. Chesney was chair of the Pediatric Advisory Subcommittee from 1999 to 2004 and chair of the Pediatric Advisory Committee (PAC) from 2004 to 2005. She has

participated in a number of pediatric meetings directed at ethical issues that were brought to the Pediatric Advisory Subcommittee and Pediatric Advisory Committee (PAC). In addition to a number of other controversial product reviews, it was during her tenure that the SSRI's and their possible association with an increase risk of suicidality in the pediatric population was reviewed. Dr. Chesney's experience in assessing drug safety in the pediatric population is enormous. During her tenure as Chair of the Pediatric Advisory Committee (PAC), over 50 products that had been studied in pediatrics were brought to the PAC for an assessment of their post-marketing safety. She has shown great thoughtfulness and care in making sure all opinions were heard and in providing a fair balance to the various perspectives. Her knowledge of pediatric trials is extensive and I think there is hardly anyone who has the experience she has with reviewing pediatric trials.

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. Chesney'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. Chesney is Professor of Pediatrics at the University of Tennessee, Director of Academic Programs at the St. Jude Children's Research Hospital and a member of the St. Jude Children's Hospital's Department of Infectious Diseases. Dr. Chesney is board certified by the American Board of Pediatrics, with a sub-board in Infectious Disease. She is a member of numerous professional societies, such as the American Academy of Pediatrics, the American Pediatric Society, the Infectious Disease Society of America, and the Society for Pediatric Research. Dr. Chesney has written over 50 book chapters and 100 journal articles and abstracts on topics such as pediatric infectious diseases, pneumococcal infections, and bacterial pathogenesis. I believe that Dr. Chesney's expertise in pediatrics and infectious diseases will contribute to the diversity of viewpoints and expertise represented and will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Patricia Chesney, M.D., a waiver that will permit her 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. Patricia Chesney outweighs the potential for a conflict of interest created by the financial interests attributed to her.

CONCURRENCE: /s/ 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.

/s/ 11/8/06

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