DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: November 6, 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 Carl Norden, M.D.

I am writing to request a waiver for Carl Norden, M.D., a voting 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 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. Norden 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. Norden 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. Norden has been asked to participate in all official matters concerning the overall benefit to risk considerations for the approved product, Ketek (telithromycin), new drug application (NDA) 21-144, manufactured by Sanofi-Aventis with the current indications of acute bacterial exacerbations of chronic bronchitis, acute bacterial sinusitis, and community acquired pneumonia. This issue is coming before a joint meeting of the Anti-Infective Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee and is considered a particular matter involving specific parties.

The committees' functions, as stated in their Charters, are as follows: The Anti-Infective 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 infectious diseases and disorders. The Drug Safety and Risk Management Advisory Committee 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 committees make their appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Norden 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. Norden has an on-going consulting agreement with ——— to work on projects for the firm as needed. Dr. Norden's last project for ——— ended in April, 2006, and concerned osteomyelitis, an infection of the bone. According to Dr. Norden, this issue is unrelated to the product and competing products coming before the committees because oral antibiotics such as Ketek (telithromycin) and its competing products are not as effective in penetrating the site of infection (i.e., bone and joint cavities) as intravenous antibiotics and, therefore, are not generally used to treat osteomyelitis. ——— manufactures ——————————— and the generic ——————— product through its subsidiary, ——————————. These products are competing products to Ketek (telithromycin).**

Dr. Norden also owns stock in ——————————. ——— ——————— subsidiary, ——————————, manufactures ——————————, a competing product to Ketek (telithromycin).

As a voting consultant advising the committees, Dr. Norden 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. Norden 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. Norden, which would permit him to participate in the matter described above.

First, Dr. Norden's interest in ———is not so substantial as to preclude his participation in this matter. He receives minimal compensation for his consulting activities.

Second, Dr. Norden's interest in ——— is unrelated to the issues to be discussed and the affected products. Arguably, his interest does not constitute a financial interest in the matter under 18 U.S.C. § 208(a). Nevertheless, in the utmost of caution, I recommend that this wavier be granted.

Third, the uniqueness of Dr. Norden's qualification justifies granting this waiver. Dr. Carl Norden is the only infectious disease physician on the committee with expertise in pharmacovigilance and adverse event reporting systems for marketed antibiotics. Dr. Norden's experience in clinical practice, academia, and industry gives him unique expertise with regard to benefit/risk consideration of marketed antibiotics, prudent use, and the formal assessment of safety in the post-marketing period.

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 advisory committee. In addition, the committees' 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 because of their demonstrated abilities. Dr. Norden is an experienced clinician and researcher in the area of infectious diseases. His experience in industry includes taking new antibiotics through development, including assessment in the post-marketing period to further define drug safety with widespread usage. His work as an academic infectious disease physician began when treatment options for respiratory infections were limited to a few antibiotics, namely penicillin,

sulfa, and chloramphenicol. As a practicing physician, Dr. Norden witnessed the emergence of serious drug side effects (e.g., chloramphenicol and aplastic anemia, penicillin and anaphylaxis) that altered their risk/benefit calculation and physician prescribing patterns, as well as the development of resistant bacteria, prompting the need for discovery of novel antimicrobial compounds to advance the public health. I believe Dr. Norden's participation will contribute to the diversity of opinions and expertise represented on at this meeting and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Carl Norden, M.D., a waiver that will permit him to participate in all official matters concerning the overall benefit to risk considerations for the approved product, Ketek (telithromycin), new drug application (NDA) 21-144, manufactured by Sanofi-Aventis with the current indications of acute bacterial exacerbations of chronic bronchitis, acute bacterial sinusitis, and community acquired pneumonia. I believe that such a waiver is appropriate because in this case, the need for the services of Carl Norden, M.D., outweighs the potential for a conflict of interest created by the financial interests attributable to him.

CONCURRENCE: /s/ 11/15/06

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

Date

DECISION:

X 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/ 11/21/06

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

Date