DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administra
Rockville MD 20857

DATE: August 28, 2006

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

THROUGH: Jenny Slaughter
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 Charles Cooney, Ph.D.

I am writing to request a waiver for Charles Cooney, Ph.D., a member of the Pharmaceutical Science 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. Cooney 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. Cooney 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. Cooney has been asked to participate in all official matters concerning the committees' discussions of FDA's efforts to assess the product quality of currently marketed levothyroxine sodium drug products. Earlier this year, FDA requested that manufacturers of currently marketed levothyroxine sodium products provide to it certain product release and stability information. The committees' will consider FDA's analyses and any clinical significance. This issue is coming before a joint meeting of the Endocrinologic & Metabolic Drugs Advisory Committee and the Advisory Committee for Pharmaceutical Science.

The functions of the Pharmaceutical Science Advisory Committee, as stated in its Charter, are to provide advice on scientific and technical issues concerning the safety, and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases, and as required, any other product for which the Food and Drug Administration has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs. The Committee may also review Agency sponsored intramural and extramural biomedical research programs in support of FDA's generic drug regulatory responsibilities.

Dr. Cooney has advised the Food and Drug Administration that he has a financial interest that could potentially be affected by his participation in the matter at issue. **Dr. Cooney serves as a consultant to ——— on a matter unrelated to that coming before the committees' for consideration. Dr. Cooney receives moderate compensation for his participation. ——————————, is distributed by ———, a subsidiary of ———.**

As a member of the Pharmaceutical Science Advisory Committee, Dr. Cooney 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. Cooney 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. Cooney, which would permit him to participate in the matter previously.

First, Dr. Cooney's interest is not so substantial as to preclude his participation in this matter. He receives moderate compensation.

Second, Dr. Cooney's interest in ———— is unrelated to the issue coming before the committee, and the affected products. Arguably, his interest does not constitute a financial interest in the particular matter within the meaning of 18 U.S.C. §208(a). Nevertheless, I recommend that this waiver be granted.

Third, this waiver is also justified, in part, because of the nature of matters to be discussed. The committees' discussions of FDA's efforts to assess the product quality of currently marketed levothyroxine sodium drug products, will not have a unique and distinct impact on any particular levothyroxine product or manufacturer. Rather, the committees' discussions and FDA's subsequent action could affect all levothyroxine products and their manufacturers to the same extent. While this participation may be covered by section 208, it poses far less risk of conflict than participation in matters that relate specifically to a particular firm in which Dr. Cooney has an interest.

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. Also, 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 as a result of their demonstrated abilities. Dr. Charles Cooney is Professor of Chemical and Biochemical Engineering in the Department of Chemical Engineering. He is the Faculty Director of the Deshpande Center for Technological Innovation, and Co-Director of the Program on the Pharmaceutical Industry at Massachusetts Institute of Technology. His research interests span a range of topics in biochemical engineering and pharmaceutical manufacturing. He has particular interest in computer control of biological processes, downstream processing

for recovery of biological products, bioreactor design and operation and mixing of dry powders. Among awards and distinctions, Dr. Cooney was nominated Founding Fellow, American Institute for Medical and Biological Engineering in 1992; received the Gold Medal from the Institute of Biotechnological Studies in 1989; the James Van Lannen Award for Distinguished Service to the Division of Microbial and Biochemical Technology of the American Chemical Society in 1985; and received the Food, Pharmaceutical and Bioengineering Division Award from the American Institute of Chemical Engineers in 1983. Dr. Cooney is a long-standing member of the American Association for the Advancement of Science, the American Chemical Society, the Division of Microbial and Biochemical Technology, and the American Institute of Chemical Engineers. I believe his participation will contribute to the diversity of viewpoints and expertise represented and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Charles Cooney, Ph.D., a waiver that will permit him to participate in all official matters concerning the committees' discussions of FDA's efforts to assess the product quality of currently marketed levothyroxine sodium drug products. Earlier this year, FDA requested that manufacturers of currently marketed levothyroxine sodium products provide to it certain product release and stability information. The joint committee will consider FDA's analyses and any clinical significance. I believe that such a waiver is appropriate because in this case, the need for the

services of Charles Cooney, Ph.D., outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE: /S/ 9/13/06

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

Date

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/ 9/14/06

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

Date