DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: September 12, 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., Chair 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 the Pharmaceutical Advisory Committee meeting where the committee will: (1) receive presentations and discuss bioequivalence issues pertaining to highly variable drugs; (2) discuss current thinking on issues and definitions pertaining to nanotechnology; (3) discuss implementation of definitions for topical dosage forms; and, 4) receive an update and discuss current strategies and direction for the Critical Path Initiatives. The issues to be discussed are particular matters of general applicability. Particular matters of general applicability focus on a discrete and identifiable class of persons (i.e., all pharmaceutical companies), but do not involve specific parties (i.e., a particular firm's product).

The function of the Pharmaceutical Science Advisory Committee, as stated in its charter, is 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 matters under discussion by the Pharmaceutical Science Advisory Committee. Dr. Cooney is a consultant to ———— concerning continuous manufacturing technology. ———— could potentially be affected by the committee's discussions.

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 matters previously described.

First, this waiver is justified, in part, because of the general nature of particular matters of general applicability. It is well recognized that particular matters of general applicability pose far less risk of a conflict of interest. Particular matters of general applicability include regulations, points-to-consider, guidelines, and policies governing classes of individuals, products, and organizations. Particular matters of general applicability do not include particular matters involving specific parties, such as recommendations regarding a specific product, or enforcement matters involving known parties. Particular matters of general applicability will not have a special or distinct impact on any of Dr. Cooney's interest, other than as part of a class.

Second, arguably, Dr. Cooney's interest in ——— does not constitute a financial interest in the particular matter within the meaning of 18 U.S.C. §208(a) since he consults on matters unrelated to the issues at hand. Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

In addition, Dr. Cooney's financial interest is not so substantial as to preclude his participation. He receives moderate compensation.

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. Cooney'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. Cooney is Professor of Chemical and Biochemical Engineering, in the Department of Chemical Engineering at the Massachusetts Institute of Technology (MIT). In addition, he is Faculty Director of the Deshpande Center for Technology Innovation, and Co-Director of

the Program on the Pharmaceutical Industry, and Massachusetts Institute of Technology Faculty Director of the Consortium on Advanced Manufacturing for Pharmaceuticals. He received the 1989 Gold Medal of the Institute of Biotechnological Studies (London), the Food Pharmaceutical, and Bioengineering Award from the American Institute of Medical and Biochemical Engineers. Dr. Cooney is on several editorial boards of professional journals, and sits on the Boards of Directors of Genzyme, BioProcessors, and Biocon, Ltd. (India). His research interests span a range of topics in biochemical engineering and pharmaceutical manufacturing. He has published over 300 research papers and co-authored or edited three books. Dr. Cooney has particular interest in bioreactor design, operation, and control, downstream processing for recovery of biological products, processing of pharmaceutical powders and manufacturing strategy in the pharmaceutical and biotech industry. The central philosophy underlying research in his laboratory is the application of multidisciplinary approaches to the development of advanced manufacturing technologies for the biochemical and pharmaceutical industry. As faculty director of the Deshpande Center, he is interested in the process of converting technological innovation into new company creation. I believe that Dr. Cooney's participation will help contribute to the diversity of viewpoints 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 Charles Cooney, Ph.D., a waiver that will permit him to participate in the Pharmaceutical Advisory Committee meeting where the committee will: (1)Receive an awareness presentation on risk management for complex pharmaceuticals; (2) Receive presentations and discuss bioequivalence issues pertaining to highly variable drugs;(3) Discuss current thinking on issues and definitions pertaining to nanotechnology; (4)Discuss implementation of definitions for topical dosage forms; and,(5) Receive an update and discuss current strategies and direction for the Critical Path Initiatives. I believe that such a waiver is appropriate because in this case, the need for the services of

Dr. Cooney outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE: /S/ 9-14-06

Jenny Slaughter
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/ 9-18-06

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

Date