DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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 Melvin Koch, Ph.D.

I am writing to request a waiver for Melvin Koch, 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. Koch 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. Koch 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. Koch has been asked to participate in the Pharmaceutical Advisory Committee meeting where the committee will: (1) receive an update on the International Conference on Harmonization (ICH) Quality Topics (Q8, Q9, Q10, Q4B, QOS) and discuss the impact on current regulatory direction; (2) receive and discuss a series of presentations from the different offices within the Office of Pharmaceutical Science on progress being made on quality-by-design (QBD) initiatives, followed by presentations from the pharmaceutical industry trade associations (the Generic Pharmaceutical Association [GPhA], and the Pharmaceutical Research and Manufacturers of America [PhRMA]) on their QBD perspectives and issues; (3) receive an awareness presentation on risk management for complex pharmaceuticals; (4) receive presentations and discuss bioequivalence issues pertaining to highly variable drugs; (5) discuss current thinking on issues and definitions pertaining to nanotechnology; (6) discuss implementation of definitions for topical dosage forms; and, (7) 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 individuals, products, and organizations (i.e., pharmaceutical and biotechnology firms), but do not involve specific parties (i.e., a specific company'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. Koch has advised the Food and Drug Administration that he has financial interests that potentially could be affected by his participation in the matters coming before the committee. Dr. Koch owns stock in ——— and ———, two companies that could be affected by the particular matters of general applicability to be discussed.

As a member of the Pharmaceutical Science Advisory Committee, Dr. Koch potentially could become involved in

matters that could affect his financial interests. 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. Koch 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. Koch, which would permit him to participate in the particular matters of general applicability 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. Koch's financial interests, other than as part of a class (i.e., all pharmaceutical and biotechnology companies).

Second, Dr. Koch's interests are not so substantial as to preclude his participation. Each stock represents a small percentage of his total net worth.

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. Koch'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. Melvin Koch is director of the Center for Process Analytical Chemistry (CPAC), a consortium of industrial, government laboratories, and academia addressing multidisciplinary challenges in Process Analytical Technology (PAT) and Process Control through fundamental and directed academic research. Prior to joining CPAC, Dr. Koch worked for the Dow Chemical Company in process research and analytical chemistry, achieving the level of Global Director of Analytical

Sciences. He is active in coordinating developments in the field of process analytical technology (PAT) between industry, government laboratories, and academia. I believe that Dr. Koch's participation will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Melvin Koch, Ph.D., a waiver that will permit him to participate in the Pharmaceutical Advisory Committee meeting where the committee will: (1) receive an update on the International Conference on Harmonization (ICH) Quality Topics (Q8, Q9, Q10, Q4B, QOS) and discuss the impact on current regulatory direction; (2) receive and discuss a series of presentations from the different offices within the Office of Pharmaceutical Science on progress being made on quality-by-design (QBD) initiatives, followed by presentations from the pharmaceutical industry trade associations (the Generic Pharmaceutical Association [GPhA], and the Pharmaceutical Research and Manufacturers of America [PhRMA]) on their QBD perspectives and issues; (3) receive an awareness presentation on risk management for complex pharmaceuticals; (4) receive presentations and discuss bioequivalence issues pertaining to highly variable drugs; (5) discuss current thinking on issues and definitions pertaining to nanotechnology; (6) discuss implementation of definitions for topical dosage forms; and, (7) 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. Koch

outweighs the potential for a conflict of interest created by the financial interests 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