DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: September 11, 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 Carol Gloff, Ph.D.

I am writing to request a waiver for, Carol Gloff 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. Gloff, 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. Gloff 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. Gloff 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 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. Gloff has advised the Food and Drug Administration that she has financial interests that could potentially be

affected by her participation in the matters to be discussed. Dr. Gloff owns stock in ———, ———, and ———. These firms could potentially be affected by the committee's discussions.

In addition, Dr. Gloff is Principal of Carol Gloff & Associates, a consulting firm to the medical products industry. She is currently consulting with ———, ——— ———, ———, ———, ———, ———, and ———. According to Dr. Gloff, her consulting is unrelated to the issues to be discussed by the committee. Dr. Gloff's primary work is as a regulatory consultant, and her consulting activities are primarily focused on writing and editing documents for regulatory submission, for example, Investigational New Drug (IND) sections, New Drug Application (NDA) sections, investigator brochures, and IND annual reports. Occasionally she reviews pharmacokinetic protocols and helps to interpret, but not analyze, data.

Finally, Dr. Gloff recently completed consulting for the ———, ——— ———, ———, ———, and ——— ———. Although she has no upcoming assignments, it is possible that these firms could contact her, as needed, to work on other projects.

As a member of the Pharmaceutical Science Advisory Committee, Dr. Gloff potentially could become involved in matters that could affect her financial interests. Under 18 U.S.C. §208(a), 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. Gloff 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. Gloff, which would permit her 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. Gloff's financial interests, other than as part of a class.

Second, arguably, Dr. Gloff's consulting interests do not constitute financial interests in the particular matter of general applicability within the meaning of 18 U.S.C. §208(a), since she consults on matters unrelated to the issues to be discussed. Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

In addition, the remuneration she receives for the majority of her consulting is moderate.

Moreover, it is unlikely that Dr. Gloff's participation in the advisory committee meeting will have an affect on her current and future consulting. Carol Gloff & Associates has been in existence for more than ten years. Dr. Gloff consults for a number of firms and does not rely upon one or two sources for her income. Over the past thirty years, Dr. Gloff worked for a variety of pharmaceutical companies, developing and executing regulatory strategies. Because she has extensive practicable experience in regulatory affairs, clinical pharmacokinetics, non-clinical pharmacology/toxicology, and product development, numerous firms seek her services.

Further, with respect to her stock interests it is significant to consider that the issues to be discussed will not focus on any particular company or product. Rather, potentially all pharmaceutical and biotechnology firms could be affected as a class. It is unlikely that the issues in which Dr. Gloff will participate will have a unique and distinct impact on her stock holdings.

Finally, 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. Gloff'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. Gloff is an expert in pharmacokinetics. She has thirty years of practicable experience in the areas of regulatory affairs, clinical pharmacokinetics, non-clinical pharmacology/toxicology, and product development. As Principal of Carol Gloff & Associates, she consults with various medical product companies in the areas of product development, pharmacokinetics, regulatory affairs, quality, and compliance. Dr. Gloff's vast knowledge and experience in these areas is essential to the committee's discussions. The depth of knowledge and expertise that Dr. Gloff possess cannot easily be replaced.

Accordingly, I recommend that you grant Carol Gloff, Ph.D., a waiver that will permit her 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. Gloff outweigh the potential for a conflict of interest created by the financial interests attributable to her.

CONCURRENCE: /S/ 9-14-06

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

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. — Date
Associate Commissioner for
Policy and Planning
Food and Drug Administration