DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: December 4, 2006

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

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 Paula Adams Hillard, M.D.

I am writing to request a waiver for Paula Adams Hillard, M.D., serving on the Advisory Committee for Reproductive Health Drugs as a consultant, 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. Hillard, 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 her employer has a financial interest. Since Dr. Hillard is a special Government employee, she is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to her or her employer.

Dr. Hillard has been asked to participate in the discussions of the current issues that influence the consideration for

approval of oral and non-oral (i.e., transdermal and intravaginal) hormonal contraceptive drug products. Issues for discussion will include clinical trial design, expectations for efficacy and safety outcomes, and measures of acceptability of the product to the user, including cycle control. These matters are coming before the Advisory Committee for Reproductive Health Drugs for consideration and are particular matters of general applicability.

The function of the Committee, as stated in its Charter, is to review and evaluate data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and related specialties, and makes appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Hillard has advised the Food and Drug Administration that she has financial interests that could potentially be affected by her participation in the matter to be discussed. Dr. Hillard is a member of ———— 's Contraception Advisory Board and a consultant to ———— and —— regarding unrelated products.

As a consultant advising the Advisory Committee for Reproductive Health Drugs, Dr. Hillard 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. Hillard 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. Hillard allowing her to participate in the matters previously described.

First, the Committee discussions are a matter of general applicability, involving an entire class of oral and non-oral hormonal contraceptive drug products and granting no advantage to any individual manufacturer. Therefore, the potential concern that Dr. Hillard's impartiality might be called into question during Committee deliberations should be minimized.

Second, given the nature of Dr. Hillard's interests, there is little likelihood that the Committee's recommendations will affect the viability of these firms or her ongoing relationships with them. Therefore, the potential concern that

Dr. Hillard's impartiality might be called into question during the Committee's deliberations should be diminished.

Third, the amount of compensation that Dr. Hillard receives for consulting and advisory board membership is not so substantial as to preclude her participation in this meeting.

Fourth, the uniqueness of Dr. Hillard's qualifications justifies granting this waiver. Dr. Hillard is an expert in adolescent gynecology and contraceptive compliance. Dr. Hillard's expertise is valuable to the committee because her views on the issue of contraceptive compliance in clinical trials and in the general population of contraceptive users will be one of the main issues to be discussed at the meeting.

Moreover, the Committee's role is advisory in nature and the Agency officials making the decisions are not bound by the recommendations of the Committee. Therefore, the Agency will take into consideration the involvements of Dr. Hillard when making a final decision.

Lastly, 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 committee. Also, 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. Paula Adams Hillard, M.D., is Professor of Obstetrics and Gynecology, Professor of Pediatrics, and the Director of Women's Health at the University of Cincinnati College of Medicine. Dr. Hillard is a nationally recognized leader on issues of adolescent gynecology and contraceptive compliance. She has authored several articles and textbook chapters on obstetrics and gynecology. *Good Housekeeping* magazine named her one of the "Best Doctors for Women". I believe that Dr. Hillard's participation will contribute to the diversity of expertise and viewpoints represented and will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Paula Adams Hillard, M.D., a waiver that will permit her to participate fully in all official matters before the Committee related to the discussions of current issues that influence the consideration

for approval of oral and non-oral (i.e., transdermal and intravaginal) hormonal contraceptive drug products. Issues for discussion will include clinical trial design, expectations for efficacy and safety outcomes, and measures of acceptability of the product to the user, including cycle control. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Hillard outweighs the potential for a conflict of interest created by the financial interests involved.

CONCURRENCE: _____/s/_____ 12/19/06
Vince Tolino 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/_____ 12/22/06
Randall Lutter, Ph.D. Date
Associate Commissioner for
Policy and Planning