DEPARTMENT OF HEALTH & HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Rockville MD 20857

DATE: November 3, 2005

TO: Shelia Dearybury Walcoff, Esq.
Associate Commissioner for External Relations
Food and Drug Administration

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

FROM: Igor Cerny, Pharm.D.
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for Edmund Capparelli, Pharm.D.

I am writing to request a waiver for Edmund Capparelli, Pharm.D., a consultant to the Center for Drug Evaluation and Research, from the conflict of interest prohibitions of 18 U.S.C. §208(a). The appointing official may grant waivers under 18 U.S.C. §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. Capparelli a waiver under section 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 his employer has a financial interest. Since Dr. Capparelli is a special Government employee, he 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 him or his employer.

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. Capparelli has been asked to participate in all official matters concerning the discussions of the current evidence related to the pharmacogenetics of warfarin as a potential basis for label updates.

Dr. Capparelli has advised the Food and Drug Administration (FDA) that he has a financial interest that could potentially be affected by his participation in the matter described above. Dr. Capparelli is a member of [redacted]) on an unrelated issue. [redacted] is the sponsor of [redacted] ([redacted]), a competing product to [redacted]

As a consultant participating in the Clinical Pharmacology Subcommittee meeting, Dr. Capparelli could potentially become involved in matters that could affect his financial interest. Under section 208, 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. Capparelli 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. Capparelli which would permit him to participate in the matter described above.

First and foremost, this waiver is justified, in part, because Dr. Capparelli's interest is unrelated to the particular matter in which he is being asked to participate, or to the competing 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, in the utmost of caution, I recommend that this waiver be granted.

Second, Dr. Capparelli's interest is not so substantial as to preclude his participation in this matter. He receives minimal compensation for serving on the [redacted]

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. Capparelli'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. Capparelli is Associate Clinical Professor of Pediatrics and Co-Director, Pediatric Pharmacology Research Unit, University of California, San Diego. Dr. Capparelli is a registered pharmacist. His research interests are in pediatric pharmacology and pharmacokinetics. He has written over 100 publications and abstracts. Dr. Capparelli is a member of various professional societies, such as the American Society of Hospital Pharmacists, American College of Clinical Pharmacy, and the American Society for Clinical Pharmacology and Therapeutics. Dr. Capparelli's participation will contribute to the diversity of expertise and opinions represented on the committee.

Accordingly, I recommend that you grant Edmund Capparelli, Pharm.D., a waiver that will permit him to participate in all official matters concerning the discussions of the current evidence related to the pharmacogenetics of warfarin as a potential basis for label updates. I believe that such a waiver is appropriate because in this case, the need for the services of Dr.

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

CONCURRENCE: Mary Ann Kellman for 11/08/05

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

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.

[signature] for 11-10-05

Shelia Dearybury Walcoff, Esq. Date
Associate Commissioner for External Relations
Food and Drug Administration

Disclosure Document for 18 U.S.C. §208(b)(3) Waiver

Edmund Capparelli, Pharm.D.

Committee: Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science

Meeting Date: November 14, 2005

I acknowledge that contingent upon public disclosure of the financial interest listed below, related to the agenda item, to discuss current evidence related to the pharmacogenetics of warfarin as a potential basis for label updates, I am eligible to receive a waiver under 18 U.S.C. §208(b)(3).

Type of Interest	Nature	Magnitude
Consulting Data Safety Monitoring Board	Sponsor of a competing product.	Less than $10,001 per year.

I hereby request that FDA make this information publicly available on my behalf at the start of the advisory committee meeting for which it is issued. The public disclosure will be accomplished by reading the statement into the record and by making a written copy publicly available at the time of the meeting. I understand that without public disclosure of this interest the waiver is not valid.

Signature of SGE

11/7/05
Date