MEMORANDUM

DATE: November 3, 2006

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

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 Jean Bronstein, R.N., M.S.

I am writing to request a waiver for Jean Bronstein, R.N., M.S., the Consumer Representative member of the Psychopharmacologic Drugs Advisory Committee, 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 Ms. Bronstein 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 her employer has a financial interest. Since Ms. Bronstein 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.

The function of the Psychopharmacologic Drugs Advisory Committee is to review and evaluate data concerning the safety and effectiveness of marketed and investigational

human drug products for use in the practice of psychiatry and related fields and make appropriate recommendations to the Commissioner of Food and Drugs.

Ms. Bronstein has been asked to participate in all official matters concerning the discussions of the results of the FDA ongoing meta-analysis of suicidality data from adult antidepressant trials. This matter is coming before the Psychopharmacologic Drugs Advisory Committee and is a particular matter involving specific parties.

Ms. Bronstein has advised the Food and Drug Administration (FDA) that she ———— have financial interests that could potentially be affected by her participation in this matter. Ms. Bronstein owns stock and a bond in ———— . ———— is the co-sponsor of ——— a product that could potentially be affected by the committees discussions. Ms. Bronstein —— ———— also own stock in ————. ———— makes ——— and ————, products that could potentially be affected by the committees discussions. These investments represent a small percentage of ——— total net worth.

As the consumer representative member of the Psychopharmacologic Drugs Advisory Committee, Ms. Bronstein could potentially become involved in matters that could affect her ———— financial interests. Under section 208, 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 Ms. Bronstein 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 Jean Bronstein, R.N., M.S., that would allow her to participate in all official matters as previously described.

First, Ms. Bronstein's ———— financial interests are not so substantial as to be deemed likely to impact her impartiality in this matter. The investments represent a small percentage of ——— total net worth.

Second, the uniqueness of Ms. Bronstein's qualification justifies granting this waiver. Ms. Bronstein is the appointed committee consumer representative. As a senior member of the committee and previous attendee of the pediatric suicidality SSRI advisory committee meetings, her participation will lend continuity and leadership for newly appointed consultants and those who have not participated in the previous SSRI meetings. In addition, Ms. Bronstein is a retired nurse with decades of experience in the field of psychiatry. Ms. Bronstein's perspective is unique, in that it respresents the consumer. Ms. Bronsteins's perspective has often lead the committee discussion to be viewed much differently than that of a researcher or physician. Since she is the only consumer representative invited, her role is of significant importance in helping to provide FDA with a balanced recommendation of the topic at hand.

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 Ms. Bronstein'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. Ms. Bronstein is a retired Staff Nurse, who was responsible for the care of and case management for acute psychiatric patients in a Partial Hospitalization Program. Since 1967, she has organized and developed many lectures, topics and courses, on such issues as "Suicide and the Nurse," "Toxic Psychosis," "Anorexia Nervosa," and "Dialectical Behavioral Therapy." Ms. Bronstein will be participating in the meeting as a Consumer Representative. Her professional consultation and research experience will be essential to the committee's discussions and will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant a waiver to Jean Bronstein, R.N., M.S., that will permit her to participate in all official matters concerning the discussions of the results of the FDA ongoing meta-analysis of suicidality data from adult antidepressant trials. I believe that such a waiver is appropriate because in this case, the need for the services of Jean Bronstein, R.N., M.S., outweighs the potential for a conflict of interest created by the financial interests attributable to her.

CONCURRENCE: /S/ 11/20/06

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/ 11/22/06

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