DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: January 17, 2006

TO: Jason D. Brodsky
Acting 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 Elizabeth Andrews, M.P.H., Ph.D.

I am writing to request a limited waiver for Elizabeth Andrews, M.P.H., Ph.D., a consultant to the Center for Drug Evaluation and Research, from the conflict of interest prohibitions of 18 U.S.C. §208(a). Waivers under section 208(b)(3) may be granted by the appointing official 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 Elizabeth Andrews, Ph.D., 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. Andrews 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. Andrews has been asked to give a presentation before the Drug Safety and Risk Management Advisory Committee on February 9, 2006. Dr. Andrews' presentation is on "Challenges of Cardiovascular Drug Safety Epidemiology in the Post-Market Drug Arena," she will also answer questions related to her presentation.

The function of the Drug Safety and Risk Management Advisory Committee, as stated in its Charter, is to advise the Commissioner of Food and Drugs on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which the Food and Drug Administration has regulatory responsibility. The committee also advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of all information gathered by the Department of Health and Human Services and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by the Department of Health and Human Services with regard to the marketing, investigation, and control of such drugs or other substances.

Dr. Andrews has advised the Food and Drug Administration that she and her employer, Research Triangle Institute (RTI) Health Solutions, have financial interests that could potentially be affected by her participation in the matter described above. Dr. Andrews is a consultant for [redacted] and [redacted] on general topics concerning risk management. According to Dr. Andrews, her consulting is unrelated to the issue coming before the committee, and are performed under contract with her employer, Research Triangle Institute (RTI) Health Solutions. Dr. Andrews receives no direct income from any of these firms. She is a salaried employee and Vice President of Pharmacoepidemiology and Risk Management, Research Triangle Health Solutions (RTI), a business unit of RTI International. [redacted] and [redacted] make [redacted]

As a consultant advising the Drug Safety and Risk Management Advisory Committee, Dr. Andrews potentially could become involved in matters that could affect her and her employer's 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. Andrews 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 limited waiver to Elizabeth Andrews, M.P.H., Ph.D. that would permit her to give a presentation before the committee on "Challenges of Cardiovascular Drug Safety Epidemiology in the Post-Market Drug Arena," and to answer questions related to her presentation. Under the terms of this limited waiver, Dr. Andrews will be excluded from participating in the committee's discussion and vote regarding approaches that could be used to study whether Attention Deficit Hyperactivity Disorder (ADHD) products increase the risk of adverse cardiovascular outcomes.

First and foremost, this limited waiver is justified because arguably, Dr. Andrews involvements do not constitute financial interests in the particular matter within the meaning of 18 U.S.C. §208(a) since she consults on topics that are unrelated to the issue coming before the committee for discussion. Nevertheless, in the utmost of caution, I recommend that this limited waiver be granted.

Second, this limited waiver is justified, in part, because of the general nature of the topic under discussion. It is well-recognized that particular matters of general applicability pose far less risk of a conflict of interest. Particular matters of general applicability will not have a unique and distinct impact on any of Dr. Andrews' imputed financial interests, but rather may affect classes of similarly situated products and manufacturers to the same extent.

Third, to further diminish the conflict created by Dr. Andrews' interests, we have decided to limit her participation to giving a presentation on the "Challenges of Cardiovascular Drug Safety Epidemiology in the Post-Market Drug Arena," and answering questions related to her presentation.

In addition, it is unlikely that Dr. Andrews' limited participation will have a unique and distinct impact on her and her employer's interests.

Further, Dr. Andrews' employer's financial interests in [redacted] are not so substantial as to preclude her participation in this matter.

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. Andrews' 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. Andrews is the Vice President of Pharmacoepidemiology and Risk Management, Research Triangle Institute (RTI) Health Solutions, a business unit of RTI International. As a epidemiologist, she provides consultations to pharmaceutical companies on therapeutics risk management programs and directs studies to address specific questions of drug safety and appropriate utilization. She oversees the conduct of large prospective patient registries, and epidemiology and outcome research using prospective databases. Dr. Andrews is a pharmocepidemiologist with unique and extensive skills, knowledge and experience in evaluating and conducting surveillance for drug safety assessment, including extensive experience within industry in the development of drug registries to monitor for specific adverse events. In her most recent industry position Dr. Andrews served as Vice President, Worldwide for Epidemiology for GlaxoSmithKline (GSK) from January to July, 2001, and prior to the Glaxo Wellcome merger with Smith Kline Beecham was in senior epidemiology positions with Glaxo Wellcome from 1982 to 2001. In those positions, Dr. Andrews was responsible for developing worldwide drug registry programs for complex and long term safety issues. I believe that Dr. Andrews' limited participation will bring an enormous amount of experience, knowledge, and will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Elizabeth Andrews, M.P.H., Ph.D., a limited waiver that would allow her to give a presentation on "Challenges of Cardiovascular Drug Safety Epidemiology in the Post-Market Drug Arena", and to answer questions related to her presentation. Under the terms of this limited waiver, Dr. Andrews will be excluded from participating in the committee's discussion and vote regarding approaches that could be used to study whether Attention Deficit Hyperactivity Disorder (ADHD) products increase the risk of adverse cardiovascular outcomes. I believe that such a limited waiver is appropriate because in this case, the need for the services of Dr. Andrews outweighs the potential for a conflict of interest created by the financial interests attributable to her.

CONCURRENCE: _____ 1/18/06

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

Date

DECISION:

✓ Limited Waiver granted based on my determination, made in accordance with section 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.

_____ Limited Waiver denied.

_____ 1.20.06

Jason D. Brodsky
Acting Associate Commissioner for External Relations
Food and Drug Administration

Date