



DEPARTMENT OF HEALTH & HUMAN SERVICES

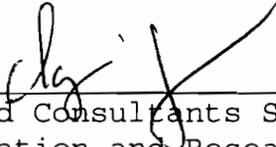
Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: March 20, 2006

TO: Jason D. Brodsky
Acting Associate Commissioner
Office 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 Thomas Pickering,
M.D., D.Phil.

I am writing to request a waiver for Thomas Pickering, M.D., D.Phil., a member of the Cardiovascular and Renal 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 Dr. Pickering 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. Pickering 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 function of the Cardiovascular and Renal Drugs Advisory Committee, as stated in its Charter, is to review and evaluate available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders and to make

appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Pickering has been asked to participate in all official matters concerning the discussion of the Agency's draft recommendations for re-labeling of anti-hypertensive drugs for outcome claims, as a follow-up to the committee's meeting on June 15, 2005, where the committee discussed class labeling of antihypertensive drugs based on the proximity of their data to outcome trials. The discussion will not focus on any particular product or firm and is a particular matter of general applicability.

Dr. Pickering has advised the Food and Drug Administration that he has a financial interest that could potentially be affected by his participation in the matter described above. Dr. Pickering is a member of _____ Speaker's Bureau. He lectures on matters unrelated to the issue coming before the committee for consideration and receives minimal compensation for his speaking. _____ has a financial connection to three of the products that could potentially be affected by the committee's discussions.

As a member of the Cardiovascular and Renal Drugs Advisory Committee, Dr. Pickering 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. Pickering 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. Pickering that would allow him to participate fully in the matter described above.

First, Dr. Pickering's personal financial interest in _____ is not so substantial as to preclude his participation in this matter. He receives nominal compensation for his speaking.

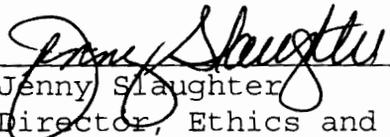
Second, arguably Dr. Pickering's interest in _____ does not constitute a financial interest in the particular matter of general applicability within the meaning of 18 U.S.C. §208(b) since he lectures on a topic unrelated to the matter at issue. Nevertheless, in the utmost of caution I recommend that this waiver be granted.

Moreover, it is important to consider that the matter in which Dr. Pickering is participating is a particular matter of general applicability. The committee's discussions will not focus on any particular product or firm. Rather, the committee's recommendations and the Agency's action on this issue could impact all firms that market or are developing antihypertensive drugs to the same extent.

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 advisory 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. Dr. Pickering is Director, Behavioral Cardiovascular Health and Hypertension Program, Columbia University College of Physicians and Surgeons. He is known for his work in behavioral influences on the recognition of white coat hypertension as a clinically important entity of behavioral origin, the role of job strain in the development of hypertension, and the use of ambulatory and home blood pressure monitoring for evaluating the cause and consequences of hypertension. He has authored more than 450 scientific articles and chapters with respect to hypertension, environmental influences on blood pressure, and advances in the treatment of hypertension. Dr. Pickering is a member of a number of prestigious professional societies, which include the American Society of Hypertension, the Society of Behavioral Medicine, the American Psychosomatic Society, and the Academy of Behavioral Medicine Research. I believe that Dr. Pickering's participation will bring an enormous amount of experience, knowledge, and expertise that is essential to the committee's discussions and will help to provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Dr. Pickering a waiver that would allow him to participate in all official matters concerning the Agency's draft recommendations for re-labeling of anti-hypertensive drugs for outcome claims, as a follow-up to the committee's meeting on June 15, 2005, where the committee discussed class labeling of antihypertensive drugs based on the proximity of their data to outcome trials. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Pickering outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE:



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

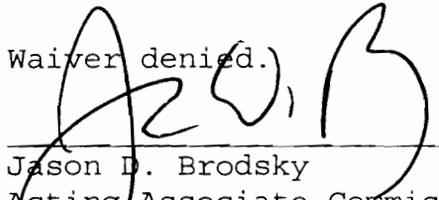
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Date

DECISION:



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.

Waiver denied.)


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

3.27.06

Date