



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: October 25, 2007

TO: Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy
Food and Drug Administration

THROUGH: Vince Tolino /s/
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

Michael F. Ortwerth, Ph.D. /s/
Deputy Director, Advisory Committee Oversight and Management Staff
Office of Policy, Planning, and Preparedness

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

SUBJECT: 712(c)(2)(B) Conflict of Interest Waiver for Thomas Pickering, M.D.

I am writing to request a waiver for Thomas Pickering, M.D., a temporary voting member of the Nonprescription Drugs Advisory Committee, from the conflict of interest prohibitions of section 712(c)(2)(A) of the Federal Food, Drug, and Cosmetic Act. Waivers under section 712(c)(2)(B) may be granted by the appointing official where "necessary to afford the advisory committee essential expertise" and where the individual has made a disclosure to FDA of the financial interests at issue. We have determined that you are the appointing official for purposes of section 712(c)(2)(B). Therefore, you have the authority to grant Dr. Pickering a waiver under section 712(c)(2)(B).

Section 712(c)(2)(A) prohibits Federal executive branch employees, including special Government employees, from participating in any particular matter in which the employee or an immediate family member has a financial interest that could be affected by the advice given to the FDA with respect to the matter. Because 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 family.

The function of the Nonprescription Drugs Advisory Committee is to review and evaluate available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad

spectrum of human symptoms and diseases and advise the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug application for such drugs. The Committee also serves as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof.

The function of the Endocrinologic and Metabolic Drugs Advisory Committee 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 endocrine and metabolic disorders and to make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Pickering has been asked to participate in the all official matters concerning the evaluation of data submitted by Merck & Co., Inc. to support the over-the-counter use of Mevacor (lovastatin) 20 milligrams a day to help lower cholesterol which may prevent a first heart attack.

This matter is coming before a joint meeting of the Nonprescription Drugs and the Endocrinologic and Metabolic Drugs Advisory Committees. This issue is a particular matter involving specific parties.

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 at issue. Dr. Pickering serves as a member of the _____ Advisory Board on _____ manufactures competing products to Mevacor (lovastatin).

As a temporary member of the Nonprescription Drugs Advisory Committee, Dr. Pickering could become involved in matters that could affect his financial interests. Under section 712(c)(2)(A), he is prohibited from participating in such matters. However, as noted above, you have the authority under section 712(c)(2)(B) to grant a waiver permitting Dr. Pickering to participate in such matters if necessary to afford this committee essential expertise.

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 because his voting participation is necessary to afford the committee essential expertise.

First, it is important to consider that Dr. Pickering's role on the Advisory Board is unrelated to the particular matter in which he is being asked to participate, or to the competing products.

Second, Dr. Pickering's interest is not so substantial as to preclude his participation in this matter. He receives modest compensation.

Third, the uniqueness of Dr. Pickering's qualification justifies granting this waiver. According to the review Division, Dr. Pickering has a highly distinguished career with a unique specialty and background in behavioral cardiology. He has directed the Behavioral Cardiovascular Health and

Hypertension program at Mount Sinai Medical Center for the past seven years and his experience and expertise in behavioral medicine as it pertains to cardiovascular disease prevention is most fitting and highly pertinent to the topic of discussion for the December 13, 2007 advisory committee convening to consider whether Mevacor (lovastatin) 20 mg can become available without a prescription. The critical topic of the day will focus on how well consumers understand the product label and whether they can appropriately use this product without the care of a physician so as to derive a cardiovascular benefit with minimal risk. It is exceedingly difficult to find committee members that have particularly focused on human behavior as it relates to medical self-care and wellness, yet this is a critical area of expertise for the consideration of prescription to OTC switches.

Mevacor is used for coronary heart disease prevention, an area of particular interest to Dr. Pickering. Although the majority of his work in this area has related to hypertension, hypertension and lipid management are tightly intertwined in the prevention of heart disease. Dr. Pickering has been a member of the Task Force on Behavioral Medicine of the National Heart, Lung, and Blood Institute and has served as President of the Academy of Behavioral Medicine Research. He has written extensively (articles and chapters) on topics that are directly relevant to this advisory committee discussion.

It is exceedingly important to have cardiologist representation at this advisory committee meeting. Up to this point, there is none, yet physicians with this specialty spend their days focused upon coronary artery disease prevention and treatment. Dr. Pickering's unique expertise identifies him, among other special Government employees, as the best that we could hope to seat at the advisory committee table. Of the 23 cardiologists considered by the division, four accepted the offer to represent the Agency's interests, most declining due to scheduling conflicts or self-reported conflicts of interests. Of the four, Dr. Pickering was deemed among the least conflicted by the review Division.

Moreover, 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 committees' 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 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 committees' discussions and will help to provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Thomas Pickering, M.D., a waiver that would allow his voting participation in all official matters concerning the evaluation of data submitted by Merck & Co., Inc. to support the over-the-counter use of Mevacor (lovastatin) 20 milligrams a day to help lower cholesterol which may prevent a first heart attack. I believe that such a waiver is appropriate because in this case, Dr. Pickering's voting participation is necessary to afford the committee essential expertise.

DECISION:

- Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that voting participation is necessary to afford the committee essential expertise.
- Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that nonvoting participation is necessary to afford the committee essential expertise
- Waiver denied.

1/5/
Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy
Food and Drug Administration

11/15/07
Date