



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
Rockville MD 20857

DATE: October 10, 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 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 Nelson Watts, M.D.

I am writing to request a waiver for Nelson Watts, M.D., a temporary voting member of the Cardiovascular and Renal 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. Watts 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. Watts 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 an immediate family member.

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. Watts has been asked to participate in all official matters concerning regulatory considerations for extending the use of phosphate binders from the dialysis population (where they are approved) to the pre-dialysis population (where no products are approved). The committee will hear presentations on this topic from Shire Development, Genzyme Corporation, and Fresenius Medical Care.

This matter is coming before a meeting of the Cardiovascular and Renal Drugs Advisory Committee. This issue is a particular matter involving specific parties.

Dr. Watts has advised the Food and Drug Administration (FDA) that he has a financial interest which could potentially be affected by his participation in the matter described above. **Dr. Watts accepted an invitation to attend \_\_\_\_\_ Advisors Meeting regarding an unrelated osteoporosis drug. According to Dr. Watts, he will receive minimal compensation for his participation in the meeting. \_\_\_\_\_ a subsidiary of \_\_\_\_\_ is an affected firm.**

As a temporary voting member of the Cardiovascular and Renal Drugs Advisory Committee, Dr. Watts 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. Watts 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. Watts that would allow him to participate fully in the matter described because his voting participation is necessary to afford the committee/panel essential expertise.

**First, it is important to consider that Dr. Watts' interest in \_\_\_\_\_ is unrelated to the phosphate binders.**

**Second, Dr. Watts' financial interest in \_\_\_\_\_ is not so substantial as to preclude his participation in this meeting. He will receive minimal compensation for attending the Advisory Meeting.**

Third, according to the review Division, the uniqueness of Dr. Watts' qualification justifies granting this waiver. Dr. Nelson Watts is a standing member and current chair for the Endocrinologic and Metabolic Drugs Advisory Committee. Dr. Watts has been asked to participate in this meeting due to his extensive expertise in the area of bone and mineral disease. The topic of considerations for phosphate binder utilization in dialysis/pre-dialysis settings will likely include discussion of serum phosphorous levels in dialysis patients, and bone/mineral effects involved. Dr. Watts' participation will add the unique perspective needed in the area of bone and mineral disease, as well as osteoporosis. Dr. Watts has published extensively on variety

of areas involving bone mineral density and osteoporosis. Dr. Watts is also currently involved in multiple clinical trials for the treatment of low bone mineral density in postmenopausal women, as well as other trials in osteoporosis and non-vertebral fractures. His participation in this meeting is essential to the topics being discussed because of the potential significant public health impact of the committee's recommendations.

Fourth, the difficulty of locating a similarly qualified individual without a disqualifying financial interest to serve on the committee also justifies granting this waiver. In an attempt to gain the appropriate representation, the review Division considered 7 individuals listed as current SGEs with expertise in endocrinology. Of the seven endocrinologists, one declined due to a scheduling conflict and the rest were not contacted or pursued by the Division because their particular areas of expertise was not in bone and mineral diseases.

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 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. Nelson Watts is Director of the University of Cincinnati Bone Health and Osteoporosis Center and Professor of Medicine, University of Cincinnati College of Medicine. He is board certified in Internal Medicine with subspecialty in endocrinology and metabolism, and board certified in bio-analysis and clinical densitometry. Dr. Watts is a member of numerous professional societies, such as the American Association of Clinical Endocrinologists, the American College of Physicians, the International Bone and Mineral Society, and the International Society for Clinical Densitometry. Dr. Watts has broad professional experience relating to endocrinology, and he has conducted extensive clinical research relating this field of study. I believe that participation by Dr. Watts in the committee's deliberations will contribute to the diversity of opinions and expertise represented on the committee.

Accordingly, I recommend that you grant Dr. Nelson Watts a waiver that would allow his voting participation in all official matters concerning the regulatory considerations for extending the use of phosphate binders from the dialysis population (where they are approved) to the pre-dialysis population (where no products are approved). The committee will hear presentations on this topic

**APPEARS THIS WAY  
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