DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MEMORANDUM

TO: Sheila Dearybury Walcoff, Esq.
Associate Commissioner for External Relations

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

FROM: Kathleen L. Walker Kathleen L. Walker 11/4/05
Chief, Integrity, Committee and Conference Management Branch
Division of Ethics and Management Operations, OMO
Center for Devices and Radiological Health

SUBJECT: Conflict of Interest Waiver for Patricia S. Choban, M.D.

I am writing to request a waiver for Patricia S. Choban, M.D., serving on the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee as a consultant, and in this capacity, serving on the Agency's Pediatric Advisory Committee as a consultant, 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 Dr. Choban 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 Dr. Choban is a special Government employee, this individual 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.

Dr. Choban has been asked to participate in Committee deliberations to discuss pediatric obesity and clinical trial designs for the evaluation of devices intended to treat pediatric obesity for future development of a guidance document.

Dr. Choban has advised the FDA that she has an imputed financial interest that could potentially be affected by her participation in the matter described above. She reported that [redacted], a manufacturer of a weight reduction device. The current value of the stockholding is approximately worth [redacted] which is less than [redacted] of their net worth.

The functions of the Committee, as stated in its Charter, are to review and evaluate available data concerning the safety and effectiveness of marketed and investigational devices and advise the Commissioner of Food and Drugs regarding recommended classification of these devices into one of three regulatory categories; recommend the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advise on any possible risks to health associated with the use of devices; advise on formulation of product development protocols and review premarket approval applications for those devices classified in this category; review classification as appropriate; recommend exemption to certain devices from the application of portions of the Act; advise on the necessity to ban a device; and respond to requests from the Agency to review and make recommendations on the specific issues or problems concerning the safety and effectiveness of devices. As a consultant to the Pediatric Advisory Committee, Dr. Choban potentially could become involved in matters that affect [redacted] Under section 208, Dr. Choban is arguably 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 this individual 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. Choban that would allow this individual to participate fully in all matters identified below:

First, the general discussion is a matter of general applicability, granting no individual/firm an advantage. Therefore, the potential concern that Dr. Choban's impartiality might be called into question during Committee deliberations should be minimized.

Second, the current value of her [redacted] is small relative to their total net worth. Therefore, the likelihood that her judgment will be influenced by this interest is minimized.

Third, the Committee decisions would not be expected to affect the viability of [redacted] or significantly alter its stock value since it is a very large, well-established organization with a diversified product line and global presence.

Fourth, the Committee's recommendations are advisory in nature. The Agency will take into consideration the SGE's reported interest when making a final decision concerning the action to be taken.

Lastly, 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, not withstanding the financial interest and affiliations they may have acquired as a result of their demonstrated abilities. Dr. Choban is employed by Bariatric Specialists of Ohio as a physician and an Adjunct Associate Professor of Human Nutrition and Food Management, College of Human Ecology, The Ohio State University. Dr. Choban has experience in treating obese patients to facilitate weight loss and in addition, has completed a fellowship in clinical nutrition.

Dr. Choban has written numerous articles and books on morbid obesity and peer reviewed many scientific journals. Active in professional societies, she has participated in numerous speaking engagements and is nationally recognized as an expert in morbid obesity. We believe that Dr. Choban's participation in the Committee deliberations will ensure a level of expertise necessary to develop advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Dr. Choban a waiver that would allow this individual to participate fully in all official matters before the Pediatric Advisory Committee related to the discussion on pediatric obesity and clinical trial designs for the evaluation of devices intended to treat pediatric obesity for future development of a guidance document. I believe that such a waiver is appropriate because in this case the need for the services of Dr. Choban outweighs the potential for a conflict of interest created by the financial interest involved.

CONCURRENCE: _____ 11/08/05

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

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.

_____ 11.10.05

Sheila Dearybury Walcoff, Esq. — Date
Associate Commissioner for External Relations