DEPARTMENT OF HEALTH & HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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 Walker 1/4/05
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 Thomas H. Inge, M.D., Ph.D.

I am writing to request a waiver for Thomas H. Inge, M.D., Ph.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. Inge 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. Inge 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 him or his employer.

Dr. Inge 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. Inge has advised the FDA that he has financial interests that could potentially be affected by his participation in the matter described above. He reports a consulting relationship with [redacted] one of 15 firms that manufacture devices for weight reduction. The purpose of his consulting is to make the gastric by-pass procedure safer. To his knowledge, no inventions or intellectual property has been developed under this consulting agreement nor does he expect that any financially significant developments will develop from this relationship.

Dr. Inge does not receive any personal monetary compensation, however, The [redacted] which is earmarked for Dr. Inge's academic research. This relationship extends from November 2002 to November 2007. Dr. Inge attended a Scientific Advisory Board meeting held on March 17-19, 2005, which assembled bariatric surgeons, who are leaders in the field, to discuss the company's strategies and state of the science of the bariatric discipline. No other meetings or consultations are scheduled at this time.

In addition, Dr. Inge reported an investigator-initiated project grant between [redacted] study involves looking at scientific endpoints and outcomes in adolescents. This study does not involve any medical device or drug therapies. For his role as a principle investigator, Dr. Inge will receive [redacted] his salary is partially supported by this research and [redacted] will receive [redacted] This study started in October 2004 and will end October 2007.

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. Inge potentially could become involved in matters that affect [redacted]. Under section 208, Dr. Inge 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. Inge 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. Inge's impartiality might be called into question during Committee deliberations should be minimized.

Second, Dr. Inge does not receive any personal compensation for his consulting arrangement; therefore, the likelihood that his judgment will be influenced by this interest is minimized.

Third, there are fifteen competing products on the market that manufacture devices for weight reduction. Although [redacted] is in its own right a well established organization with a diversified product line and global presence, therefore, Committee decisions would not be expected to affect the viability of this firm.

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. Inge is employed by The Cincinnati Children's Hospital Medical Center as an Assistant Professor of Surgery and Pediatrics. He is also employed by the Comprehensive Weight Management Center as their Surgical Director, offering surgery for overweight adolescents with complications from their excess weight. He has been awarded numerous grants for his research including a recent award from NIH to study diabetic precursors in teenage bariatric patients and as a co-investigator to study psychosocial outcomes in teenage bariatric patients. He has published numerous scientific and clinical manuscripts and is a consultant to the Task Force on Obesity of the American Academy of Pediatrics. He is active in many professional societies and most recently was the past Chair of the American Society for Bariatric Surgery. He is very familiar with the issues of weight management in severely obese pediatric populations and also has an understanding of the advantages and disadvantages of surgical weight loss procedures in pediatric age groups. We believe that Dr. Inge'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. Inge a waiver that would allow this individual to participate fully in all official matters before the 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. Inge outweighs the potential for a conflict of interest created by the financial interest involved.

CONCURRENCE: Marylynn Kellman for 11/08/05

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

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.

11-10-05

Sheila Dearybury Walcoff, Esq.
Associate Commissioner for External Relations

Date