



MEMORANDUM

TO: Randall Lutter, Ph.D.  
Associate Commissioner for Policy and Planning

THROUGH: Jenny Slaughter \_\_\_\_\_ /S/ 08/16/06 \_\_\_\_\_  
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

FROM: Kathleen L. Walker \_\_\_\_\_ /S/ 08/15/06 \_\_\_\_\_  
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 Connie F. Whittington, M.S.N., R.N.

I am writing to request a waiver for Connie F. Whittington, M.S.N., R.N., a nonvoting consumer representative member of the Orthopaedic and Rehabilitation Devices Panel of FDA's Medical Devices Advisory Committee, 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 Ms. Whittington 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 Ms. Whittington 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.

Ms. Whittington has been asked to participate in the Panel discussions on a premarket approval application (PMA) from [-----] for the [-----]. This system is a two-piece articulating stainless steel device that is inserted into the intervertebral disc space at a single level using an open anterior approach. The device is indicated for skeletally mature patients with cervical degenerative disc disease (DDD) at one level from C3-C7.

Ms. Whittington's employer has a financial interest that could potentially be affected by her participation in this matter. Her employing institute, Piedmont Hospital is a surgical site for the [-----] study. Ms. Whittington had no personal or financial involvement with this trial, and no knowledge of

the study funding. She is the Director of Nursing Services at the hospital and has no relationship with the principal investigator, [-----]. The only payment to Piedmont Hospital was an institutional review board (IRB) payment of [-----], and this payment was for continued access rather than the pivotal study.

The Office of Device Evaluation within the Center for Devices and Radiological Health provided the following relevant study data:

- Total number of sites involved: [----]
- Total number of patients enrolled in the trial: [----]
- Total number of patients investigational devices implanted: [----]
- Total number of control devices implanted: [----]
- Total number of patients treated at Piedmont Hospital: [-----]
- Date of first study enrollment: [-----]
- Date of last study enrollment: [-----]

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 the premarket approval 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 specific issues or problems concerning the safety and effectiveness of devices. As a nonvoting member of the Orthopaedic and Rehabilitation Devices Panel, Ms. Whittington potentially could become involved in matters that affect [-----] and its unit, [-----]. Under section 208, Ms. Whittington 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 this individual to participate in such matters, as you deem appropriate.

For the following reasons, I believe it would be appropriate for you to grant a waiver to Ms. Whittington allowing this individual to participate in matters identified below.

First, although Ms. Whittington's institution was a surgical site in the sponsor's trial, she had no knowledge of the study, had no direct, personal involvement and received no compensation. The fact that this financial interest is imputed to her from her employer should lessen any potential concern for bias.

Second, the Agency officials making the decisions are not bound by the recommendations of the Panel. Therefore, the Agency will take into consideration the involvement of the SGE's employer when making a final decision.

