



MEMORANDUM

TO: Jason D. Brodsky  
Acting Associate Commissioner for External Relations

THROUGH: Jenny Slaughter /S/ 4/13/06  
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

FROM: Kathleen L. Walker /S/ 4/11/06  
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 E. James Potchen, M.D.

I am writing to request a waiver for E. James Potchen, M.D., serving on the Radiological Devices Panel of FDA's Medical Devices 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. Potchen 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. Potchen 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. Potchen has been asked to participate in the Panel discussion on the reclassification of full field digital mammography systems (FFDMS). Currently, FFDMS are Class III devices requiring premarket approval applications. Relevant for this meeting, 12 manufacturers of full field digital mammography systems were identified; 51 firms with competing technologies were identified, 2 for tomosynthesis and 49 for standard full screen mammography.

Dr. Potchen has advised the FDA that he has financial interests, which could potentially be affected by his participation in this matter. He currently provides consulting services for [---] (also known as [---]), a manufacturer of FFDMS and film screen mammography. He consults on the [---]. He serves as a member of the Radiology Advisory Council and reports that the Council takes no official position on FFDMS.



