



MEMORANDUM

TO: Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy

THROUGH: Vincent Tolino
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Kathleen L. Walker /S/ 06/20/07
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 Edward N. Hanley, Jr., M.D.

I am writing to request a waiver for Edward N. Hanley, Jr., M.D., serving on the Orthopaedic and Rehabilitation 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. Hanley 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. Hanley 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. Hanley has been asked to participate in the Panel discussions on a premarket approval application (PMA) from Medtronic Sofamor Danek (a unit of Medtronic, Inc.) for the *Bryan Cervical Disc Prosthesis*. This system is a non-fusion artificial disc device that is to be implanted via an open anterior approach. It is indicated in skeletally mature patients with cervical degenerative disc disease at one level from C3-C7. This matter is coming before the Orthopaedic and Rehabilitation Devices Panel for consideration and is a particular matter involving specific parties.

Dr. Hanley’s employer has a financial interest that could potentially be affected by his participation in this matter. His institute, Carolinas Health Care System, has been identified as a clinical study site for the sponsor’s PMA. Dr. Hanley has no personal or financial involvement with the study, and no knowledge of its funding. He believes the study was conducted by neurosurgeons and therefore, he had no managerial responsibility over the investigators.

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

Total number of sites involved with the BRYAN prosthetic: [--]

Total number of BRYAN patients enrolled in the trial: [---]

Total number of control patients enrolled in the trial: [---]

As part of the continued access phase, an additional [--] patients received the BRYAN device.

Total number of patients treated at the Carolinas Health Care System: [--] subjects ([--] investigational; [--] control)*

Date of first study enrollment: [-----]

Date of last study enrollment: [-----]

Amount to institute: \$[-----]

[--] investigational devices were also donated to the hospital (total value: \$[-----])

[-----]

*[-----]

In addition, Dr. Hanley reported owning [---] shares in Medtronic, Inc., currently valued at \$[-----], which represents less than [---] of his net worth. Medtronic, Inc. is the parent of Medtronic Sofamor Danek, the sponsor of the PMA.

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 consultant to the Orthopaedic and Rehabilitation Devices Panel, Dr. Hanley potentially could become involved in matters that affect Medtronic Sofamor Danek (parent: Medtronic, Inc.). Under section 208, Dr. Hanley 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 Dr. Hanley allowing him to participate in matters identified below.

First, although Dr. Hanley's institute is involved in the sponsor's trial, he has no knowledge of the study, no direct, personal involvement and receives no compensation. The fact that this financial interest is imputed to him through his 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 SGE's involvement when making a final decision concerning the action to be taken.

Third, the value of Dr. Hanley's stockholding represents less than [----] of his net worth. Therefore it is unlikely that his judgment will be influenced by these interests.

Fourth, Panel recommendations would not be expected to affect the viability of Medtronic, Inc. or significantly alter its stock value since Medtronic is a very large, well-established organization with diversified product lines and global presence.

Fifth, there are more than 50 firms marketing or pursuing development of a device to treat degenerative disc disease of the cervical spine. The availability of multiple firms/products should mitigate the potential perception of bias on the part of this SGE.

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, notwithstanding the financial interest and affiliations they may have acquired as a result of their demonstrated abilities. Dr. Hanley is the Chairman of the Department of Orthopaedic Surgery and the Department of Engineering at the Carolinas Medical Center in North Carolina. In the Center's attempt to find other qualified individuals with expertise in the area of orthopaedic spine surgery, we conducted a search of the 18 NIH groups listed in the Federal Advisory Committee Act (FACA) database and the NIH employee listing. The FACA search identified SGEs with dental research focus and the NIH employee search found employees with orthopaedic research at the cellular level. These areas of research are not relevant to the Panel discussion. Therefore, we request to use the services of Dr. Hanley because he has the knowledge and expertise on the subject matter being discussed. He is a nationally recognized spine specialist and researcher with a background in laboratory and clinical investigations. With

