



MEMORANDUM

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

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

FROM: Kathleen L. Walker _____/S/____ 1/19/07
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 Philip B. Gorelick, M.D.

I am writing to request a waiver for Philip B. Gorelick, M.D, serving as a consultant to the Center for Drug Evaluation and Research, and in this capacity, serving as a consultant to the Circulatory System 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 Dr. Gorelick 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. Gorelick 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. Gorelick has been asked to participate in the Panel’s discussion of clinical trial designs for patent foramen ovale (PFO) closure devices intended to prevent recurrent stroke. These matters are coming before the Circulatory System Devices Panel for consideration and are particular matters of general applicability. In addition, several sponsors [-----

-----]. Each sponsor’s presentation will be held in a closed session to permit the discussion and review of trade secret and/or confidential information. These matters are coming before the Circulatory System Devices Panel for consideration and are particular matters involving specific parties.

Dr. Gorelick has advised the FDA that he has financial interests which could potentially be affected by his participation in these matters. He reported a consulting arrangement with [-----], the parent of [----], a competing [-----] firm to the PFO closure device firms. His consulting involves development of [-----], an issue unrelated to the PFO agenda. Dr. Gorelick receives approximately \$[-----] yearly for [-----].

Dr. Gorelick reported that he lectures and consults for [-----], a competing [-----] firm to the PFO device firms. Although the lecture topic is [-----], it does not address PFO devices. He estimated his fees for the past year at \$[-----]. His institute receives [-----] fees. The arrangement is [----] but he has no pending involvement.

His consulting involves [-----]. He also advises their [-----]. The issues are [-----]. His estimated income for 2006 for both involvements is approximately \$[-----].

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 Circulatory System Devices Panel. Dr. Gorelick potentially could become involved in matters that affect [-----], and [-----]. Under section 208, Dr. Gorelick 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. Gorelick allowing him to participate in matters identified below.

First, given the nature of the unrelated consulting Dr. Gorelick provides to both [-----], it is unlikely that Panel recommendations will impact the economic stability of the companies or his continued relationship with them. The possibility that Dr. Gorelick's impartiality will be called into question should be minimal.

Second, the Panel's role is advisory in nature and 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 with the firms when determining the action to be taken.

Third, Dr. Gorelick's past speaking engagements involved lectures that addressed no specific manufacturer's product and were made prior to his knowledge of the Panel meeting date and agenda. Because the lectures were of a general nature, it is unlikely that the outcome of this Panel meeting would impact any future engagements the SGE may have with the company.

Fourth, there are approximately [--] firms that are pursuing development of a PFO closure device and [--] firms identified as marketing and/or pursuing development of a competing technology intended to prevent recurrent stroke. The availability of multiple competitors 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. Gorelick is Head of the Department of Neurology and Rehabilitation at the University of Illinois at Chicago. Due to the complex nature of the topic, it is essential that the Panel has expert neurologists as part of its composition. Dr. Gorelick is one of three neurologists available to discuss these complex issues. In the Center's attempt to find another qualified neurologist, we searched extensively through the 18 NIH groups listed in the Federal Advisory Committee Act (FACA) database. The search yielded no individual with experience equivalent to Dr. Gorelick. We further canvassed NIH personnel listing for individuals with comparable experience and could not find anyone who was available. Therefore, we request to use the services of Dr. Gorelick, who brings a unique perspective to this meeting as a neurologist and vascular cognitive impairment specialist. The Panel meeting shall include a discussion of optimal ways to obtain evidence regarding whether patent foramen ovale closure in the heart decreases the risk of subsequent stroke and death. With this discussion it is critical to involve both neurology and cardiology experts. The Agency recognizes Dr. Gorelick as an expert neurologist, adept at designing meaningful clinical trials and with a knowledge base that includes an understanding of the history and uses of PFO closure devices intended to prevent recurrent stroke. His extensive research and publications include the management of stroke and stroke prevention. We believe Dr. Gorelick's participation in this meeting will ensure the level of expertise required to provide advice and recommendations that are fair and comprehensive.

