

Food and Drug Administration Rockville MD 20857

MEMORANDUM

DATE:

July 31, 2006

TO:

Randall Lutter, Ph.D.

Associate Commissioner for

Policy and Planning

Food and Drug Administration

THROUGH:

Jenny Slaughter

Director, Ethics and Integrity Staff

Office of Management Programs

Office of Management

FROM:

Igor Cerny, Pharm.D. /s/

Director, Advisors and Consultants Staff Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for Stephen George, Ph.D.

I am writing to request a waiver for Stephen George, Ph.D., a consultant to the Center for Drug Evaluation and Research, from the conflict of interest prohibitions of 18 U.S.C. §208(a). The appointing official may grant waivers under section 208(b)(3) 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 Stephen George, Ph.D., a waiver under 18 U.S.C. §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 any other person whose interests are imputed to the employee under 18 U.S.C. §208, has a financial interest. Since Dr. George is a special Government employee, he is under a statutory obligation to refrain from participating in an official capacity in any particular matter having a direct and

predictable effect on a financial interest attributable to him, his spouse, minor child, or general partner; an organization or entity for which he serves as an officer, director, trustee,

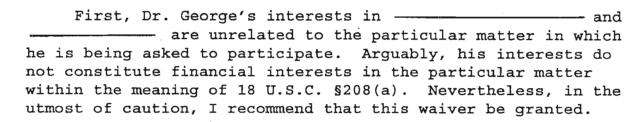
general partner, or employee; and, a person with whom he is negotiating for, or has an arrangement concerning, prospective employment.

Dr. George has been asked to participate in all official matters concerning New Drug Application (NDA) 020-287, Fragmin (dalteparin sodium), sponsored by Pfizer, Inc., for the proposed indication of extended treatment of symptomatic venous thromboembolism (VTE), such as proximal deep venous thromboses (DVT) and/or pulmonary embolism (PE), to reduce the recurrence of VTE in patients with cancer. This matter is coming before the Oncologic Drugs Advisory Committee for consideration.

The functions of the Oncologic Drugs Advisory Committee, as stated in its Charter, are to review and evaluate available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer, and to make appropriate recommendations to the Commissioner of Food and Drugs.

As a consultant advising the Oncologic Drugs Advisory Committee, Dr. George potentially could become involved in matters that could affect his financial interests. Under 18 U.S.C. §208(a), he 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 Dr. George 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. Stephen George that would permit him to participate in the matter described previously.



Second, Dr. George's interests in ______ and ____ are not so substantial as to preclude his participation in the matter described previously. He receives minimal compensation for serving on the Data Monitoring Committees.

Further, 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 interests and affiliations they may have acquired as a result of their demonstrated abilities. Dr. George is Director and Professor of Biostatistics, Department of Biostatistics and Bioinformatics at the Duke University Medical Center. Dr. George also serves as the Director of the Statistical Center and Group Statistician for the Cancer and Leukemia Group B (CALGB) at Duke University. He is an expert in biostatistical and clinical trials methodology and has written numerous articles on such topics as sequential clinical trials in cancer, practical problems in the design, conduct and analysis of cooperative clinical trials, and monitoring practices in cancer trials. I believe his participation will contribute to the diversity of opinions and expertise represented on the committee and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Stephen George, Ph.D., a waiver that would allow him to participate in all official matters concerning New Drug Application (NDA) 020-287, Fragmin (dalteparin sodium), sponsored by Pfizer, Inc., for the proposed indication of extended treatment of symptomatic venous thromboembolism (VTE), such as proximal deep venous thromboses (DVT) and/or pulmonary embolism (PE), to reduce the recurrence of VTE in patients with cancer. I believe that such a waiver is appropriate because in this case, the need for the services of Stephen George, Ph.D., outweighs the potential for a conflict of interest created by the financial interests attributable to him.

CONCURREN	CE: /s/	8/4/06
	Jenny Slaughter	Date
	Director, Ethics and Integrity Staff	
	Office of Management Programs	
	Office of Management	
DECISION:		
X	Waiver granted based on my determination, maccordance with section 18 U.S.C. §208(b)(3) the need for the individual's services outwith the potential for a conflict of interest crithe financial interest attributable to the individual.), that reighs
	Waiver denied.	
	/s/	8/11/06
	Randall Lutter, Ph.D.	Date
	Associate Commissioner for	

Policy and Planning

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