



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.

Dr. George has advised the Food and Drug Administration that he has financial interests that could potentially be affected by his participation in the matter described previously. Dr. George serves as a member of \_\_\_\_\_ 's and \_\_\_\_\_,' Independent Data Monitoring Committees for studies of unrelated products. \_\_\_\_\_ and \_\_\_\_\_ make competing products to Fragmin, the product at issue.

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.

First, Dr. George's interests in \_\_\_\_\_ and \_\_\_\_\_ are unrelated to the particular matter in which he is being asked to participate. Arguably, his interests do not constitute financial interests in the particular matter within the meaning of 18 U.S.C. §208(a). Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

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.

