



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 William Hiatt, M.D.

I am writing to request a waiver for William Hiatt, M.D., a member of the Cardiovascular and Renal Drugs Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a). The appointing official may grant waivers under 18 U.S.C. §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 Dr. William Hiatt 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 any other person whose interests are imputed to the employee under 18 U.S.C. §208, has a financial interest. Since Dr. Hiatt 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. Hiatt has been asked to participate in all official matters regarding New Drug Application (NDA) 20-287, Fragmin (dalteparin sodium injection), sponsored by Pfizer, Inc., with the proposed indication for the extended treatment of symptomatic venous thromboembolism (VTE) (proximal deep vein thrombosis (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.

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. Hiatt has advised the Food and Drug Administration that he has a financial interest that could potentially be affected by his participation in the matter at issue. **Dr. Hiatt serves on a Speaker's Bureau for _____.** He gives general topics lectures on peripheral arterial disease (PAD). PAD is an umbrella term that encompasses several different conditions (e.g., claudication, Deep Vein Thrombosis (DVT)), that result from a disruption in blood flow to the lower extremities. _____ and _____ manufacture competing products to Fragmin.

As a member advising the Oncologic Drugs Advisory Committee, Dr. Hiatt could potentially become involved in matters that could affect his financial interests. Under section 208, 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 William Hiatt, M.D. 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 William Hiatt, M.D., that would permit him to participate in the matter previously described.

First, arguably Dr. Hiatt's financial interest in _____ and _____ does not constitute a financial

interest in the particular matter within the meaning of 18 U.S.C. §208(b)(3). Nevertheless, we recommend that this waiver be granted.

Second, his interest is not so substantial as to be deemed likely to impact his impartiality. He receives moderate compensation for his services.

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 various advisory committee members and Dr. Hiatt's participation will contribute to the balance of views represented and the diversity of opinions and expertise. 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. William Hiatt, is President of the Colorado Prevention Center (CPC) and has served as its Executive Director since 1996. He is also Professor of Medicine and Chief of the Section of Vascular Medicine at the University of Colorado Health Sciences Service in Denver, Colorado. Among his professional affiliations, Dr. Hiatt has served as a Fellow, Trustee and President of Vascular Medicine and Biology and is a member of the American Heart Association, the Council on Circulation, the American College of Physicians, Society for General Internal Medicine and the Western Association of Physicians Association. He has published numerous peer-review articles, abstracts, book chapters, reviews and editorials. Dr. Hiatt has also received several awards and honors, including the Alpha Omega Alpha Medical Society, George Packard Award in Surgery, and the Kaiser Family Foundation Faculty Scholarship Award in General Internal Medicine. Dr. Hiatt's expertise in vascular medicine will contribute to the diversity of expertise and viewpoints represented and will provide a foundation for developing advice and recommendations that will be fair and comprehensive.

