



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: August 15, 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 John Ellis, M.D.

I am writing to request a waiver for John Ellis, M.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 Dr. Ellis, 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. Ellis 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. Ellis has been asked to participate in all official matters concerning discussion of clinical data for aprotinin injection (trade name, Trasylol), an approved product, New Drug Application 020-304, sponsored by Bayer Pharmaceuticals Corporation, a part of Bayer HealthCare AG, a subsidiary of Bayer AG, with the indication for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft (CABG) surgery. This matter is coming before the Cardiovascular and Renal Drugs Advisory Committee.

The function of the Cardiovascular and Renal Drugs Advisory Committee, as stated in its Charter, is to review and evaluate available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders and to make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Ellis has advised the Food and Drug Administration (FDA) that he has a financial interest that could potentially be affected by his participation in the matter at issue. Dr. Ellis is a faculty member participating in the 2006 Anesthesia Camps Continuing Medical Education (CME) program. The first program occurred July 27-29 and the next is scheduled for October 5-7. The Office of Medical Education at State University of New York (SUNY) Upstate Medical University and DestinationCME LLC jointly co-promote the Anesthesia Camps. DestinationCME LLC organizes CME programs for anesthesiology professionals and is Dr. Ellis' Limited Liability Company (LLC). Within the past 12 months, [redacted] contributed funding to SUNY Upstate Medical University, which accredited the CME program. The CME program did not [redacted] It is possible that [redacted], in the future, will provide additional funding in support of the program. [redacted] makes [redacted] [redacted], a competing product to Trasylol.

As a consultant participating in the Cardiovascular and Renal Drugs Advisory Committee meeting, Dr. Ellis 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. Ellis 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. Ellis, which would permit him to participate in the matter previously described.

First, this waiver is justified because arguably, Dr. Ellis' interest does not constitute a financial interest in the particular matter within the meaning of 18 U.S.C. §208(a) since his interest is unrelated to Trasylol and its competing products. Nevertheless, I recommend that this waiver be granted.

Second, the funding from [] is minimal and not so substantial as to preclude Dr. Ellis' participation in this matter.

Moreover, it is important to note that the funds from [] were paid directly to SUNY, not to destination CME LLC, and according to Dr. Ellis, the program did not [] [] .

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. Ellis' participation in 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. Ellis is Professor of Anesthesia & Critical Care, Department of Anesthesia & Critical Care at the University of Chicago Hospitals. His research focuses on sympatholytic therapies for patients undergoing vascular surgery and on the ability of these therapies to reduce myocardial ischemia and postoperative hypercoagulability. Dr. Ellis has a variety of published research in the area of cardiothoracic and vascular surgery related to anesthetic conditions, including a

