



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

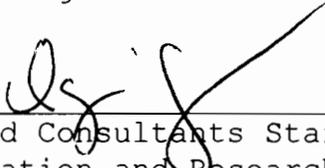
MEMORANDUM

Food and Drug Administration
Rockville MD 20857

DATE: March 20, 2006

TO: Jason D. Brodsky
Acting Associate Commissioner
Office for External Relations
Food and Drug Administration

THROUGH: Jenny Slaughter
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Igor Cerny, Pharm.D. 
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for Frederick Kaskel, M.D.

I am writing to request a waiver for Frederick Kaskel, 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. Kaskel 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. Kaskel is a special Government employee, he 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.

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. Kaskel has been asked to participate in all official matters concerning the discussion of the Agency's draft recommendations for re-labeling of anti-hypertensive drugs for outcome claims, as a follow-up to the committee's meeting on June 15, 2005, where the committee discussed class labeling of antihypertensive drugs based on the proximity of their data to outcome trials. The discussion will not focus on any particular product or firm and is a particular matter of general applicability.

Dr. Kaskel has advised the Food and Drug Administration (FDA) that his employer, the Albert Einstein College of Medicine of Yeshiva University, Children's Hospital at Montefiore, has a financial interest which could potentially be affected by his participation in the matter at issue. Dr. Kaskel is Director, Division of Pediatric Nephrology, Department of Pediatrics. His Department has a contract with _____ to study _____ for pediatric use in children (6-16 year olds) with hypertension. Dr. Kaskel's only involvement in this study is as Division Director. _____ is an approved product for use in the treatment of hypertension in adults and one of the many products that could potentially be affected by the committee's discussions.

As a member of the Cardiovascular and Renal Drugs Advisory Committee, Dr. Kaskel could potentially become involved in matters that could affect his imputed financial interest. 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 Dr. Kaskel 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. Kaskel that would allow him to participate fully in the matter described above.

First, Dr. Kaskel's imputed interest is not so substantial as to preclude his participation in this matter.

Second, it is important to note that Dr. Kaskel himself, has no financial interest in either the drug under study or the company. Although the financial interest of an employer impute to the individual under 18 U.S.C. §208, generally there is less likelihood that the judgment of the individual will be affected by an imputed interest of an employer than by a personal financial interest.

Third, it is unlikely that Dr. Kaskel's participation in the committee's discussions of class labeling of antihypertensive drugs, will have an impact on his employer's study of an antihypertensive in children. Even if it were possible that _____ would be more or less likely to continue to fund this study, the financial impact on the Albert Einstein College of Medicine of Yeshiva University, Children's Hospital at Montefiore would likely be minimal. The Institution has an annual budget of over \$1.9 billion. The hospital is ranked top referral site for pediatric nephrology treatment.

Moreover, it is important to consider that the matter in which Dr. Kaskel is participating is a particular matter of general applicability. The committee's discussions will not focus on any particular product or firm. Rather, the committee's recommendations and the Agency's action on this issue could impact all firms that market or are developing antihypertensive drugs to the same extent.

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. Kaskel'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

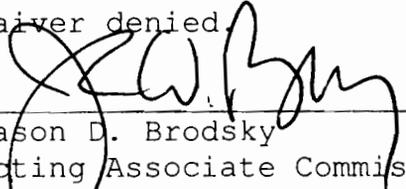
if the agency could not call upon experts who have become eminent in their fields, notwithstanding the financial interests and affiliations they may have acquired as a result of their demonstrated abilities. Frederick Kaskel, M.D., is Director, Division of Pediatric Nephrology, Vice Chairman, Affiliate & Network Relations, Department of Pediatrics, Attending Physician, and Professor of Pediatrics, the Albert Einstein College of Medicine, Children's Hospital at Montefiore. He is board certified in pediatrics and is a nationally and internationally recognized leader and expert in pediatric nephrology. He has performed basic and clinical research in numerous areas of kidney disease in children, specifically related to the diagnosis and management of hypertension in children, pediatric chronic renal failure, and the physiologic determinants of neonatal renal function. His expertise in these areas is demonstrated by his numerous publications and his membership in various professional societies, such as the American Society of Pediatric Nephrology, American Society of Nephrology, and the National Kidney Foundation. Dr. Kaskel played a key role in the development of a newer focus on the molecular and genetic determinants of renal health and disease. I believe that Dr. Kaskel's participation 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.

Accordingly, I recommend that you grant Dr. Kaskel a waiver that would allow him to participate in all official matters concerning the Agency's draft recommendations for re-labeling of anti-hypertensive drugs for outcome claims, as a follow-up to the committee's meeting on June 15, 2005, where the committee discussed class labeling of antihypertensive drugs based on the proximity of their data to outcome trials. I believe that such

a waiver is appropriate because in this case, the need for the services of Dr. Kaskel outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE:  3/21/06
Date
Jenny Slaughter
Director, Ethics and
Integrity Staff
Office of Management Programs
Office of Management

DECISION: 
Waiver granted based on my determination, made in accordance with section 208(b)(3) that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest attributable to the individual.

Waiver denied.  3/28/06
Date
Jason D. Brodsky
Acting Associate Commissioner
Office for External Relations
Food and Drug Administration