



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: September 13, 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. ISC
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for William Jusko, Ph.D.

I am writing to request a waiver for William Jusko, 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 Dr. Jusko 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. Jusko 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,

As a consultant advising the Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science, Dr. Jusko 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. Jusko 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 Jusko, Ph.D., which would permit him to participate in the matters previously described.

First, this waiver is justified, in part, because of the general nature of particular matters of general applicability. It is well recognized that particular matters of general applicability pose far less risk of a conflict of interest. Particular matters of general applicability include regulations, points-to-consider, guidelines, and policies governing classes of individuals, products, and organizations. Particular matters of general applicability do not include particular matters involving specific parties, such as recommendations regarding a specific product, or enforcement matters involving known parties. Particular matters of general applicability will not have a special or distinct impact on any of Dr. Jusko's financial interests other than as part of a class.

Second, arguably, Dr. Jusko's consulting interests do not constitute financial interests in the particular matter of general applicability within the meaning of 18 U.S.C. §208(a) since he consults on matters unrelated to the issues at hand. Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

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. Jusko'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. Jusko is Professor and Chairman of

Pharmaceutical Sciences, School of Pharmacy and Pharmaceutical Sciences, University of Buffalo. He received his Ph.D. degree from the State University of New York at Buffalo. He has received many awards, such as Doctor Honoris Causae (Jagiellonian University), Distinguished Service Award from ACCP, Research Achievement Award in Pharmacokinetics, Pharmacodynamics, and Drug Metabolism from AACP. His research interests involve basic, clinical, and theoretical pharmacokinetics and pharmacodynamics with a special emphasis on corticosteroids and immunosuppressive agents. He is a member of several professional societies, including American Association of Pharmaceutical Scientists, American Society for Clinical Pharmacology and Therapeutics and Academy of Pharmaceutical Research and Science, among others. I believe that Dr. Jusko's participation will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Dr. William Jusko a waiver that will permit him to participate in the Clinical Pharmacology Subcommittee (CPSC) (, of the Advisory Committee for Pharmaceutical Science, meeting where the committee will: (1) hear an update on previous CPSC meeting recommendations and receive an introduction to the three new topics of this meeting; (2) discuss and provide comments on the evaluation of transporter-based drug interactions; and, (3) consider the impact of using prior knowledge on drug development and regulatory decisions. discussed are particular matters of general applicability. I believe that such a waiver is appropriate because in this case, the need for the services of

**APPEARS THIS WAY
ON ORIGINAL**

