



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

DATE: February 11, 2008

TO: Randall W. Lutter, Ph.D.  
Deputy Commissioner for Policy  
Food and Drug Administration

THROUGH: Vince Tolino \_\_\_\_\_ /S/  
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

Michael F. Ortwerth, Ph.D. \_\_\_\_\_ /S/  
Deputy Director, Advisory Committee Oversight and Management Staff  
Office of Policy, Planning, and Preparedness

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

SUBJECT: 208(b)(3) Conflict of Interest Waiver for Mary Relling, Pharm.D.

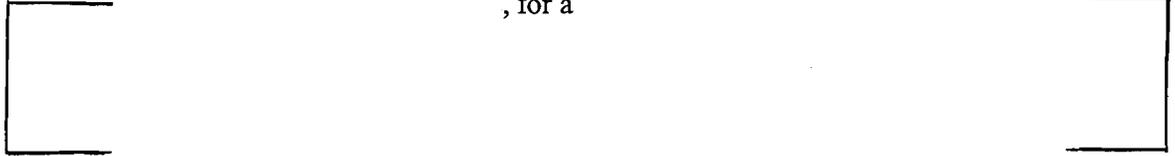
I am writing to request a waiver for Mary Relling, Pharm.D., a temporary member of the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology, from the conflict of interest prohibitions of 18 U.S.C. §208(a). Waivers under section 208(b)(3) may be granted by the appointing official where "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. Mary Relling 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 her employer has a financial interest. Because Dr. Relling is a special Government employee, she 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 her or her employer.

The function of the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology is to provide advice on scientific, clinical and technical issues related to the safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases, the quality characteristics which such drugs purport or are represented to have, and as required, any other product for which the Food and Drug Administration has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs. The Committee may also review Agency sponsored intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

Dr. Relling has been asked to participate in the March 18, 2008, meeting of the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology. The committee will meet in open session to discuss the new Clinical Pharmacogenomics (PGx) concept paper. Key issues to be discussed include: (a) an industry survey on collection of PGx samples; and, (b) the applications of PGx in clinical development. These issues are particular matters of general applicability.

Dr. Relling has advised the Food and Drug Administration (FDA) that her and her employer have a financial interest that could potentially be affected by her participation in the matters described above. Dr. Relling's \_\_\_\_\_ and her department at the St. Jude Children's Research Hospital have received minimal compensation for patent royalties from \_\_\_\_\_, a part of \_\_\_\_\_, for a



As a temporary member to the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology, Dr. Relling potentially could become involved in matters that could affect her, her \_\_\_\_\_ and her employer's financial interests. Under section 208, she 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. Relling 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. Relling that would allow her to participate in the matter described because the need for her services greatly outweighs the conflict of interest created by this financial interest.

First, the issues to be discussed by the committee are particular matters of general applicability, involving an entire class of products and granting no advantage to any individual manufacturer. Therefore, the committee recommendations would not be expected to have a significant financial impact on any specific firm and the potential perception of bias on the part of Dr. Relling should be mitigated.

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.

Moreover, according to the Review Division, Dr. Relling is a world renowned expert in the field of pharmacogenetics and clinical pharmacology. She has also engaged in translational research (bench to bedside) extensively which is a process relative to translating findings in new drug development research into applications in clinical practice.

She is currently the Chair of Pharmaceutical Sciences at the St. Jude Children's Research Hospital, Memphis. She received her Pharm.D. Degree from the College of Pharmacy at University of Utah. Dr. Relling's current research deals with finding genetic variations to predict drug-induced second cancers, osteonecrosis and neurotoxicity in children. Her specific research topics include: antineoplastic pharmacokinetics and pharmacodynamics in children, pharmacogenetics of antileukemic therapy, and host- and treatment-related risk factors for secondary malignancies. She has extensive research publications in the areas of pharmacogenomics, pharmacokinetics, and pediatrics.

Dr. Relling's experience and expertise in pharmacogenomic research will provide invaluable insights to the discussion of the pharmacogenomic concept paper. The pharmacogenomic topic will relate to new drug development. It will focus on a concept paper not guidance. It will be intended to lay out options for:

- 1) what in vitro studies can highlight the need to conduct in vivo studies in general looking at mechanisms of metabolism.
- 2) what options exist for conducting early clinical studies in volunteers to address questions as to if genetics matters to dose response.

The discussion will not deal with any specific drug or product. The discussion are general concepts, and not specific to drug or regulatory requirement for approval or label claims, we believe that Dr. Relling's interest in \_\_\_\_\_ is not directly related to the topic. In addition, her connection to \_\_\_\_\_, and has no bearing on the development of new drugs.

Further, it is critical to have Dr. Relling participate in the meeting since two other pharmacogenomic experts have been recused from the meeting due to greater conflicts.

The review Division feels strongly that Dr. Relling's background and expertise will lead to an appropriate and stimulating discussion and assist the Commissioner to move the issues at hand forward.

Accordingly, I recommend that you grant Mary Relling, Pharm.D., a waiver that would allow her voting participation in all official matters concerning the new Clinical Pharmacogenomics (PGx) concept paper, including: (a) an industry survey on collection of PGx samples; and (b) the applications of PGx in clinical development, I believe that such a waiver is appropriate because in

