



DEPARTMENT OF HEALTH & HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Rockville MD 20857

DATE: September 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 Vierling, M.D.

I am writing to request a waiver for John Vierling, 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. Vierling 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. Vierling 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. Vierling has been asked to participate in the Antiviral Drugs Advisory Committee meeting to discuss the clinical trial design issues such as the identification of appropriate control arms, populations for study, endpoints, and long-term follow-up in the development of products for the treatment of chronic hepatitis C infections. These matters are coming before the Antiviral Drugs Advisory Committee for consideration and are particular matters of general applicability.

The function of the Antiviral 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 acquired immune deficiency syndrome, human immunodeficiency virus related illnesses, and other viral, fungal and mycobacterial infections, and to make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Vierling has advised the Food and Drug Administration that he and his employer, the Baylor College of Medicine, have financial interests that could potentially be affected by his participation in the matter at issue. _____, _____ and _____ are providing funding to Baylor College of Medicine for studies on Hepatitis C infection. Dr. Vierling is the Principal Investigator (PI) for the studies that involve products that could potentially be affected by the committee's discussion.

Dr. Vierling consults for _____, _____ and _____ regarding hepatitis C, the companies that could potentially be affected by the committee's discussions. He receives minimal compensation for his consulting.

In addition, Dr. Vierling is President of a non-profit member organization, the American Association for the Study of Liver Diseases (AASLD). He is responsible for the training awards program that is funded by _____, _____, _____ and _____, companies that could potentially be affected by the committee's discussions. He receives moderate compensation for his services.

As a non-voting consultant advising the Antiviral Drugs Advisory Committee, Dr. Vierling potentially could become

involved in matters that could affect his and his employer's 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. Vierling 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. Vierling, which would permit him to participate in the committee's discussions of the clinical trial design issues regarding hepatitis C Virus infections.

First, Dr. Vierling's personal and imputed financial interests are not so substantial as to preclude his participation in this matter. He receives moderate compensation for his consulting. The funding provided by _____, _____ and _____ is also not a significant interest to the Baylor College of Medicine. Baylor receives over _____ per year in research support from Federal, State and private sources.

Second, the products that are being studied, _____, _____, _____, and _____, are already approved and marketed for the treatment of HCV infections.

Third, the uniqueness of Dr. Vierling's qualification justifies granting this waiver. Dr. Vierling is one of the most influential hepatologist in the world. Because of position in the field of hepatology and his unparalleled clinical and research experience, the division believes that Dr. Vierling's qualifications are unique. The division also believes that a recusal of Dr. Vierling would severely impact the validity of all of the discussions at the meeting and perhaps necessitate the meeting's cancellation, which would be a serious disservice to the public, industry, and academia.

Fourth, the difficulty of locating a similarly qualified individual without a disqualifying financial interest to serve on the committee also justifies granting this waiver. Because the universe of hepatologists is small, and that of those involved in the care and clinical evaluation of therapy for hepatitis C infections is even smaller, it has been

exceedingly difficult to find consultants and committee members, who are knowledgeable about clinical trial design issues in the development of products for the treatment of the chronic HCV infected population, yet have not had any involvement with sponsors in the development of new treatments for this disease. The division feels that only hepatologists have the requisite expertise to discuss both treatment of HCV infections and clinical trial design. A reduction in the number of hepatologists in the committee, therefore, will render much of the discussion useless, and may call into question the validity of any committee recommendations to the Agency.

Moreover, this waiver is also 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, legislation, guidelines, points-to-consider, and policies governing classes of organizations, individuals, and products. Particular matters of general applicability do not include particular matters involving specific parties, such as specific grants, contracts, recommendations regarding a specific product, or enforcement matters involving known parties. The committee's discussions of clinical trial design issues such as the identification of appropriate control arms, populations for study, endpoints, and long-term follow-up in the development of products for the treatment of chronic hepatitis C infections will not have a unique and distinct impact on Dr. Vierling's financial interests, but rather may affect classes of similarly situated products and manufacturers to the same extent. While this participation may be covered by section 208, it poses far less risk of bias than participation in matters that relate specifically to a particular firm or organization in which Dr. Vierling has an interest.

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. John M. Vierling, M.D., is professor of Medicine and Surgery at the Baylor College of Medicine in Houston, Texas; Director of Baylor Liver Health and Chief of Hepatology. In addition, he is the director of Advanced Liver Therapies, a center devoted to clinical research in hepatobiliary diseases at St. Luke's Episcopal Hospital. Dr. Vierling is board certified in internal medicine and gastroenterology. He received his Medical degree from Stanford University School of Medicine, where he was elected to Alpha Omega Alpha. His research interests are in the immunologic mechanisms of hepatobiliary injury (autoimmune and alloimmune liver diseases and hepatitis B and C virus infections), in which the host immune response plays an important role. Dr. Vierling is president of the American Association for the Study of Liver Diseases, which is the preeminent hepatology organization in the United States. He is member of the International Association for the Study of Liver; European Association for the Study of Liver; American Gastroenterological Association; American Federation for Clinical Research and International Liver Transplantation Society, and NIH Liver Tissue Procurement and Distribution advisory board. He has published numerous articles about various aspects of chronic hepatitis C virus infections. His honors include: Phi Beta Kappa, Alpha Omega Alpha, presidencies of both the Western Gut Club and the Southern California Society for Gastroenterology, and recurrent selection by his peers as one of the Best Doctors in America. I believe that Dr. Vierling's participation will contribute to the diversity of opinions and expertise represented on the committee and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

**APPEARS THIS WAY
ON ORIGINAL**

