



DEPARTMENT OF HEALTH & HUMAN SERVICES

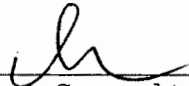
Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: February 2, 2006

TO: Jason D. Brodsky
Acting Associate Commissioner
Office of 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 Pamela J. Haylock,
R.N., M.A., Ph.D.(c)

I am writing to request a waiver for Pamela J. Haylock, R.N., M.A., Ph.D.(c), a member of the Oncologic 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 Pamela J. Haylock, R.N., M.A., Ph.D.(c), 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 Pamela J. Haylock, R.N., M.A., Ph.D.(c), 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 functions of the Oncologic Drugs Advisory Committee, as stated in its Charter, are to review and evaluate available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer, and to make appropriate recommendations to the Commissioner of Food and Drugs. Temporary subcommittees consisting of two or more committee members may be established as needed to address specific issues within their respective areas of expertise. Subcommittees make preliminary recommendations regarding specific issues for subsequent action by the full Committee.

Ms. Haylock has been asked to participate in all official matters concerning clinical studies of daunomycin to be conducted under the Best Pharmaceuticals for Children Act (BPCA). This issue is coming before the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee for consideration.

Ms. Haylock has advised the Food and Drug Administration (FDA) that she and _____ have a financial interest that could potentially be affected by her participation in these matters. _____ makes a product that could be affected by the subcommittee's discussions.

As a member of the Oncologic Drugs Advisory Committee, Pamela J. Haylock, R.N., M.A., Ph.D.(c), could potentially become involved in matters that could affect her and her spouse's financial interest. 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 Pamela J. Haylock, R.N., M.A., Ph.D.(c), 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 Pamela J. Haylock, R.N., M.A., Ph.D.(c), that would allow her to participate fully in the matter described above.

First, Ms. Haylock and _____ stock interest represents a minimal percentage of their total net worth and is

not so substantial as to preclude her participation in this matter.

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 Ms. Haylock's participation in will contribute to the balance of views represented and the diversity of opinions and expertise. The subcommittee'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. Pamela J. Haylock, R.N., M.A., Ph.D.(c), is the Oncologic Drugs Advisory Committee's Consumer Representative. Her role is to represent the consumer's perspective on the issues and actions before the advisory committee and interested consumers, associations, consumer organizations, and coalitions. She is a Registered Nurse who works as a self-employed oncology consultant and is also currently a Ph.D. student at the University of Texas Medical Branch School of Nursing. She provides cancer specific resources to health care and community organizations for planning cancer care services, cancer program management and implementation, and programs for professional staff development, staff support, public and professional education. Ms. Haylock has authored more than 100 articles, book chapters, and textbooks attesting to her expertise on cancer. I believe her participation will contribute to the consumer's perspective and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Pamela J. Haylock, R.N., M.A., Ph.D.(c), a waiver that would allow her to participate in all official matters concerning clinical studies of daunomycin to be conducted under the Best Pharmaceuticals for Children Act (BPCA). I believe that such a

waiver is appropriate because in this case, the need for the services of Pamela J. Haylock, R.N., M.A., Ph.D.(c), outweighs the potential for a conflict of interest created by the financial interest attributable to her.

CONCURRENCE: Mary Ann Kellam for JS 2/6/06
Jenny Slaughter Date
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.
Jason D. Brodsky 2.9.06
Jason D. Brodsky Date
Acting Associate Commissioner
Office of External Relations
Food and Drug Administration