



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: December 5, 2007

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

THROUGH: Vince Tolino 15/
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

Michael F. Ortwerth, Ph.D. 15/
Deputy Director, Advisory Committee Oversight and Management Staff
Office of Policy, Planning, and Preparedness

FROM: Igor Cerny, Pharm.D. 15/
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: 208(b)(3) Conflict of Interest Waiver for Sean Hennessy, Pharm.D., Ph.D.

I am writing to request a waiver for Sean Hennessy, Pharm.D., Ph.D., a temporary voting member to the Gastrointestinal Drugs Advisory Committee, 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. Sean Hennessy 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. Because Dr. Hennessy 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 Gastrointestinal 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 gastrointestinal diseases and to make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Hennessy has been asked to participate in the discussions of the safety and efficacy of Entereg (alvimopan), new drug application (NDA) 21-775, Adolor Corporation, for the proposed indication of acceleration of time to upper and lower gastrointestinal recovery following partial large or small bowel resection surgery with primary anastomosis. Originally developed by Eli Lilly, licensed to Shire Pharmaceuticals Group, currently GlaxoSmithKline and Adolor Corporation are in collaborative agreement for development and commercialization

This matter is coming before a meeting of the Gastrointestinal Drugs Advisory Committee. This issue is a particular matter involving specific parties.

Dr. Hennessy has advised the Food and Drug Administration (FDA) that he has a financial interest that could potentially be affected by his participation in the matter described above. Dr. Hennessy is a consultant to _____ developing the protocol for a study of a product that may or may not be done at the University of Pennsylvania. The product under study is unrelated to Entereg and the competing products. _____, and _____, subsidiaries of _____, make generic versions of metoclopramide, a competing product to Entereg.

In addition, Dr. Hennessy's employer, the University of Pennsylvania, is in discussions with _____ concerning an unrelated study. Dr. Hennessy is also a consultant to a law firm that is representing _____ on an unrelated matter. Entereg (alvimopan) was originally developed by Eli Lilly and licensed to Shire Pharmaceuticals Group prior to Adolor and GlaxoSmithKline acquiring rights. Both Eli Lilly and Shire Pharmaceuticals Group will receive royalties from sales of Entereg. Arguably, Dr. Hennessy's interests do not constitute financial interests in the particular matter under section 208(a) since they are unrelated to the issue at hand. Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

As a temporary voting member of the Gastrointestinal Drugs Advisory Committee, Dr. Hennessy potentially could become involved in matters that could affect his 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. Hennessy 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. Hennessy that would allow him to participate in the matter described because the need for his services greatly outweighs the conflict of interest created by this financial interest.

First, Dr. Hennessy's consulting is unrelated to Entereg and the competing products.

Second, Dr. Hennessy's financial interest in _____ is not so substantial as to preclude his participation in this matter. He receives nominal compensation for his consulting.

