



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: 712(c)(2)(B) 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 section 712(c)(2)(A) of the Federal Food, Drug, and Cosmetic Act. Waivers under section 712(c)(2)(B) may be granted by the appointing official where it is "necessary to afford the advisory committee essential expertise" and where the individual has made a disclosure to FDA of the financial interests at issue. We have determined that you are the appointing official for purposes of section 712(c)(2)(B). Therefore, you have the authority to grant Dr. Hennessy a waiver under section 712(c)(2)(B).

Section 712(c)(2)(A) prohibits Federal executive branch employees, including special Government employees, from participating in any particular matter in which the employee or an immediate family member has a financial interest that could be affected by the advice given to the FDA with respect to the matter. 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.

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 that may or may not be done at the University of Pennsylvania, on an unrelated issue. ————— and —————, subsidiaries of —————, make generic versions of metoclopramide, a competing product to Entereg.**

As a temporary voting member to the Gastrointestinal Drugs Advisory Committee, Dr. Hennessy could become involved in matters that could affect his financial interest. Under section 712(c)(2)(A), he is prohibited from participating in such matters. However, as noted above, you have the authority under section 712(c)(2)(B) to grant a waiver permitting Dr. Hennessy to participate in such matters if necessary to afford this committee essential expertise.

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.

Dr. Hennessy has a Pharm.D. from the University of the Sciences in Philadelphia, and a Master of Science in Clinical Epidemiology (MSCE) and a PhD in Epidemiology (with a minor in biostatistics) from the University of Pennsylvania. He is the only member of the Drug Safety and Risk Management Advisory Committee with this combination of expertise, which will benefit the Gastrointestinal Drugs Advisory Committee meeting. Dr. Hennessy's unique expertise will inform the discussion on multiple levels. He brings expertise in clinical pharmacy and drug use settings. Given the epidemiologic nature of the data and the complexity of the analyses to be discussed, the committee would greatly benefit by the participation of an expert epidemiologist and pharmacist to ensure a critical and balanced examination of the complex risk/benefit issues. Dr. Hennessy has that necessary expertise in epidemiologic methods and analyses. Dr. Hennessy has also applied his clinical and epidemiology expertise to studying adverse events and therefore he is very qualified to examine the balance of risks and benefits in patient populations. Dr. Hennessy's expertise is critical to a balanced and informed discussion of the issues and he offers broad expertise. In addition, the committee would benefit by the participation of an additional epidemiologist because

the risk/benefit issues to be addressed are very complex and will require expertise in epidemiologic methods and analyses. An additionally epidemiologist will help to ensure adequate and varied scientific analysis and discourse. I believe that participation by Dr. Hennessy in the committee's deliberations will contribute to the diversity of opinions and expertise represented on the committee.

Moreover, 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.

Accordingly, I recommend that you grant Sean Hennessy, Pharm.D., Ph.D., a waiver that would allow his voting participation in all official matters concerning 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. I believe that such a waiver is appropriate because in this case, Dr. Hennessy's voting participation is necessary to afford the committee essential expertise.

DECISION:

- Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that voting participation is necessary to afford the committee essential expertise.
- Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that nonvoting participation is necessary to afford the committee essential expertise
- Waiver denied.

151  
Randall W. Lutter, Ph.D.  
Deputy Commissioner for Policy  
Food and Drug Administration

12/21/07  
Date