

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. Michael Epstein 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. Epstein 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. Epstein is on _____ Speakers Bureau and lectures regarding their product _____ for use in _____ constipation, an indication unrelated to the indication coming before the committee. _____ is a competing product to Entereg.

As a member of the Gastrointestinal Drugs Advisory Committee, Dr. Epstein 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. Epstein 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. Epstein 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.

Michael S. Epstein, M.D., is Assistant Professor of Medicine at the Uniformed Services of Health Sciences, Bethesda, Maryland, and Staff Gastroenterologist, Anne Arundel Medical Center, Annapolis, MD. He has had broad experience treating a variety of gastrointestinal disorders over his lengthy career. He is very knowledgeable regarding clinical trial conduct and practice, having participated in several studies on a wide variety of gastroenterological diseases. His broad experience gives him a unique ability to understand the complications of extended hospital recovery and the potential benefits of earlier discharge from the hospital. This is highly important, as one of the major factors balancing the potential cardiovascular risk is a practical evaluation of the shortened hospital time weighed against such risk. In addition, Dr. Epstein will have the unique perspective of being able to comment on the proposed risk management plan and its potential to mitigate the potential risks. We have had extreme difficulty in locating similarly qualified gastroenterologists without a disqualifying financial interest to serve on the committee. The division feels that it is very important to gain the perspective of several gastroenterologists to consider a wider perspective and account for all aspects of the product under review. After

