



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

DATE: January 23, 2008

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

THROUGH: Vince Tolino 151  
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

Michael F. Ortwerth, Ph.D. 151  
Deputy Director, Advisory Committee Oversight and Management Staff  
Office of Policy, Planning, and Preparedness

FROM: Igor Cerny, Pharm.D. 151  
Director, Advisors and Consultants Staff  
Center for Drug Evaluation and Research

SUBJECT: 208(b)(3) Conflict of Interest Waiver for James C. Eisenach, M.D.

I am writing to request a waiver for James C. Eisenach, M.D., a temporary member of the Anesthetic and Life Support 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. Eisenach 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. Eisenach 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 Anesthetic and Life Support Drugs Advisory Committee is to review and evaluate available data concerning the safety and effectiveness of marketed and investigational

human drug products for use in anesthesiology and surgery and make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. James Eisenach has been asked to participate on March 11, 2008, to discuss new drug application NDA 22-225, sugammadex sodium injection (Org25969), proposed trade name Bridion, sponsored by Organon USA, a subsidiary of Schering-Plough Corporation, proposed indication of routine reversal of shallow and profound neuromuscular blockade (NMB) induced by rocuronium or vecuronium and immediate reversal of NMB at 3 minutes after administration of rocuronium.

This matter is coming before a meeting of the Anesthetic and Life Support Drugs Advisory Committee. This issue is a particular matter involving specific parties.

Dr. Eisenach 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. Eisenach is a consultant to \_\_\_\_\_ on an unrelated issue. \_\_\_\_\_ a subsidiary of \_\_\_\_\_ is the sponsor of \_\_\_\_\_, the product \_\_\_\_\_ and \_\_\_\_\_, a competing product.

As a temporary member to the Anesthetic and Life Support Drugs Advisory Committee, Dr. Eisenach 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. James C. Eisenach 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. Eisenach 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. Eisenach's consulting is unrelated to sugammadex sodium injection and the competing products.

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

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.

James C. Eisenach, M.D., is Professor of Anesthesiology as well as Physiology and Pharmacology at Wake Forest University in North Carolina Baptist Medical Center, where he is also the Vice Chairman for Research in the Department of Anesthesiology and a member of the Graduate Faculty for the Molecular Medicine Program. At Wake Forest he is recognized as a savvy and

skillful clinical anesthesiologist in the surgical, obstetrical and pain management arenas. He has served at the national level on multiple committees. Most relevant of which for this ALSDAC meeting are the Board of Directors for the Society for Obstetric Anesthesia and Perinatology, Scientific Advisory Board for the Association of University Anesthesiologists, and the American Society of Regional Anesthesia and Pain Medicine. In addition, Dr. Eisenach has served on the ALSDAC in the past and has been a consultant to the Gastrointestinal Drugs Advisory Committee. At NIH, he has served on the Advisory Panel for Funding Directions at the National Institute of General Medical Sciences (NIGMS) and on the Speaker and Advisory Panel for Funding in Biomarkers and Surrogate Outcomes.

Dr. Eisenach's current research interests are in the areas of obstetrical anesthesia with an emphasis on the management of labor pain and the impact of anesthesia on the fetus. This research has included evaluation of ST segment depression during cesarean section, and the assessment of pharmacokinetic and pharmacodynamic parameters of anesthetic drugs in animal models.

Fourteen anesthesiologists, with similar but not identical, expertise, were invited to participate. Five cannot attend due to schedule conflicts and one is recused. Of the eight planning to attend, Dr. Eisenach is the only one with Obstetric Anesthesia and Perinatology expertise. His presence on the ALSDAC when it meets to consider the safety and efficacy of Bridion will allow input from an individual who is uniquely qualified to raise and address concerns related to the pregnant patient, the fetus and the newborn especially those that require a substantial knowledge of pharmacodynamics, pharmacokinetics, and electrocardiographic activity in these special patient populations.

Accordingly, I recommend that you grant James C. Eisenach, M.D., a waiver that would allow him to participate in all official matters concerning new drug application NDA 22-225, sugammadex sodium injection (Org25969), proposed trade name Bridion, sponsored by Organon USA, a subsidiary of Schering-Plough Corporation, proposed indication of routine reversal of shallow and profound neuromuscular blockade (NMB) induced by rocuronium or vecuronium and immediate reversal of NMB at 3 minutes after administration of rocuronium. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. James Eisenach outweighs the potential for a conflict of interest created by the financial interest attributed to him.

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.

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

2/5/08  
Date