



Waiver to Allow Participation in a Food and Drug Administration
Advisory Committee

DATE: April 29, 2009

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

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

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

FROM: Kathleen L. Walker /S/
Chief, Integrity, Committee and Conference Management Branch
Division of Ethics and Management Operations, OMO
Center for Devices and Radiological Health

Name of Advisory Committee Member: H. Hunt Batjer, M.D., F.A.C.S.

Committee: Neurological Devices Panel of the Medical Devices Advisory Committee

Meeting date: May 14, 2009

Description of the Facts on Which the Waiver is Based:

Dr. H. Hunt Batjer currently serves on the Neurological Devices Panel, which reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in the neurological system and makes appropriate recommendations to the Commissioner of Food and Drugs.

Type, Nature, and Magnitude of the Financial Interest(s):

Dr. Batjer's employer, Northwestern University, was chosen as a clinical site for the premarket approval application (PMA) study coming before the Panel; however, no patients were enrolled. As Chairman of the Department of Neurological Surgery at Northwestern University, Dr. Batjer had management responsibilities for this study and received no personal compensation. The Department received [-----] when the trial began

in 2006. The sponsor has advised that currently no outstanding amounts are owed to the School of Medicine where Dr. Batjer serves as Chairman, except that there may be a close-out fee between \$500 - \$2,000, depending on the date of the study closure at the site.

Description of the Particular Matter to Which the Waiver Applies:

Dr. Batjer has been asked to participate in the meeting to discuss, make recommendations, and vote on a Premarket Approval Application for the DuraSeal Xact™ Sealant System, sponsored by Confluent Surgical, Inc., a unit of U.S. Surgical, a Tyco Healthcare Company. This device is indicated for use as an adjunct to sutured dural repair to obtain watertight closure during spinal surgery.

Basis for Granting the Waiver:

The need for Dr. Batjer's services outweighs the potential conflict of interest. Dr. Batjer's participation is necessary to provide the committee with essential expertise. FDA has substantial need for Dr. Batjer's services because his valuable expertise is not otherwise available. Dr. Batjer is the Michael J. Marchese Professor and Chairman of the Department of Neurological Surgery at Northwestern University, Feinberg School of Medicine. He also serves as Chief for the Division of Neurological Surgery for the Evanston Northwestern Healthcare program for Evanston, Illinois and surrounding areas. Dr. Batjer is widely-recognized in the neurological field and has been Secretary and President of the Congress of Neurological Surgeons. He has held Visiting Professorships at national and international medical centers and universities, including Harvard, Johns Hopkins, Yale, and the Universities of Virginia and Chicago. Dr. Batjer is also a prolific author on neurosurgery and has held positions on many neurological journal boards as editor and reviewer.

Dr. Batjer has been involved in complex cranial neurosurgery for the past 30 years focusing on cerebrovascular disease and cranial base exposures. In recent years, he has used the DuraSeal product for cranial and cranial base applications and conducts over 100 complex cerebrovascular and cranial base procedures per year. With this experience he can provide expert opinion on the practicalities of using a sealant and on the standard of care modalities for sealing dural incisions. As the acting chair for this Panel meeting, he has the opportunity to maintain the Panel's focus on the pertinent issues regarding cerebrospinal fluid leaks through dural incisions. His reputation in the field of neurosurgery provides the Panel with an authoritative perspective for discussing the device under review. Dr. Batjer will be one of only two neurosurgeons on the Panel, which also has two orthopedic surgeons. The Center sought the participation of four other neurosurgeons and three other orthopedic surgeons, however, due to personal or professional conflicts, those individuals could not participate. The Center's search included the database of the Center for Drugs Evaluation and Research, however, no neurosurgeon with comparable expertise and without conflict could be found.

The potential for conflict of interest is very low. The amount of the financial interest is very low and it is imputed to Dr. Batjer's employer rather than being a direct interest of his.

I believe that Dr. Batjer's extensive knowledge and experiences as a neurosurgeon greatly outweighs any of the perceived conflicts of interest and his presence will contribute to the opinions and expertise represented on the Panel.

Thus we are requesting a waiver for Dr. H. Hunt Batjer, a voting member of the Neurological Devices Panel, from the conflict of interest prohibitions of 18 U.S.C. § 208(a).

Certification:

The individual may participate – The need for the Special Government Employee's services outweighs the potential for a conflict of interest.

The individual may participate – The individual's participation is necessary to afford the advisory committee essential expertise.

Limitations on the Regular Government Employee's or Special Government Employee's Ability to Act:

Non-voting

Other (specify):

Denied – The individual may not participate.

/S/
Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy

4/29/09
Date