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

DATE: September 4, 2018

TO: Rachel Sherman, M.D., M.P.H.
Principal Deputy Commissioner
Office of the Commissioner, Food and Drug Administration

THROUGH: Russell Fortney
Director, Advisory Committee Oversight and Management Staff
Office of Special Medical Programs

FROM: Laura E. Bailey, M.S.
Chief, Committee Management Branch
Division of Workforce Management, OM
Center for Devices and Radiological Health (CDRH)

Name of Advisory Committee Meeting Member: Nicole R. Gonzales, M.D.

Committee: Neurological Devices Panel of the Medical Devices Advisory Committee

Meeting date: September 27, 2018

Description of the Particular Matter to Which the Waiver Applies:

The Panel will discuss, make recommendations and vote on information regarding a premarket approval application (PMA), sponsored by Sequent Medical, Inc., a subsidiary of MicroVention, Inc., a unit of Terumo Corporation, for the Woven Endobridge (WEB) Aneurysm Embolization Device. The WEB device consists of a wire mesh that is folded and pinned to create a spherical or semispherical ball that is placed inside the sac of the intracranial aneurysm. The wire mesh acts to restrict blood flow into the aneurysms and promotes endothelial growth across the neck which helps to secure the aneurysm and reduce or eliminate the likelihood of aneurysmal rupture. The proposed indications for use of the WEB device is for the embolization of wide neck bifurcation intracranial aneurysms.

The topic to be discussed during the meeting is a particular matter involving specific parties.

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

Nicole R. Gonzales, M.D. serves as temporary voting member of 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. The PMA for the WEB Aneurysm Embolization Device is the particular matter under review by the Panel at this meeting. Data from the WEB® Intrasaccular Therapy Study (WEB-IT) in subjects with wide neck bifurcation intracranial aneurysms supports the PMA. Dr. Gonzales' employer, University of Texas Health Science Center at Houston Medical School (UTHealth), is one of (b) (4) clinical sites for the WEB-IT clinical study. UTHealth treated two patients, or 1.3% of the total treated in the study. This site is no longer recruiting participants, but follow-up for one subject is expected to continue until September 2020. Funding to UTHealth from the start of the WEB-IT clinical study in 2015 to the present was between $10,001 and $25,000. UTHealth will be awarded between $5,001 and $10,000 to fund the remaining IRB annual renewal fees and follow-up visit payments.

Dr. Gonzales is not personally involved with the WEB-IT clinical study at UTHealth. Dr. Gonzales is Associate Professor in the Department of Neurology - Stroke Program. The study's investigator is on the faculty of the (b) (6) Department of Neurosurgery. Dr. Gonzales does not oversee or have any relationship with the investigator's activities, including any clinical trial involvement. Dr. Gonzales and the investigator are colleagues that sometimes co-manage patients.

Basis for Granting the Waiver:

Dr. Gonzales has unique qualifications and specialized expertise needed for this particular matter.

The upcoming panel meeting focuses on aneurysms, a devastating neurological disorder that requires medical attention by vascular neurologists, and Dr. Gonzales is a highly trained and well respected clinical neurologist with significant experience in vascular neurology. She received her medical degree from McGovern Medical School of the University of Texas Health Science Center at Houston, with an internship and residency at the University of Colorado. She completed a neurovascular fellowship at the University of Texas Medical School and currently holds academic appointments at McGovern Medical School. Dr. Gonzales is board certified by the American Board of Psychiatry and Neurology in both Neurology and Vascular Neurology. She is a member of multiple professional organizations including the American Academy of Neurology and the World Stroke Organization. Dr. Gonzales has served as a member of the FDA Peripheral and Central Nervous System Drugs Advisory Committee on multiple occasions, and her contributions to the committee's discussions have been significant, demonstrating a commitment to the interests of public health.

There is limited expertise available and it is difficult to locate similarly qualified individuals without a disqualifying financial interest.

The CDRH division responsible for the review of this PMA believes that this will be a complex panel discussion due to the need to understand converging topics in neurovascular aneurysm treatment, medical imaging, and interpreting clinical trial results. The panel will be asked to consider the impact of each of these different factors both individually and collectively. During the panel preparation process, the division approached multiple individuals with experience in these areas; however, these experts were ineligible due to financial conflicts, or were unavailable due to scheduling conflicts. The division has not been able to identify another individual that approaches Dr. Gonzales' level of experience and expertise as a vascular neurologist and former FDA committee participant.

The particular matter is not sensitive.

The particular matter to be addressed by the panel is not considered sensitive. While this is a first-of-a-kind technology, the topic of intracranial aneurysm treatment has been discussed at multiple panel meetings (2015 and 2018), and these meetings were not found to be sensitive. This meeting is not expected to be different than the two prior panels.

Dr. Gonzales' expertise in this particular matter is necessary in the interest of public health.

Dr. Gonzales has served as a committee member on neurological related advisory committee meetings for the Center for Drugs Evaluation and Research on multiple occasions. Her contributions to the committee's discussion have demonstrated a commitment to the interest of public health. Additionally, in the interest of public health, it is critical for the Agency to review new products that can potentially provide treatment for intracranial aneurysms, which can be life threatening if left untreated. The durability of the repair with the device under review is a significant issue to be addressed by the panel given that a device failure could lead to death, and public health demands a rigorous review of the data and a productive discussion among the advisory committee members. Dr. Gonzales' knowledge of vascular neurology and clinical trial design, along with her experience as a committee member, will provide the necessary expertise for this important discussion.

Any potential for a conflict of interest is greatly outweighed by the strong need for Dr. Gonzales' expertise in this matter.

Dr. Gonzales' employer is one of the (b)(4) U.S. sites participating in the WEB-IT clinical study for the device under discussion: the WEB Aneurysm Embolization Device. However, she does not have any involvement or oversight with the study itself. Dr. Gonzales is a faculty member in the Department of Neurology and is not involved in interventional treatment cases conducted in the Department of Neurosurgery where the clinical study is being conducted. Dr. Gonzales does not oversee or have any relationship with the study investigator's activities. Additionally, the study site enrolled a total of two subjects, a small percentage (1.3%) of the U.S. sample size. Any potential conflict of interest created by this situation is greatly outweighed by the need for Dr. Gonzales' significant expertise as a committee member and as an expert in clinical studies for vascular neurology, both of which are imperative to the success of this panel meeting.

Accordingly, I recommend that you grant a waiver for Dr. Nicole R. Gonzales, a temporary voting member of the Neurological Devices Panel, from the conflict of interest prohibitions of 18 U.S.C. § 208(a), with respect to the above-described particular matter.

Certification:

_____ The individual may participate, pursuant to 18 U.S.C. 208(b)(3) – The need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved.

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

_____ Non-voting

_____ Other (specify):

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_____ Denied – The individual may not participate.

/S/ **9/11/2018**

Rachel Sherman, M.D., M.P.H. Date
Principal Deputy Commissioner
Office of the Commissioner, Food and Drug Administration