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February 13, 2013

Victor Krauthamer, PhD, Acting Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Building 62, Room 3108
Silver Spring, Maryland 20993

RE: Consideration of Neurostimulation for Epilepsy, FDA Neurological Devices Panel Meeting, February 22, 2013

Dear Dr. Krauthamer:

The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) appreciate the opportunity to provide comments to the Food and Drug Administration regarding neurostimulation for epilepsy patients, in advance of consideration of the NeuroPace Responsive Neurostimulation System by the Neurological Devices Advisory Panel meeting on February 22, 2013.

Epilepsy affects over one percent of the US population (>2.5 million people). Yet over a third of these individuals (> 700,000) will not find significant relief from medications. The likelihood that these people will be helped by a traditional surgery is less than 10 percent, leaving a large portion of patients with either medically or surgically untreatable epilepsy. These numbers have not changed for at least 10 years. Neurostimulation has been a therapy that has proven success in otherwise medically refractory or surgically inappropriate patients with epilepsy. Neurostimulation represents a line of therapy that has over 20 years of FDA approved indications, including success with refractory pain, Parkinson's disease, essential tremor, dystonia, urinary incontinence, gastric disorders and epilepsy. It is a line of therapy that utilizes the safe nature of focused electrical stimulation to correct – or "modulate" – neural circuits that are dysfunctional. There have been over 1,000,000 of such neuromodulatory devices implanted in the past 25 years worldwide. It is an accepted and safe alternative to other forms of medical or surgical treatments.

With regard to the need for new implantable neurostimulator devices, the field is quite young and the technology is primitive when compared to other implantable devices such as those used in cardiac rhythm management. Presently there are no implantable neurostimulators that can actually sense dysfunctional rhythms of neural circuitry and then tailor a unique treatment strategy for each patient based on review of the electrical data collected over weeks to months by the prescribing physicians. This technology was first developed by Neuropace in their RNS (Responsive Neurostimulation System), proposed over a decade ago and receiving IDE approval for initial clinical testing in 2003. While all other

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neurostimulators merely deliver a preprogrammed set of stimulation instructions, the Neuropace RNS actually collects the electrical activity from patients through the implanted electrodes, allows physicians to receive data transmitted wirelessly from the device to a secure web-site for analysis, and then allows physicians to send a customized neurostimulation "prescription" to the device. The "prescribed neurostimulation therapy" utilizes the sensing capacity of the implant to deliver therapeutic stimulation only over a short duration of the detected seizure in the individual, with the hope of aborting the seizure process. The results of the treatment can be monitored, re-assessed by the physician at any time and an adjusted therapeutic paradigm reloaded into the device for improved seizure monitoring and treatment. This is the first-of-its-kind, closed feedback neurostimulation system potentially available for US patients. It represents a significant technology upgrade when compared to any presently implantable neurostimulation device.

The safety profile of this system proposed by Neuropace has been through greater than 8 years of clinical testing under the FDA. Over the majority of this time, the data has been methodically discussed and presented at numerous scientific and clinical meetings. Neurosurgeons are keenly aware of the significant need of patients whose seizures cannot be helped by medications and surgical intervention. The more than 500,000 patients in this category have not seen significant benefit from other "open loop" stimulators – i.e., neurostimulators which cannot detect seizures or deliver a customized stimulation therapy based on a seizure detection method. While the method of implantation and management of the device are similar to other common surgical and diagnostic procedures, it is the unique combination of the sensing capability with the capacity to develop a customized therapy for each individual that represent a true technology breakthrough in implantable neurostimulation devices. Approval of this device would be in the vanguard of second generation neurostimulator devices available for patients with neurological disease.

Again, thank you for the opportunity to provide our views. The AANS and CNS are hopeful that this technology will be available to clinicians soon, so as to offer the more than 500,000 epilepsy patients an option they do not have presently.

Sincerely,

Mitchel S. Berger, MD, President
American Association of Neurological Surgeons

Ali R. Rezai, MD, President
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