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January 19, 2007

Janet L. Scudiero
Executive Secretary of the Neurological Devices Panel
FDA

RE: January 26, 2007 Neurological Devices Panel meeting

To Whom It May Concern:

I am writing in support of the application for Transcranial Magnetic Stimulation (TMS) as a treatment for major depression. I serve as the electroconvulsive therapy program director at the University of Michigan and have treated the most severely depressed patients for over a decade. I also have growing experience in other brain neuromodulation strategies for depression and served as one of the principal investigators for the Neuronetics pivotal trial of TMS in major depression at our site.

The illness of depression is devastating for many and wreaks havoc on families and patients' ability to function in society. Recent data support that our current medication treatments routinely fail to achieve remission or complete wellness. The burden of depression is enormous, and the disability incurred by this illness is estimated to be second only to heart disease by 2020 and is already a top 5 source of disability according to the World Health Organization.

With this growing problem, psychiatry needs well tolerated and novel ways of improving mood disorders. TMS is one of these strategies. Although TMS has been studied for over a decade, the Neuronetics trial is the largest of all trials and the data support its superiority over sham TMS. This trial incorporated the isolated strengths of many of the older trials so that duration of treatment and dosage were maximized.

The trial data also support that TMS is extremely safe and well tolerated. The most common things that our patients experienced were local pain or headache over the stimulation site. A few had facial twitching that was described as not at all uncomfortable or mildly/moderately so. Most of the side effects experienced

appeared to lessen or dissipate during the first week of study and most patients did not drop out. Although cognitive side effects can occur with ECT, our experience was that subjects tolerated TMS very well with no complaints of memory problems. The application data also supports that TMS is well tolerated cognitively.

During this trial, we studied many patients that I would have considered for electroconvulsive therapy given the severity, duration, and recurrence of their depression. Many of them responded to TMS very well. I was extremely pleased and excited to see such improvement for these very sick people. It is exceptionally rewarding to witness depressed patients return to normal functioning with good sleep, reduced agitation and anxiety, revival of their sense of humor, and eliminate suicidal thoughts. Patients are also thrilled to "have my life back". So, based on my review of the application data and clinical experience I am very supportive of TMS and its use for major depression.

Sincerely,

A handwritten signature in cursive script, appearing to read "Daniel F. Maixner".

Electronically signed 1.19.07

Dr. Daniel F. Maixner MD