

THE UNIVERSITY OF TEXAS
SOUTHWESTERN MEDICAL CENTER
AT DALLAS

Mustafa M. Husain, M.D.
Professor
Chief, Geriatric Psychiatry Division
Director, Neurostimulation Lab

Department of Psychiatry
Department of Internal Medicine

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To: FDA Neurological Devices Panel

Re: Review of the NeuroStar TMS Therapy System

This letter pertains to the January 26, 2007 meeting of the FDA Neurological Devices Panel to review the NeuroStar TMS Therapy System. I was the Principle Investigator at the University of Texas Southwestern Medical Center at Dallas for the Neuronetics rapid-Transcranial Magnetic Stimulation (rTMS) studies for depression and was able to witness firsthand the effect rTMS had on our patients. I have been the Principle Investigator for many studies over the years involving neurostimulation treatments for the treatment of severe, refractory, depression. At our site, patients had long standing Major Depressive Disorder (MDD) and many had tried multiple antidepressant therapies without much benefit. Their illness had left them feeling miserable, hopeless, and unable to function.

With full explanation of the study procedures, including the time commitment of five days a week of acute treatment, and a clear message that we did not know how effective the treatment would be, patients were still eager to participate in the study. Once enrollment was complete, we had patients coming from all over the state of Texas. The outcome of this treatment for our patients, who we saw and evaluated on a daily basis during acute treatment, was that some did not show initial improvement, some felt better, and others felt a significant reduction of depressive symptoms and an improved quality of life. One of the benefits many patients mentioned, except for mild scalp pain during the treatment which could be resolved with a topical ointment, was the lack of treatment side effects that they experienced with other antidepressant treatments. Although our patients initially viewed rTMS as something out of science fiction, they grew very comfortable with the treatment and welcomed the procedure. Many hoped the treatment would be available to them should they need it in the future.

The opportunity for a return of normalcy is what these very depressed people are wanting and are searching for. Because we followed these patients through their treatments and for months after the end of their treatment, it was clear that rTMS made a positive impact on many. Given the limited antidepressant treatments available for patients with severe, treatment refractory depression, rTMS would be an asset to those who would benefit from its utility.

Sincerely,

Mustafa M. Husain, M.D.
Professor of Psychiatry and Internal Medicine
Director, Neurostimulation Research Laboratory

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