

Dear Sirs:

I am a board certified psychiatrist specializing in mood disorders. I have been a principle investigator in the Neuronetics funded study on repetitive Transcranial Magnetic Stimulation (rTMS) currently under review by the FDA. I am writing to provide my opinions about the current status of depression treatment and my experience with Neuronetics and rTMS.

Despite multiple pharmacological treatment options for depressed patients, many either do not respond to medications or are intolerant of them. The recently published data from the NIMH sponsored STAR-D trial suggests that over a third of patients with depression are not able to experience remission despite aggressive, multi-tiered, sequential treatment. As well, many of us have many patients who have been intolerant of multiple medications and we have little to offer these desperate patients. While ECT has a niche with many severely ill folks and VNS has provided another alternative, rTMS may provide a less invasive alternative.

rTMS has been studied for depression for some 20 years, but its development has been severely limited by a plethora of differing treatment strategies, different equipment and many studies with too low a number of participants to support an FDA submission for approval. Ultimately, its development has been delayed due to the expense in getting sufficient data to demonstrate safety and efficacy of a consistent mode of treatment. Neuronetics managed to obtain sufficient funding to rigorously test the effectiveness of a particular treatment paradigm. Their thoughtful and elegant study design is a benchmark for other device trials within mental health.

The results of their study support a good effect of rTMS on patients with difficult to treat depressions with minimal adverse effects. Our experience as a site for this study was very positive. We have continued to follow several patients clinically after the blinded parts of the study and have seen good maintenance of effect and excellent tolerance of the procedure.

rTMS would be a valuable addition to the tools we have to treat the often crippling illness of depression. I fully support its approval by the FDA.

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