

Dear Ms. Scudiero,

I am writing to express my support for FDA approval of the NeuroStar TMS device which will be reviewed for treatment of depression at the Neurological Devices Panel meeting on January 26, 2007. I am one of the principal investigators in the efficacy and safety studies for the device. I grant my permission to post my comments on the public comment website of the FDA.

My practice is comprised primarily of patients with major depressive disorder and largely those with treatment resistant depression. Major depression is a devastating illness which severely compromises the ability of its victims to function in usual life—family, school, work, etc. According to the World Health Organization, it is one of the major causes of lost productivity in the world today and it is climbing. While there are many antidepressant drugs available to treat major depression, the response rates are less than satisfactory. The most recent STAR-D study suggests that only one-third of patients with major depression will have an adequate response to a single medication. Sequenced treatment or augmented treatment may double the remission rate. After exhausting all known effective treatments for major depression (antidepressants with different mechanisms, talk therapies and electroconvulsive therapy), as many as one-third of patients still will not have responded adequately. In addition, there are many patients who are intolerant to the many side-effects of anti-depressant medications. The net result is that despite a panoply of treatments, there still is a huge unmet need for new effective treatments for major depression.

Transcranial magnetic stimulation is a very valuable treatment for our patients with major depression and should play a significant role in clinical care. I will not reiterate the study outcome data which you are reviewing, but it clearly demonstrates that rTMS is effective—even in patients who have been relatively treatment resistant—and it is very safe. In the clinical trials, no patients experienced any serious adverse effects, and those “side-effects” that did occur were transient and mild and, frankly, inconsequential compared to the usual side-effect profiles of antidepressant medications. In addition to being effective and safe, rTMS has the additional advantage of durability after treatment. Patients remitting after a course of rTMS continued their remissions at a much higher rate than our historic “gold standard,” ECT.

I think that TMS has a distinct role in the treatment of major depression. It should be available as a primary treatment option or as an additional therapy for patients failing to respond to other treatments. In my experience, it is effective, safe, well-tolerated and durable. I urge the panel to recommend approval.

Sincerely,

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