

January 19, 2007

To the FDA Neurological Devices Panel:

This letter pertains to the January 26, 2007 meeting of the Neurological Devices Panel. We grant permission for the FDA to post these comments publicly on the FDA website.

Our team has participated in research involving repetitive transcranial magnetic stimulation (rTMS) for major depression since 1998. Our initial research involved a pilot study comparing rTMS and electroconvulsive therapy (ECT). Subsequently, we were very excited to be involved in a recent multi-site clinical trial of rTMS for major depression. The study used a double-blind, randomized, sham-controlled design in over 300 subjects. The trial incorporated experience from previous research, utilized a very rigorous study methodology and involved careful screening and assessment procedures to evaluate the efficacy of rTMS using the Neuronetics Model 2100 CRS magnetic stimulator.

In the context of these studies, we have had a very positive experience with this novel modality. The thought of a new, potentially effective treatment drew significant interest. For example, we were contacted by thousands of patients interested in rTMS. We were also struck by the level of need for alternative treatments for depression as evidenced by these patients. Many people who suffer from major depression do not obtain relief with current antidepressant therapies. Patients enrolled in our studies had often failed multiple antidepressant trials, had few treatment options remaining, and were hesitant to risk the cognitive side effects associated with ECT.

Our experience was that rTMS was well tolerated with a very low discontinuation rate compared to antidepressant medication trials. This was especially noteworthy given that this population frequently could not tolerate psychotropic medication due to untoward side effects. Additionally, rTMS was not associated with cognitive side effects that often accompany treatment with ECT. Furthermore, we found the therapeutic antidepressant benefit achieved with rTMS was usually maintained well beyond the acute treatment period. Many subjects reported feeling like themselves for the first time in years.

In conclusion, we wholeheartedly support FDA approval of the rTMS device for treatment of major depression. We have observed firsthand the benefit this treatment has given patients, including many who had given up hope of their depression ever improving.

Jeffrey Rado, M.D.  
Sheila Dowd, PhD  
Jennifer Strong, B.A.  
Jane Strong, APRN  
Philip Janicak, M.D.  
Psychiatric Clinical Research Center  
Department of Psychiatry

Rush University Medical Center