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January 19, 2007

To: Neurologic Devices Panel  
Food and Drug Administration

Re: January 26, 2007 Meeting of Neurologic Devices Panel

This letter is submitted to express my support for the approval of transcranial magnetic stimulation therapy (TMS), for the treatment of refractory depressive disorders.

I am a psychiatrist currently in a full time outpatient practice, and with more than 20 years past clinical experience in a variety of treatment settings. During that time, there have been many improvements in the treatment of depressive disorders. Numerous new antidepressant medications have become available, with generally lower frequency and severity of adverse effects, as compared to the older tricyclic antidepressants and monoamine oxidase inhibitors. Research has verified the efficacy of psychotherapy, particularly cognitive behavioral therapy. Electroconvulsive therapy, for more severe, and more treatment resistant disease, has been gradually improved to decrease cognitive and other adverse effects. Vagal nerve stimulation has become available. Augmentation strategies, involving combinations of medications, vitamins, supplements, hormones and other treatments, have been increasingly used, sometimes successfully.

Still, depressive illness remains a common, costly, and frustrating problem, among children, adolescents, adults, and the elderly. Most individuals who seek treatment experience significant improvement, but many fail to achieve full improvement, or remission of symptoms, despite appropriate and aggressive treatment. Depression is a painful condition. Failure to gain remission significantly impairs quality of life. In addition, persistent depressive symptoms often result in continued functional impairment in multiple areas, such as relationships with family and peers, occupational performance and earning capacity, academic performance. The high cost of treatment sometimes prevents access to adequate care. Effective and safe additions to our current treatment armamentarium are needed.

I have not been personally involved in research on transcranial magnetic stimulation. However, based on my review of the existing research to date, TMS has shown ability to produce significant and measurable improvement in numerous trials, in both open and placebo controlled groups. More recent studies, using improved techniques and parameters, have shown more consistent results. Studies have also repeatedly demonstrated the safety of the procedure, and lack of adverse interaction with concurrent medications. TMS has already been approved for treatment of depression in other countries, including Canada and Israel.

TMS is generally well tolerated. It is unlikely to cause adverse effects often associated with antidepressant medications. To my knowledge, it has not been associated with a risk of increased suicidal ideation. It is unlikely to cause increased appetite or weight gain. It is unlikely to cause constipation, dry mouth, tachycardia or orthostatic hypotension. It is unlikely to cause sedation or sexual dysfunction. It does not induce nor is it a substrate of hepatic enzymes, nor is it likely to be associated with hepatic, renal, hematologic, dermatologic problems, or with potential changes in cardiac conduction and rhythm.

When medication treatment fails to relieve severe depression, electroconvulsive therapy is currently often the treatment of choice. Based on the available information, TMS appears to offer several potential advantages over ECT, in many situations. TMS is not associated with transient cognitive impairment, or with potential complications of anesthesia. Since it can be safely done in an outpatient setting and without anesthesia, the cost per procedure should be relatively low. ECT generally requires an operating or procedure room, recovery room, anesthesiology services, a treating psychiatrist, and nursing staff, resulting in a cost up to several thousand dollars for each treatment session. Many patients refuse appropriate recommendations for ECT, due to fear about the procedure. TMS is not associated with the stigma which is unfortunately attached to ECT. TMS should also be more acceptable to patients who are anxious about the need for a general anesthetic, or about treatment in a hospital setting. ECT, on the other hand, will likely remain a preferred therapy for patients with more severe conditions, such as characterized by the presence of intense suicidal ideation, malnutrition associated with depression, or presence of psychosis.

Because it is quite expensive and requires surgical placement, vagal nerve stimulation is generally used only for those who have very prolonged and chronic depressive illness. Although it can provide prolonged efficacy, it generally becomes effective only gradually, over a course of several months, rather than in a short time.

In summary, TMS, if administered under the supervision of psychiatrists with training and expertise in its use, has the potential to provide an additional effective and safe treatment for depression, which is greatly needed. It would likely be used for those with relatively severe conditions, who have failed to respond to adequate medication therapies, or who have not tolerated potentially effective medications, and who might otherwise respond only to ECT. I encourage you to consider it favorably for approval.

Thank you for your consideration of my comments.

Sincerely yours,

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