



March 8, 2007

FDA Panel, Neurological Devices

Regarding: January 26, 2007 meeting of the Neurological Devices Panel

Distinguished Members of the Panel:

I wish to offer my public support in favor of the approval of transcranial magnetic stimulation (TMS) in the treatment of major depressive disorder, and give my permission for my comments to be posted on the FDA website. I am a board certified psychiatrist and have been in academic practice for the past 15 years. From my perspective as Director of the Electroconvulsive Therapy (ECT) service at Wake Forest University Baptist Medical Center I can clearly see a need for TMS in the treatment of moderate to severe major depression, including those individuals who have demonstrated treatment resistance or medication intolerance. This historically been the province of ECT—but my experience supported by the literature suggests that patient acceptance of ECT can be a significant hurdle. As well, there are clearly patients who are unable to tolerate ECT and the attendant risk of anesthesia and cardiac stress, and for some the hampering effects upon cognition.

Over the recent holiday season, I lost a patient to suicide—a devastating event for his family and a demoralizing failure for our treatment team as all our best efforts came to naught and we simply ran out of options. This unfortunate individual could not tolerate ECT because of severe obesity and resultant problems with airway management during the postictal period (he became severely agitated upon emergence.) We clearly need a treatment alternative that can approach the effectiveness of ECT but is better tolerated.

As a Principal Investigator at the Wake Forest site for the recent Neurostar device pivotal trials I have observed firsthand the advantages that properly administered TMS affords for depressed patients. I have reviewed the results from the sham-controlled and open studies we conducted and believe that the data largely speak for themselves. Taken in concert with the controlled studies that preceded this trial, I think the evidence is irrefutable as to the benefit of active prefrontal TMS over sham in the treatment of major depression. The effect appears also to be of a clinically

significant magnitude, and durable upon withdrawal of TMS when accompanied by appropriate antidepressant maintenance treatment. Furthermore, the safety and tolerability data for this multicenter study is remarkable.

In summary, I hope that this committee will conclude as I have that this device is not only promising, but is now also a proven alternative for the millions of Americans afflicted by major depressive disorder. Thank you for your careful consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Peter B. Rosenquist, M.D.", written in a cursive style.

Peter B. Rosenquist, M.D.

Associate Professor

Department of Psychiatry and Behavioral Medicine

Wake Forest University School of Medicine