

The following is for the committee and may be posted on your web site with other commentaries on TMS and Neuronetics' [application](#):

Dear Jan Scudiero,

I am writing to the FDA's Neurological Devices Panel to strongly support approval of a forthcoming device, developed by Neuronetics, Inc., that will allow office-based treatment of major depression with transcranial magnetic stimulation (TMS). As a citizen, physician, life-long psychiatric educator, and person with family members with intractable major depression, I heartily endorse approval of TMS methodology as delivered by this device. This non-invasive, non-convulsive device offers the potential for improvement (as documented in many clinical trials) in a significant percentage of patients who currently suffer from major depression and have not experienced relief despite aggressive treatment with other modalities. With significantly greater ease of use than ECT, TMS has so far been documented to have as significant or almost as significant benefits, with a substantially better side effect profile. Patients who require have required ECT in the past for major depression will now have the option of being treated with TMS. Such patients desperately await the option of possibly benefiting from treatment with this device. They await your actions.

I would refer, from a vast literature, to Mark George and Robert Belmaker's comprehensive text "Transcranial Magnetic Stimulation in Clinical Psychiatry (APA 2007). I have professional known Dr Belmaker since 1972, when he and I were both Clinical Associates at NIMH, and have followed his outstanding career as an eminent psychiatric researcher since then. This is an authoritative text and does a remarkable job of presenting an enormous literature on TMS. There are other many publications supportive of TMS methodology in major depression which I will not cite as they are cited in other positive appeals to the committee and in literature that is well known. Major depression is, from the nosological perspective, and from emerging genetic data, a heterogeneous condition (as is the case with all psychiatric disorders), and it is not surprising that many patients respond to TMS while others do not – this is the nature of psychiatric disorders. What is surprising, and quite wonderful, is the fact that patients who do not respond to multiple other FDA approved treatments do respond to TMS. Also, to reiterate, and as is well known, in addition to the very clear possible benefits for patients, TMS has a remarkable risk-benefit ratio and a very acceptable side effect profile.

My own experience with TMS as a clinical procedure goes back into the 1990's, when I was Clinical Professor of Psychiatry at Case Western Reserve University and I referred patients with intractable major depression and with intractable depersonalization disorder for TMS to Harvard, which was already an investigational treatment there. I have followed the evolution of use and understanding of this approach to depression with great interest over subsequent years, and am delighted that this TMS device from Neuronetics is now before the FDA.

Disclosure. I have absolutely no ties to Neuronetics or to any other parties or persons involved in the development of TMS. I have no financial ties, no grants and no projects in this area. My enthusiasm for this device is born of my own free-will, and expertise/critical judgment as a psychiatrist. And especially from my deep concern for those who suffer from major depression and my opinion that many will benefit greatly from the availability of an office-based form of TMS.

Sincerely,

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