

Joe Byrd

December 18, 2006

Janet L. Scudiero  
Center for Devices and Radiological Health (HFZ-410)  
Food and Drug Administration  
9200 Corporate Blvd  
Rockville, MD 20850

REF: Code 3014512513, Neuronetics rTMS device for treatment of major depressive disorder

Dear Ms. Scudiero,

I participated in a clinical trial of a repetitive transcranial magnetic stimulation (rTMS) device made by Neuronetics, Inc for the treatment of major depressive disorder. I would like to share my perceptions of rTMS with you, to help in the FDA's evaluation of this particular tool.

To jump to the chase, my results are long-lasting and nothing short of spectacular – when all previously attempted treatments had little impact and came with troubling side effects.

I had dysthymia with frequent bouts of major depression almost constantly for nearly thirty years. Although I never attempted suicide, I dreamed of it often and wished I had the courage to go through with it. At night I would plead not to wake up the following morning.

Such was my existence for the majority of my life.

The black cloud that wouldn't go away affected far more people than me. It affected more than my family and closer relationships. It affected my employers and coworkers when I was able to work, and it affected every taxpayer when I wasn't. One could even say it affected national security; it impacted my work for 7 years as an extremely depressed officer in the armed forces.

For the past 15 years, I tried unsuccessfully to treat my depression with a combination of talk therapy and medication. Over the years I tried every class of anti-depression drug on the market, usually in a cocktail of two or three or even more drugs at a time. SSRI's. Wellbutrin. SNRI's. Tricyclics. MAOI's. Lithium. Remeron.

The results were mixed (at best) and never lasted more than a few months (at best). The side effects were significant, from profuse sweating to severe hand tremors.

In desperation, I asked my psychiatrist about electro-convulsive therapy (ECT). Despite the severity, side effects, and cost of the treatment, I was fearful but ready to make an appointment. My psychiatrist suggested I first consider participating in an rTMS study, and I contacted the trial coordinator immediately.

The rTMS treatment was not a walk in the park. I found it uncomfortable, like a woodpecker pecking my head, and it sometimes caused my face to slightly twitch involuntarily during the treatment. It required nearly daily sessions for several weeks, which may have been difficult to keep had I been working at the time.

But it worked! With no side effects! And it's lasted for going on a year and a half now!

Immediately prior to receiving rTMS I was unemployable, receiving disability payments from the government, suffering severe side effects from medication, and often praying for death. Now, I'm a well paid, effective, and successful executive who can navigate life's ups and downs realistically. I'm taking a single maintenance medication, and yes, it has side effects, but it's a price I'm willing to pay for the most dramatic change I've experienced.

Instead of praying for death, I'm grateful for life, the good and the bad. I'm grateful I had the opportunity to receive rTMS, and firmly believe that everyone with hard-to-treat depression should have that same opportunity. It is particularly important to have rTMS as an option to try before undergoing more intrusive therapies that may have more severe side effects.

rTMS saves lives. It allows unproductive members of society to become productive, and to contribute in meaningful ways even beyond social and economic. As someone who has experienced this treatment first-hand, I strongly urge you to make rTMS available to the American public as quickly as possible. *You* will be saving lives.

Sincerely,

Joe Byrd