

From: Herbert and Joyce Stein [fabrik@bellsouth.net]

Sent: Sunday, January 07, 2007 10:52 AM

To: Scudiero, Janet L.

Subject: VNS Therapy for TRD (Cyberonics) - Neurological Devices Panel of the Medical Devices Advisory Committee meeting to be held on January 26, 2007

Dear Ms. Scudiero,

As per our previous communication I would appreciate if you would please take this document and kindly submit it to the Neurological Devices Panel of the Medical Devices Advisory Committee meeting to be held on January 26, 2007, as I shall not be able to attend in person. I would appreciate if my testimony would be read and entered into the public record.

My name is Herbert Stein, mental health advocate and pro-activist. I have been married to my spouse, Joyce, for 43 years and I have also acted as her support person and health care advocate through these many years. Among the many hats I've worn I have been a depression lay-expert to Joyce as well as a former DBSA (Depression Bipolar Support Alliance) President, Board Member and trained facilitator of a local chapter. I had received an appointment as a Guardian Advocate in the State of Florida and I am a retired business executive and entrepreneur. Currently I remain active as a vocal mental health advocate and pro-activist as I share unbiased information relating to VNS Therapy and MDD (Major Depressive Illness) on a website I established as a repository for the information I've garnered through the years entitled VNSdepression.com.

By way of public disclosure, we have received no monies nor remuneration of any kind from the sponsor (Cyberonics) other than my spouse receiving \$20 payments as a research study subject upon each research visit as one of the earliest study subjects, at the time the D-01 study was active at the Medical University of South Carolina under the direction of the esteemed researcher and professor, Dr. Mark George and his colleague Dr. Ziad Nahas. After my spouse's implantation in December 1999 and some four years later I made a decision that the therapy was safe, beneficial and efficacious and that it could benefit others, I purchased some public shares in the company. The website VNSdepression.com is funded solely by me. I accept no advertising or donations whatsoever and the sponsor has no involvement with the website other than upon occasion to answer medical and technical questions which I ask relating to the VNS Therapy.

I am here to tell you the time has come to stop the discrimination and stigmatization of these uniquely and seriously ill disenfranchised patients unable to advocate for themselves. The time has come to recognize these illnesses on an equal footing and with parity with other medical illnesses and to make a concerted effort to give those suffering these horrific mood state illnesses an equal opportunity to achieve wellness as one would do with any other medical illness.

I do not come before you to state that VNS Therapy is a panacea. It is not! For that matter all these years have proven the same for other treatments. There is no panacea! What VNS Therapy represents is a new, innovative and unique treatment option for the patient to consider in collaboration with one's trusted, compassionate and knowledgeable licensed psychiatrist(s) when other treatment options have proven ineffective. It affords a ray of hope to those patients who have already tried multiple therapies and combinations of therapies ineffectively through decades of what I refer to as the Trial and Error Approach to Wellness. It is a unique therapy requiring no patient compliance. It works safely for a percentage of the very worst of the worst and most seriously ill patients.

I first and foremost advocate for the education of the patient and his/her support persons and I encourage hope and persistence to not give in or give up and in this instance I do my best to present a realistic and balanced understanding of the VNS Therapy for the seriously ill depression patient.

For those of us who have carefully and intently followed and participated in the history of this therapy we know of the seemingly poor results obtained from the D-02 double-blind study. It is not a question of the therapy representing a seemingly possible failure but a blunder in establishing the proper format of the study. The study was doomed to inevitable failure at the onset. This is a medical device and not a drug. The protocol for the study was based upon drug study protocols and it short acute phase study. Quite frankly, knowing that which I do today, an ethical device study of this kind is almost impossible to be established. Anyone having knowledge of this therapy knows that the study subjects realistically cannot be blinded. More importantly what is becoming evident is the fact the longer the therapy is continued in service the greater the possibility of response and efficacy and the more amazing fact of obtaining longer-term remissions unheard of in other conventional therapies for this unique population of patients.

My spouse has for the first time in some 37 years been almost continuously depression free with little or no medications over the past 6 years through the use of the VNS Therapy. She has been confronted with extremely stressful situational events and yet her mood states remain stable, constant and depression free. I realize and it has been thrown up to me on a number of occasions that my empirical observations and detailed notes over four decades of my spouse's travails is anecdotal evidence and that I am not a medical professional so what could I possibly know or contribute. But I shall also remind the medical community and this esteemed panel to not exhibit what I refer to as Professional Arrogance or the Deity Syndrome. The clinical experiences I have been carefully observing in my spouse are being observed and reported by your colleagues in clinical settings and in other patients with similar history to my spouse and I refer you to the recent write-in to CMS (Medicare national) in which over 300 professionals have acknowledged the need for this therapy and/or have had clinical experiences validating my observations. Furthermore the APA has also come out with a public statement representing some 36,000 members having no affiliation to the sponsor also validating the need for this innovative and unique treatment option. While my spouse's own Psychiatrist, Ely Pelta, MD, also cited the seemingly poor results of the D-02 in our discussions, his real-time clinical experiences with some 14 of the worst of the worst of his patients implanted with the prosthesis is in actuality showing beneficial results as opposed to the study findings.

I would also like to challenge this panel as I did Drs. Laurie and Wolfe of Public Citizen in their much publicized statements and who have never responded to my question, to please cite for me in the medical records a placebo effect lasting 3 or more years as experienced by my spouse and others utilizing the VNS Therapy for TRD as they allege. Maybe it is time that we write into the medical records a new phenomenon which we shall credit to Drs. Laurie and Wolfe and assign the medical term Multi-year Continuous Placebo Effect Phenomenon in their honor for blindly stumbling upon this effect with the VNS Therapy.

The VNS Therapy and newer innovative approaches are desperately needed in my opinion and especially in view of the recently published study in January 2007 edition of Neuropsychopharmacology (2007) 32, 244-254 entitled The Cognitive Effects of Electroconvulsive Therapy in Community Settings. I chuckle to myself as four decades ago I already

knew and so had many other patients as to the long-lasting potential side-effects ECT has upon memory and cognition. It has now taken an esteemed panel of researchers to confirm what we, the patients and anecdotal empirical observers and support persons knew all along or what comes back to and what I again refer to as the Professional Arrogance and/or Deity Syndrome of some medical professionals.

I also bring to the attention of this esteemed panel a recent study in which it was stated:

CONCLUSIONS: rTMS was not as effective as ECT, and ECT was substantially more effective for the short-term treatment of depression.

A Randomized, Controlled Trial With 6-Month Follow-Up of Repetitive Transcranial Magnetic Stimulation and Electroconvulsive Therapy for Severe Depression

<http://ajp.psychiatryonline.org/cgi/content/abstract/164/1/73>

Also add the following remarks from an Israeli study of rTMS:

However, Harel said that at the end of their month-long therapy, many sank back into their previous states of depression and were prescribed medication.

He said this indicated that TMS patients may require continuous treatment if the upgraded therapy is approved for wider use.

http://ca.today.reuters.com/news/newsArticle.aspx?type=oddlyEnoughNews&storyID=2006-12-07T133835Z_01_L05573469_RTRIDST_0_LIFESTYLE-ISRAEL-DEPRESSION-COL.XML&archived=False

I come before you not to belittle or negate the efforts of the medical professionals but to thank them and you for your efforts to help while at the same time to reach an agreement and understanding that while studies may appear seeming failures, mechanisms of action unknown, diagnosis of illnesses unscientific (DSM IV Manual), lack of quantifiable testing results from blood tests, MRI, CT Scans, X-rays etc the fact is these illnesses are real, excruciatingly painful, debilitating and in many instances deadly. The real-time clinical experiences of the medical professionals attending to this seriously ill and unique population of patients should not be easily dismissed as just anecdotal too but as the basis to continue the research into the how's

and why's of the therapy. In reality the efficacy of VNS Therapy in clinical settings is also confirmation that a reasonable percentage of a very unique population of patients is obtaining efficacy and that the treatment is safe. This therapy option, well into 10 or more years of use, has demonstrated safety and should most definitely be made available and approved by all health insurance organizations to those who suffer TRD (Treatment Resistant Depression) and are educated and making an informed and un-coerced medical decision in collaboration with their attending physicians. At the moment, there is no other therapy affording long-term remissions as is being exhibited with the VNS Therapy for this population of patients and also uniquely not requiring patient compliance which is also a major issue with many other therapy regimens.

I thank you for this opportunity to advocate and to do my little part in sharing my thoughts and activism for mental wellness for all those who are unable to do so and who suffer these horrific illnesses. I also wish to state that hopefully with this new legislature and the year 2007 will finally bring understanding, eliminate the stigma and discrimination against those that suffer these serious medical illnesses of mood disorders and acknowledge these illnesses on par with other medical illness while at the same time establishing parity with the health insurance industry.

I also would like to take this opportunity once again to thank Dr. Daniel Schultz, although my not knowing the details and inner workings of the FDA, for what I consider his very courageous decision and apparent far better understanding of the dire needs of this unique population of patients than some of the professional number crunchers in his organization.

Lastly, I wish all that have the opportunity to read or hear my testimony a very Healthy, Happy, Prosperous and Peaceful New Year.

Sincerely,
Herbert Stein

Joyce and Herbert Stein
VNSdepression.com

