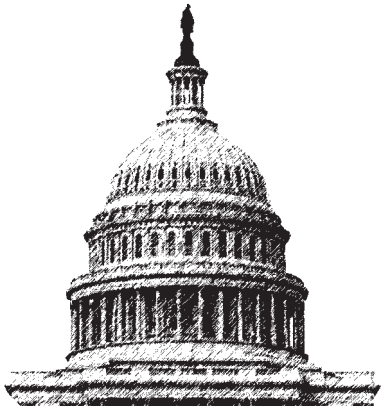
VNS Therapy™ connections™

February 2008 Volume 4, Issue 1

US Congress discusses Mental Health Parity bill

On September 18, the US Senate passed the Mental Health Parity Act of 2007 (S. 558) by a unanimous vote. This critical legislation will ensure that Americans with employer-sponsored health insurance and their families receive mental health care coverage at the same level as coverage for general health problems.

Senators Pete V. Domenici (R-New Mexico), Michael B. Enzi (R-Wyoming), and Edward M. Kennedy (D-Massachusetts) sponsored this historic legislation to end mental health insurance discrimination. ''The passage tonight of the Mental Health Parity bill underscores our commitment to treat all patients facing all diseases with the dignity and respect they deserve,'' said Senator Kennedy. "This new legislation will bring dramatic new help to millions of Americans who today are denied needed mental health care."



In the House of Representatives, 3 committees have approved a similar but somewhat broader bill (H. R. 1424). The House bill has 270 co-sponsors, more than half the House membership. Negotiations on parity have taken place between the House and Senate. Both chambers, of course, have to agree on and pass the same parity bill. You can read more about mental health parity and follow the bill through Congress at http://takeaction.mentalhealthamerica.net.

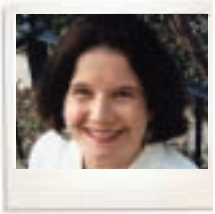
Study investigates VNS Therapy dosing

Cyberonics is sponsoring a study to compare the safety and effectiveness of various doses of VNS Therapy in people with treatment-resistant depression (TRD). Approximately 460 patients will participate in this study at up to 30 locations. Some of these study sites are screening people to see if they meet the criteria for this study.

The study is expected to run until the end of January 2010. Patients who enroll in the study will participate for at least 1 year. More than 200 patients are currently enrolled.

"This important study was designed to increase our clinical knowledge of VNS Therapy," said Scott Aaronson, MD, Director of Clinical Research Programs at Sheppard Pratt Health System in Towson, Maryland. "Many patients experience a meaningful and sustained improvement with VNS Therapy . . . Our goal for this . . . study is to determine which VNS Therapy dosing regimen, if any, will enable us to assist these patients in reaching even better outcomes more quickly."

To learn more about this study, please contact your psychiatrist or your VNS Therapy Regional Case Manager, or go to www.clinicaltrials.gov/ct/show/NCT00305565.



INSIDE

- Meet the patient—Susan
- A long-term response to VNS Therapy
- Ask the doctor: How can I tell if the VNS Therapy battery is running down?
- A timely tip: Winter exercise!

Please see the full indication and safety information on page 4.

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After VNS Therapy, I felt like my students were finally getting their money's worth.

Meet Susan, a VNS Therapy patient

Susan, a 59-year-old English professor, has known depression for more than 40 years. Like many people with a family history of mood disorders, the Missourian experienced her first depression in her late teens.

She was diagnosed with the disease in 1983 and began psychoanalysis—4 hours a week for 4-1/2 years. It helped her to deal with important life issues better, but she still felt depressed. In 1990, Susan had two tragedies in a short time—her mother and her only child died within a 6-month period. Shortly after, she found herself in a serious bout of major depression.

In 1991, she began taking antidepressants. Initially, she had good results, but they lasted only 4 to 5 months. She eventually tried about 20 medications—including antidepressants, anxiety drugs, and antipsychotics—without relief. "It was a terrible experience," she recalled. "I was antisocial and withdrawn, and had very little energy to complete routine tasks like laundry. My depression was paralyzing, like living in a twilight." She took early retirement from teaching.

In 2001 her psychiatrist told her about VNS Therapy. A university nearby was conducting a clinical study. "I had reservations, but my doctor told me that there may be a greater risk if I didn't take this next treatment step." Susan met all study criteria, so she entered the clinical trial. By year's end, she noticed a gradual improvement in mood.

Her remission has lasted more than 6 years. In February 2007, she returned to work part-time. "After VNS Therapy, I felt like my students were finally getting their money's worth."

She currently takes 4 medications, considerably fewer than in the past, and sees her psychotherapist every 2 weeks. "VNS Therapy gave me a chance at a real life that medications alone could not."

Long-term response to VNS Therapy in TRD[1]

The August 2007 online issue of the medical journal *Primary Psychiatry* contained the report of a woman whose response to VNS Therapy has lasted almost 7 years. Thomas L. Schwartz, MD, and Anne Costello, RN, of the State University of New York, Upstate Medical Center and University Hospital in Syracuse, NY, described Mrs. R, a 52-year-old woman who had been depressed for 11 years without relief.

Upon referral to a clinical study of VNS Therapy in 2000, Mrs R had a stressful life caring for elderly and chronically ill family members. Her depression was resistant to many medications. When she first came to Dr Schwartz, she was taking 4 antidepressants plus ongoing psychotherapy. She had never attempted suicide or required hospitalization for depression. She had refused ECT because she believed its risks outweighed the potential benefit.

Mrs R met the enrollment criteria and entered the study of VNS Therapy in December 2000. Aside from initial voice alteration and cough, which subsided to a manageable level over several months, she experienced no other side effects from the procedure or ongoing treatment.

After 16 weeks of VNS Therapy, Mrs R's score on a standard depression questionnaire had decreased from 33 to 15. She maintained this response for 5 months, had an adjustment disorder lasting 2 to 3 months, and then returned to a sustained response which has lasted more than 6 years.

She has continued the medications and psychotherapy. Although her symptoms fluctuate, most often in response to stressful life events, the depression has not returned. As her psychiatrist noted, this type of long-term benefit is remarkable for a patient with TRD.

Mrs R and her psychiatrist noted that she deals with stress better than before. She described an "evenness of mood" that she had not felt since before her first diagnosis. She stated that her depressive symptoms, social functioning, and quality of life were "on average 60% to 70% better" with VNS Therapy.

Reference: 1. Schwartz TL, Costello A. Charting a sustained response to vagus nerve stimulation in treatment-resistant major depressive disorder. *Prim Psychiatry*. 2007;14(8):66-68.

VNS Therapy™ connections™

February 2008 Volume 4, Issue 1

Ask the doctor

Pamela Sullivan, MD
Morgantown, WV

How will my doctor know if the VNS Therapy battery is running down?

According to reports, the battery life with the current VNS Therapy pulse generator ranges from 3 to 8 years.[1]* Most of this experience comes from people receiving VNS Therapy for epilepsy, but people with TRD report similar battery life. The battery life is highly dependent on device settings.

Because a person's VNS Therapy settings may change over time, the battery should be tested regularly, especially when the dosage is adjusted. The testing procedure enables the physician to estimate how much life is left in the battery. It also provides a special signal to indicate when it's time to evaluate the battery for replacement.

Replacing the battery involves changing the pulse generator that contains the battery. This is a minor outpatient surgical procedure. Typically, the surgeon does not replace the lead, but rather connects it to the new device. Sometimes it takes several dosing sessions to reestablish the stimulation settings used before the generator replacement.

As always, you should tell your physician about any changes (up or down) in your mood and discuss any stimulation-related side effects during your office visits.

*For the full range of settings in relationship to battery life, see the *Physician's Manual* or ask your psychiatrist.

Reference: 1. Data on file, Cyberonics, Inc.; Houston, TX.

NOTE: The testimonials in this document are only examples of VNS Therapy results. Individual treatment results will vary.

Connections: a VNS Therapy resource program for you

- Brochures
- Live phone conferences—VNS Therapy Phone Facts Sessions
  - Hear from a patient about his or her experience with VNS Therapy
  - Listen to a psychiatrist experienced with VNS Therapy
  - Tuesdays, February 5 and 19, March 4 and 18, April 1 and 15
  - 7:00 PM Central Time
  - Call TOLL-FREE 1-866-598-9336
- Nurse case managers who can answer your questions about VNS Therapy and help with insurance benefits verification
- For more information, call **1-877-NOW-4VNS** (1-877-669-4867) or visit **www.VNSTherapy.com**

Timely tip: When in doubt, go out!

Yes, days are short and winter weather can be daunting. But don't let that keep you inside all day. Make sunshine and exercise your priorities, especially in winter. And they're free!

So make an extra effort to get outdoors today. Also, look for places where you can walk, even when the weather is at its worst—for example, a mall or an indoor track.

Cyberonics®

DCNE08-21-2000-14

VNS THERAPY™ VAGUS NERVE STIMULATION

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SAFETY INFORMATION FOR THE VNS THERAPY™ SYSTEM*

INTENDED USE/INDICATIONS – UNITED STATES
The VNS Therapy System is indicated for the adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments.

CONTRAINDICATIONS
The VNS Therapy System cannot be used in patients after a bilateral or left cervical vagotomy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy on patients implanted with the VNS Therapy System. Diagnostic ultrasound is not included in this contraindication. Injury or damage can occur during diathermy treatment whether your VNS Therapy System is turned "ON" or "OFF".

WARNINGS
This device is a permanent implant. It is only to be used in patients with severe depression who are unresponsive to standard psychiatric management. It should only be prescribed and monitored by physicians who have specific training and expertise in the management of treatment-resistant depression and the use of this device. It should only be implanted by physicians who are trained in surgery of the carotid sheath and have received specific training in the implantation of this device.

Physicians should inform patients about all potential risks and adverse events discussed in the VNS Therapy System *Physician's Manual*, including information that VNS Therapy has not been determined to be a cure for depression. Patients being treated with adjunctive VNS Therapy should be observed closely for clinical worsening and suicidality, especially at the time of VNS Therapy stimulation parameter changes or drug or drug dose changes.

The safety and efficacy of the VNS Therapy System have not been established for uses outside the approved indications for use. Device malfunction could cause painful stimulation or direct current stimulation. Device removal requires an additional surgical procedure. Do not manipulate the Pulse Generator and Lead through the skin.

Patients who have pre-existing swallowing, cardiac, or respiratory difficulties (including, but not limited to, obstructive sleep apnea and chronic pulmonary disease) should discuss with their physicians whether VNS Therapy is appropriate for them since there is the possibility that stimulation might worsen their condition. Patients with the VNS Therapy System or any part of the VNS Therapy System implanted should not have full body MRI.

PRECAUTIONS
The safety and efficacy of the VNS Therapy System have not been established for use during pregnancy. Patients who smoke may have an increased risk of laryngeal irritation.

ADVERSE EVENTS
The most commonly reported (≥10%) side effects from stimulation included hoarseness, increased cough, neck pain, dyspnea (shortness of breath), dysphagia (difficulty swallowing), paresthesia (prickling feeling in the skin), and laryngismus (sore throat). The most commonly reported (≥10%) side effects from the implant procedure included incision pain, hoarseness, incision site reaction, device site pain, device site reaction, pharyngitis (sore throat), dysphagia, and hypesthesia (numbness).

*THE INFORMATION CONTAINED IN THIS SUMMARY REPRESENTS PARTIAL EXCERPTS OF IMPORTANT PRESCRIBING INFORMATION TAKEN FROM THE PRODUCT LABELING. THE INFORMATION IS NOT INTENDED TO SERVE AS A SUBSTITUTE FOR A COMPLETE AND THOROUGH UNDERSTANDING OF THE VNS THERAPY SYSTEM, NOR DOES THIS INFORMATION REPRESENT FULL DISCLOSURE OF ALL PERTINENT INFORMATION CONCERNING THE USE OF THIS PRODUCT. (CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.)

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