



VNS Therapy™

connections™

December 2006

Volume 2, Issue 7

The Depression and Bipolar Support Alliance— An organization that can help you

A support group can play an important role in helping with your depression. There is a whole organization of people, many with mood disorders, dedicated to offering you important resources and support.

The Depression and Bipolar Support Alliance (DBSA) is the nation's leading patient-directed organization focusing on depression and bipolar disorder. With their motto "we've been there, we can help," DBSA is a not-for-profit organization whose goals include:

- Promoting public understanding about the impact and management of these life-threatening illnesses by providing up-to-date, scientifically based information. For example, the DBSA is part of the Depression is Real Coalition, a public information campaign to tell Americans the truth about depression
- Supporting research into diagnosis, more effective and tolerable treatments, and potential cures
- Ensuring that people living with mood disorders are treated fairly

DBSA has a grassroots network of more than 1,000 patient-run support groups across the country, attended by more than 55,000 people every year. These include support groups for the families and friends of people with depression.

DBSA publishes many educational materials about living with mood disorders, available free of charge.

DBSA advocates in Washington, D.C., on behalf of people living with mood disorders, on issues including increased research funding, insurance parity, and patient confidentiality.

DBSA holds annual conferences for its constituents and for scientists. It sponsors research in medical journals and surveys on important issues related to mood disorders.

To find more information about the DBSA, go to their Web site, www.DBSAAlliance.org.

Finding a support group near you

People coping with depression can benefit from the support of people who have been there and who understand. DBSA chapters can provide that support—and much more.



The DBSA sponsors support groups all across the United

States and abroad. For a complete list, go to: www.DBSAAlliance.org.

Other organizations also sponsor support groups. Look for local chapters affiliated with the National Alliance on Mental Illness at www.nami.org/template.cfm?section=your_local_NAMI and the National Mental Health Association at www.nmha.org/affiliates/directory/index.cfm.

INSIDE!

- Meet Paulette, a person receiving VNS Therapy
- Ask the doctor
- Tips for December mornings



Meet Paulette, a VNS Therapy patient since 2000

Paulette had depression for years before she actually sought treatment. The Florida graduate student felt exhausted and leaden, but when she tried to sleep, she couldn't. She was completely dependent on her husband for simple things like getting out of bed in the morning or making dinner. Soon her depression was too overwhelming for her to continue with her graduate program.

Paulette finally sought treatment after seeing a segment about depression on television. She tried a wide range of medications, as well as talk therapy, but nothing helped her.

I have a second chance at life.

She lost 25 pounds. She couldn't function on a very basic level. Her memory was gone, and she couldn't even carry on a conversation or answer questions. Her relationship with her husband was extremely strained, and she didn't have the energy to maintain friendships.

Paulette spent months struggling with thoughts of suicide. Since the medications had not helped, she finally decided to look for another option. In a 2000 visit with her psychiatrist, Paulette learned about a clinical study of VNS Therapy.

Since getting VNS Therapy in September 2000, Paulette's life has improved significantly. Her depression has lifted. She still takes 5 different medications. "Before VNS Therapy, the medicines did not work for me. Now they work better. So possibly the stimulation helps the medications work better."

Now, at the age of 60, she functions much better. Things that were once enormous undertakings for her, like going to the grocery store or cooking, are simple again. "I have a second chance at



life," she says. She's second vice president in the local chapter of the Depressive and Bipolar Support Alliance, and making progress towards a PhD in English. "I'm so thrilled with VNS Therapy that I want to spread the word so others can experience hope for the first time."

Ask a VNS Therapy patient

How did you find out about VNS Therapy?

Michele: Since neither antidepressants nor electroconvulsive therapy (ECT) worked for me, I began searching the Internet for other treatment options. When I learned about VNS Therapy, my decision to pursue VNS Therapy was instantaneous.

Connie: My psychiatrist first told me about VNS Therapy. He explained it and gave me the VNS Therapy information packet and some journal articles about it. At my next appointment, after I had read them and done some computer research, we decided to start the process for receiving VNS Therapy—the beginning of the only significant treatment for my treatment-resistant depression (TRD). I had the VNS Therapy procedure March 21, 2006, and have been depression-free for almost 4 months.

What did friends and family say about your decision to have VNS Therapy?

Michele: My family and friends understood the hardship I was going through, but didn't know how to help me. They were all very supportive, and felt my decision to have VNS Therapy was excellent.

Connie: My decision to have VNS Therapy was received with mixed reactions. After many, many unsuccessful treatments, my husband and two adult sons felt that VNS Therapy might be another treatment that probably would not work. The procedure made them a little more concerned for me. I am extremely grateful that they left the decision up to me. With me, my family prayed and hoped that VNS Therapy would be effective.

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



Ask the doctor

Howard Houghton, MD

Assistant Professor
of Clinical Psychiatry
University of Missouri-Columbia



My depression has always come back after a while. Will VNS Therapy help me stay well?

Major depression is frequently recurrent, so many people have more than one episode. It is understandable that you might feel frustrated to improve, only to have another depression episode a few months later. Certainly, you should adhere to your treatment plan and keep your mental health provider advised of any changes. Despite doing this, however, some people have additional episodes of depression. VNS Therapy is a good treatment option for these people.

VNS Therapy was specifically studied in patients who have had many recurrences. In a study of 205 people with treatment-resistant depression (TRD) observed for one year, approximately 144 had experienced three or more recurrences.¹ After a year of VNS Therapy, 127 people with three or more recurrences of depression were just as likely to experience improvements from VNS Therapy as those with fewer recurrences. About 30% of people with three or more recurrences experienced significant mood improvements.² This compared with response rates no higher than 16% for a comparison group of 73 people who received antidepressant treatment without VNS Therapy.²

Among the 127 observed people with three or more recurrences of depression, 18% experienced remission at one year—they became depression-free. Again, this was similar to the rate for people with fewer recurrences.² The remission rates for a comparison group of 73 people with three or more recurrences of depression who received antidepressant treatment without VNS Therapy were no higher than 10%.²

Research suggests that most people who improved on VNS Therapy maintained the improvement long-term. Up to 70% of the people with TRD who showed substantial clinical benefit within 3 or 12 months after starting VNS Therapy maintained the improvement at 2 years.³



© 2006 Cyberonics, Inc. All rights reserved.
Cyberonics® is a registered trademark of Cyberonics, Inc.
VNS Therapy™ and Connections™ are trademarks of Cyberonics, Inc.
DCNE06-21-2000-09

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, December 5 and 19, January 9 and 16
 - 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, visit www.VNSTherapy.com or call **1-877-NOW-4VNS** (1-877-669-4867)



Tips for December mornings

Do long dark nights make it harder for you to get up in the morning? Here are a few suggestions.

- Put your alarm clock on the far side of the room, so you have to stand to turn it off
- Use a timer to turn on the lights at the same time as your wakeup call
- Make your bed as soon as you get up and before you do anything else. This will make it less tempting to climb right back under the covers

References: **1.** Rush AJ, Sackeim HA, Marangell LB, et al. Effects of 12 months of vagus nerve stimulation in treatment-resistant depression: a naturalistic study. *Biol Psychiatry*. 2005;58:355-363. **2.** Data on file, Cyberonics, Inc.; Houston, Tex. **3.** *Depression Physician's Manual*. VNS Therapy™ Pulse Model 102 Generator and VNS Therapy™ Pulse Duo Model 102R Generator. Houston, Tex: Cyberonics, Inc.; July 2006.

Please see the full indication and safety information enclosed.

CYBERONICS, INC.
100 Cyberonics Boulevard, Houston, Texas 77058 USA
Tel: 1-877-NOW-4VNS/1-877-669-4867
Fax: 1-281-218-9332
www.VNSTherapy.com

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.

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.

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.

ADVERSE EVENTS

The most commonly reported ($\geq 10\%$) 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 ($\geq 10\%$) 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.)