Senate Report Puts Kink in VNS Device Coverage

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A Senate committee report showing that a vagus nerve stimulation device was approved for treatment-resistant depression over the objections of "more than 20 [Food and Drug Administration] scientists, medical officers, and management staff" could add to the reported difficulties of securing insurance coverage for the device.

The report, the culmination of a yearlong investigation by the Senate Finance Committee, said that given the findings, "it is questionable whether or not the VNS Therapy System for TRD met the agency's standard for safety and effectiveness."

The committee said it began investigating the treatment-resistant depression approval after allegations about potential improprieties were brought to its attention.

The VNS device was approved in July 2005 for treatment-resistant depression. It has been available for treatment-resistant epilepsy since 1997, and is covered by Medicare and Medicaid for that indication.

Medicare has paid for VNS for treatment-resistant depression in some individual cases but has not yet made a coverage decision, according to Skip Cummins, chief executive officer of Cyberonics Inc., the company that makes the VNS device.

Mr. Cummins said he thought that the approval was proper and added that a senior FDA official with a lot of device experience had overruled reviewers who had less familiarity with treatment-resistant depression and implantable devices. "The report itself is full of half-truths and distortions, and reflects the perspectives of fewer than eight FDA staffers who disagreed with the ultimate decision," he said.

The committee investigation found that Dr. Daniel Schultz, director of the FDA's Center for Devices and Radiologic Health, decided to approve the device despite objections from other FDA staffers.

The Neurological Devices Panel of the Medical Devices Advisory Committee voted 5-2 in June 2004 to approve VNS for treatment-resistant depression, with the conditions that the company conduct a postmarketing dosing study and compile an outcomes registry.

In August 2004, the FDA issued a nonapprovable letter, going against the panel's recommendation. Cyberonics submitted additional data and responded to a warning letter, citing manufacturing deficiencies. Eventually, with Dr. Schultz's guidance, the company won approval, according to the Senate Committee report, which questioned the propriety of his assistance.

"Instead of relying on the comprehensive scientific evaluation of its scientists and medical officers, it appears that the FDA lowered its threshold for evidence of effectiveness," the report said.

Mr. Cummins disagreed. "We believe that all the data from all the studies [are] considerably more important than the details of the FDA's internal debate about the data," he said.

In two studies, after 2 years of VNS adjunctive therapy, 56% of the patients had a meaningful clinical benefit, more than one-third had at least a 50% improvement in symptoms, and 20% were free from symptoms, he said (J. Clin. Psychiatry 2005;66:1097-104 and Biol. Psychiatry 2005;58:364-73).

"The safety of this device is extraordinarily well known," said Dr. A. John Rush, a VNS investigator and a paid adviser to Cyberonics. Dr. Rush is the Betty Jo Hay Distinguished Chair in Mental Health at the University of Texas Southwestern Medical Center in Dallas and is the vice chairman for research in the department of psychiatry.

Reimbursement for treatment-resistant depression, however, has been spotty. Mr. Cummins said 115 different insurers have approved 1-35 individual implants each. In August 2005, the Blue Cross Blue Shield Association's Technology Evaluation Center said that given the available evidence, it could not make a coverage recommendation. Cyberonics helps patients and physicians get prior authorization. So far, it has received 7,000 such requests, but only 550 patients have been granted approval, Mr. Cummins said.

He alleged that at least three patients have committed suicide when their appeals for treatment were denied.

Overall, the company estimates that 15%-20% of the 4 million Americans with depression have a treatment-resistant form of the illness. Cyberonics also said that 250,000 Medicare beneficiaries are disabled with the illness. ■

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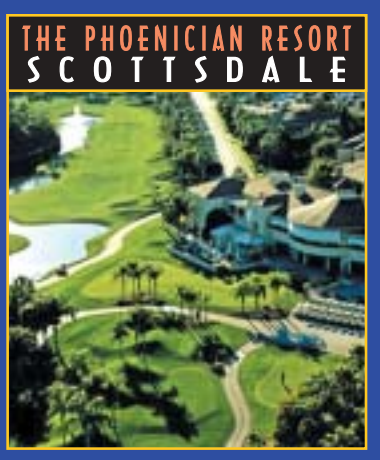

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