



Senator questions Cyberonics device approval

Reuters

WASHINGTON - A senior U.S. regulatory official cleared Cyberonics Inc.'s implanted depression device over objections from staff scientists, Sen. Charles Grassley said on Thursday as he questioned the product's approval.

The Senate Finance Committee chairman said he worried the device may not meet the usual Food and Drug Administration criteria for safety and effectiveness.

"I am greatly concerned the FDA standard for approval may not have been met here, and if that's the case it raises further difficult questions about whether Medicare or Medicaid dollars should be used to pay for this device now," Grassley, an Iowa Republican, said during a speech on the Senate floor.

Grassley's committee oversees the Medicaid and Medicare health-care programs for the poor, elderly and disabled.

The committee issued a staff report saying Dr. Daniel Schultz, director of the FDA device branch, approved the Cyberonics application over objections from more than 20 agency scientists, medical officers and management staff. FDA reviewers saw Cyberonics' data as "weak," the report said.

"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.

The Cyberonics product, called the Vagus Nerve Stimulation (VNS) Therapy System, is a stopwatch-sized device that is implanted into the chest and delivers electrical pulses to the brain. The FDA approved it in July 2005 for treating adults with depression that had not responded to other therapies.

FDA spokeswoman Julie Zawisza said the agency had not seen Grassley's remarks. She said it was not unusual for an official at Schultz's level to overrule staff recommendations.

The Cyberonics device was approved after the company provided the FDA with additional information showing it could help patients with no other treatment options, she said.

Schultz did not reply to telephone or e-mail requests for comment.

Cyberonics said research showed the VNS device was safe and effective for relieving treatment-resistant depression, a disabling illness that can last years and end in suicide.

"We believe that all the data from all the studies is considerably more important than the details of FDA's internal debate about the data," Cyberonics Chief Executive Skip Cummins said in a statement.

The therapy also may save money for Medicare and other insurers over the long term, Cyberonics

said.

Grassley, an outspoken FDA critic, said the agency should have made the internal dissent public.

"The FDA has limited the kind and quality of information publicly available to patients and their doctors and deprived them of information that may be relevant to their own risk-benefit analysis," the report said.

Shares of Houston-based Cyberonics fell 54 cents, or 1.8 percent, to close at \$29.94 on Nasdaq on Thursday.

Copyright 2006 Reuters News Service. All rights reserved. This material may not be published, broadcast, rewritten, or redistributed.

Copyright © 2006 ABC News Internet Ventures