

Medtronic Says Device For Spine Faces Probe

BY DAVID ARMSTRONG
AND THOMAS M. BURTON

The Department of Justice is investigating the off-label use of a Medtronic Inc. implant for promoting bone growth, bringing government scrutiny of such unapproved uses to the heart of the \$189 billion medical-device industry.

The probe—in combination with a government safety warning and whistleblowers' lawsuits—has created what Medtronic Chief Executive William A. Hawkins termed Tuesday a “perfect storm” that suppressed sales of Infuse Bone Graft. The biologically engineered protein is widely used in surgeries to fuse spinal vertebrae.

The Minneapolis device maker reported that Infuse, which had been expected to generate 14% growth in the company's fiscal second quarter, instead produced flat sales of \$198 million. Infuse has brought in over \$3 billion in sales since it was approved in 2002.

Shares of Medtronic, the largest company that makes only medical devices, were down 13% to \$31.60 in 4 p.m. New York Stock Exchange composite trading. The company declined to comment on the Justice Department investigation, which it disclosed Tuesday as it released earnings. The Justice Department also declined to comment.

As a health-care buyer through its insurance programs, the federal government has recovered billions of dollars from drug companies in recent years over charges that their products were promoted for uses beyond those

Please turn to page B7

Medtronic Spinal-Fusions Product Faces an Inquiry

Continued from page B1

approved by the Food and Drug Administration. The cases have often featured government allegations that doctors received secret inducements from companies to use their products off label.

But such government accusations against medical-device companies—many of whose products are used widely for non-FDA-approved purposes—have been more limited. Doctors can deploy FDA-approved drugs and products any way they see fit, but companies aren't permitted to promote off-label applications or to pay doctors inducements to do so.

"While the law establishes that doctors can prescribe any approved treatment, but off-label promotion by manufacturers is not allowed, there's growing concern that the line is being crossed, and a Justice Department review is the right kind of response to those questions," said Sen. Charles Grassley (R., Iowa) who has been looking into whether inducements by Medtronic have led doctors to use its products off-label.

Medtronic said it hasn't marketed Infuse for off-label uses, and has fully complied with federal laws. It has called Infuse a "revolutionary" product that saves patients the trauma of bone grafts taken from the hip to use in spinal fusions.

Infuse is a man-made liquid form of bone morphogenetic protein, or BMP. It is implanted between vertebrae soaked in a sponge-like substance enclosed in a metallic cage. Ideally, BMP causes bone growth that fills in the gap between vertebrae to replace damaged disks.

A number of patients say they have been harmed in off-label uses of Infuse, which is approved by the FDA only for a small sec-

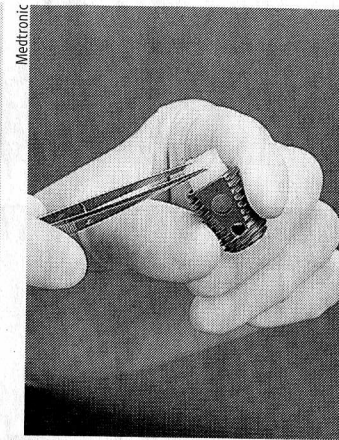
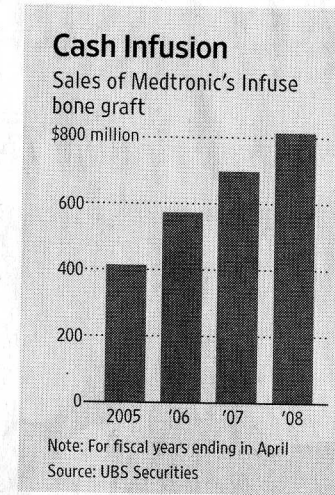
tion of the spine in the lower, lumbar region. At least 280 reports of side effects involving Infuse have been made to the FDA. About three-quarters of those reports involve off-label use. In July, the agency issued a safety alert about complications from the off-label use of Infuse in the neck, or cervical, area of the spine.

The FDA said it received 38 reports over four years of complications from cervical uses of Infuse, some life-threatening. The complications included swelling of the neck and patients reporting difficulty swallowing, breathing and speaking. Several required emergency treatment, including tracheotomies and the insertion of feeding tubes. Medtronic said the number of reported Infuse problems is small compared to the 631,000 units it has sold.

At a recent spine conference, a group of North Carolina surgeons reported on a study that found a complication rate of 59% in cervical spine surgeries with Infuse, as compared to a 21% complication rate using conventional fusion surgery, which involves bone grafts or collagen. The study, conducted between July 2005 and December 2007, examined 76 patients.

Todd S. Jarosz, the Statesville, N.C., spine surgeon who wrote the study, said Infuse patients suffered a range of side effects including inflammation that required the installation of a feeding tube, and severe breathing problems that required a tracheotomy, which involves an incision and insertion of tube into the airway. Dr. Jarosz said Infuse continues to be used by many surgeons in the cervical spine.

A Medtronic consultant, Dr. Kenneth Burkus, who was present at the spine meeting suggested the problems could have



Medtronic's Infuse bone graft is implanted between vertebrae

stemmed from too high a dose.

Depositions in a malpractice lawsuit brought by Laurie DeNeui, of Rushmore, Minn., focused on off-label Infuse use and Medtronic salesman Curt Messler's relationship to her spinal surgeon, Bryan J. Wellman of Sioux Falls, S.D. Mr. Messler said in his depositions in the case that he was with Dr. Wellman in the operating room "a lot" when he used Infuse. He also said he considered Dr. Wellman a friend and said the men saw each other socially.

Ms. DeNeui didn't sue Medtronic and reached a confidential settlement with the company of possible claims.

About four days after her October 2005 operation to fuse cervical vertebrae, Ms. DeNeui said in an interview, her neck swelled up, she had trouble swallowing and she started choking on food. Soon, she said, she started having difficulty breathing. Ms. DeNeui, 46, said the problems prevented her from returning to work as a teacher and baffled several specialists. Steroid treatment helped ease the breathing and gagging problems, but caused her to gain

weight and contract diabetes.

Dr. Wellman denies any malpractice. In a deposition, he said Mr. Messler encouraged him to use Infuse in cervical spine operations, and that he has done more than 100 such procedures with the product. Dr. Wellman said he discussed with Mr. Messler the right dosage of the Infuse material to use in the surgeries but determined the dosage on his own.

Mr. Messler, who isn't a physician, has a degree in criminal justice, and his prior work history included owning a bar and jobs with New York Life Insurance Co. and Procter & Gamble Co. In his depositions, Mr. Messler denied encouraging Dr. Wellman to use Infuse for unapproved applications or discussing how much to use.

Medtronic said it didn't believe it or its employees were engaged in any wrongdoing in the case, which it declined to discuss in detail. It said Ms. DeNeui signed a consent form permitting Medtronic representatives to be in the operating room. The company said it is common for its representatives to be present during surgeries using its products be-

cause of their complexity.

Dr. Wellman said in his deposition he saw medical advantages in Infuse, and that using it was "in the best interest" of patients. Neither Dr. Wellman nor Mr. Messler would comment on the suit.

In three whistleblower lawsuits seeking damages on behalf of the government, former Medtronic employees alleged illegal marketing by the company, including inducements paid to doctors to use Infuse and other Medtronic spine products. The company has said all payments to doctors are "fully compliant with the law."

Medtronic has been depending heavily on Infuse since sales in so many of its other products, such as cardiac defibrillators, have slowed. The company has lowered its revenue forecast for this fiscal year to a range of \$14.6 billion to \$15 billion, down from its earlier \$15 billion to \$15.5 billion.

The company reported quarterly net income of \$571 million, or 51 cents a share, down from the year-ago figures of 58 cents and \$666 million. The current quarter was affected by 16 cents in per-share charges principally related to litigation and research. Sales rose 14% to \$3.57 billion, but were about \$116 million below the consensus estimates of analysts.

In a conference call with investors and analysts, Mr. Hawkins said that "although the second quarter was challenged," Medtronic "can continue to show double-digit earnings growth." Among other things, he said the company will seek to build sales of Infuse overseas and to do clinical trials that might expand approved uses of the product beyond those already allowed by the FDA.