



## THE NEW YORK TIMES

July 6, 2005

When F.D.A. Says Yes, but Insurers Say No

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Medical device makers devote years and millions of dollars to winning regulatory approval for new products. But all that work does not necessarily produce the kind of data that persuades insurers to pay for the products once they hit the market.

Take what has happened since the Food and Drug Administration gave Johnson & Johnson clearance last fall to sell an implantable spinal disk called the Charite (shar-ee-TAY).

The initial reaction was just what the company had hoped. The few surgeons trained during clinical trials to implant the disk were peppered with calls from would-be patients who had been putting off the hazards of spinal fusion for years in the hope of getting a new disk. Hundreds of surgeons signed up for Johnson's three-day sessions to learn how to perform the demanding procedure.

Eight months later, though, most private insurers still refuse to cover the cost of the procedure, which is generally \$30,000 to \$45,000 for a single disk. And while Medicare does provide some coverage, its reimbursement level for hospitals is far less than the cost of the disk, which Johnson lists at \$11,500 but sells at discounts of as much as 20 percent to its high-volume customers.

The insurers, including the government, say that they need to see more clinical studies documenting the disk's durability and performance for various types of patients.

The data that Johnson provided to the Food and Drug Administration to win approval to sell the disk followed patients for just two years after the implant. Insurers say that young and middle-aged adults make up such a large percentage of the patients getting the disk that they need to know more about how it will wear over decades and the health impact on patients when it fails.

Laboratory tests submitted to the F.D.A. suggested that the disk can last 80 years. But critics say that conclusion does not square with the condition of some disks retrieved from ailing European patients or with X-rays showing relatively rapid deterioration of the disks in some patients.

"The lab tests do not represent what happens in the body," said Dr. Steven Kurtz, a biomechanics expert who has analyzed wear and tear in five failed Charite disks for

Exponent, a consulting firm. "Some patients might go 20 years or more with no problems but I wouldn't advise anyone to count on more than 10. And some could be less."

Johnson and supporters of the disk say that nearly all the problems to date have been in cases where the wrong size disk was used or the disk was not properly centered.

The F.D.A. required Johnson to show that the Charite matched spinal fusion in terms of safety and pain relief over the two-year study period. But as insurers saw it, that just meant that the device was no better than spinal fusion. And many insurers consider the fusion surgery to be overprescribed and of little longterm value.

Moreover, some insurers and doctors said, the form of spinal fusion surgery adopted in the late 1990's as the point of comparison in the clinical trials no longer represents the state of the art in fusion surgery.

"Charite needs to show substantial improvement in the patients' quality of life and clinical outcomes," said Michael Chee, a spokesman for Blue Cross Blue Shield of California, a unit of WellPoint that is one of many large Blue Cross insurers that has denied coverage for Charite.

The insurers' resistance has already cost Johnson hundreds of implant sales, according to analysts like Robin R. Young, a consultant and orthopedics newsletter publisher in Wayne, Pa.

Mr. Young said that the number of disks implanted in the United States since last October - about 1,500 was 25 percent lower than what he had projected through the end of May. And some surgeons said such figures understated the challenge.

"About 80 percent of my patients who could be candidates for the disk aren't covered for it by their insurance," said Dr. Scott G. Tromanhauser of the Boston Spine Group.

Some patients end up feeling forced into spinal fusion surgery, however reluctant they may be.

"It's very depressing," said John Lech, a computer programmer for the Wachovia Corporation in Winston-Salem, N.C., whose back pain restricted him to working at home. Mr. Lech, 38, said he had sought coverage, beginning last November, to have the lowest disk in his back replaced.

He said he gave up hope after a May 2 hearing in which Wachovia's work benefits committee accepted the recommendation of United Health Care, the bank's insurer, that the procedure not be reimbursed. Mr. Lech underwent spinal fusion on May 17.

But that was a step that Andy Sethi of Duncanville, Tex., could not bear to take. Last winter after Aetna turned down his second appeal, Mr. Sethi, a 28-year-old registered nurse, said he borrowed \$40,000 on three credit cards and \$30,000 from friends and relatives to cover all the costs associated with an operation. In January, at the Texas Back Institute in Dallas, he received two Charite disks.

Mr. Sethi said that he was back at work within two months. At about the same time Aetna became one of the first national insurers to begin covering disk implants. But it was too late for Mr. Sethi, who said in a recent interview that he would be filing for bankruptcy protection this month to clear his debts.

The insurance issues surrounding the artificial disk are hardly unique. Insurers are also taking a cautious stance toward a treatment that is used as an alternative to neck surgery as a way of clearing blockages in the carotid arteries leading to the brain; Guidant is the domestic pioneer in the alternative treatment, which involves balloon angioplasty and stents inserted via a catheter.

Doctors have been criticizing both Medicare and private insurers for restricting the classes of heart patients the insurers deem eligible to receive implanted heart rhythm management devices from companies like Medtronic, St. Jude Medical and Guidant.

Such insurance battles can take years to play out. Seven years after Oratec Interventions, based in Menlo Park, Calif., gained F.D.A. clearance to sell a device that treats back disk pain by heating damaged tissue through a catheter, the device continues to be categorized as experimental and not reimbursable by most insurers. Oratec sold itself to Smith & Nephew in 2002.

Johnson is so large and diversified that delays in gaining insurance coverage for a new product are less burdensome than they would be for a start-up.

Still, during a conference call on April 19 to discuss first-quarter earnings, Johnson found it necessary to reassure analysts that it was confident most insurers would eventually follow the lead of companies that have already decided to pay for the disk implant. Those include Aetna, Kaiser Permanente and Horizon Blue Cross Blue Shield.

Johnson is hoping to gain more support after the publication on July 15 of two articles on the F.D.A. trial data in *Spine*, a peer-reviewed medical journal. "We expect that will lead to a new round of policy reviews," said John Argiro, director of reimbursement for DePuy Spine, the Johnson subsidiary that makes the disk.

Mr. Young, the orthopedics consultant, said that failure to gain traction with major insurers could force Johnson to cut its prices and eventually lead analysts to reduce sharply their estimates of the potential artificial disk market.

At the time the disk was approved, analysts said that Johnson's revenue from Charite sales this year could be as much as \$100 million and that the total market for such disks from Johnson and others could top \$1 billion by 2010.

The insurance picture could become more complicated if, as expected, the F.D.A. gives Synthes of Switzerland clearance to sell its ProDisc by the end of this year. Maverick from Medtronic and FlexiCore from Stryker may also reach the domestic market in the next few years. These and other companies are also developing artificial disks for the upper, or cervical, spine that could be implanted with a much simpler operation.

Some insurance industry critics say that the industry moves slowly because insurers profit from delaying decisions to cover new technology. "Insurers don't really care about the science as long as the answer comes out that they don't have to pay for it," said Dr. John Pelozo, a Dallas spine surgeon. He describes Charite as flawed in its design, but says he worries that the same arguments the insurers use to deny coverage will be extended to other disks that receive regulatory approval.

Device makers are not so cynical about the insurers - in public at least - but part of their argument for coverage invariably includes claims that their new technology saves insurers' money.

Although the disks themselves cost more than the cages, screws and bone-growth promoters used in fusion, disk patients tend to leave the hospital sooner and recover fully in half of the three or four months common for fusion patients.

Some research suggests that disk patients also retain more range of motion, and that the artificial disk is less likely than fusion to accelerate the deterioration of adjacent disks.

So far, though, while Johnson and rival disk makers have plenty of individual success stories based on more than 20 years of sales in Europe, they have no compelling long-term research studies to support their cost comparisons.