The New York Times

Business/Financial Desk; SECTC

F.D.A. Panel Supports Artificial Disks for Upper Spine

By BARNABY J. FEDER
983 words
20 September 2006
The New York Times
Late Edition - Final
10
English

GAITHERSBURG, Md., Sept. 19 -- An independent panel of reviewers voted unanimously Tuesday to recommend that federal medical regulators approve the first artificial replacement for failing disks in the upper spine.

The panel told the Food and Drug Administration that the stainless steel device, made by Medtronic, performed at least as well in its clinical trials as spinal fusion -- a common surgical procedure. But the group attached several conditions to its approval, including a requirement that Medtronic perform additional safety studies if the product goes on the market.

While the F.D.A. is not required to follow the panel's recommendation, the agency is expected to approve Medtronic's application by next spring. Analysts are forecasting that Medtronic would then grab an early lead in what some analysts estimate could become a $1 billion market in the next decade.

Johnson & Johnson, Synthes, Stryker and numerous smaller device companies are also developing upper spine, or cervical, disks. Analysts estimate that 250,000 cervical fusion operations are performed annually in the United States.

The artificial disks are meant to address conditions like numbness in the arms in addition to the severe pain and immobility sometimes associated with disk degeneration.

Tuesday's panel recommendation comes nearly two years after Johnson & Johnson introduced the first artificial disk, a device for the lower, or lumbar, portion of the spine called the Charite. That disk has run into strong resistance from insurers and criticism from some surgeons who say it is an unacceptably hazardous alternative to spinal fusion. Several lawsuits have been filed this year by Charite patients whose operations failed.

A second lumbar disk, the ProDisc from Synthes of Switzerland, was approved by the F.D.A. last month.

Supporters of arthroplasty, as the use of artificial disks is called, say cervical implants will be more widely used and quickly accepted than the lumbar products. The cervical procedure, they say, is less hazardous, easier to revise and involves techniques that are more familiar to surgeons. "There's almost unanimous opinion that arthroplasty will fare better in the cervical area," said Robin R. Young, a medical device industry market consultant based in Wayne, Pa.

Still, Mr. Young and other analysts say insurers may be slow to embrace cervical disks for one of the same reasons that they are treating lumbar disks as unproven technology -- the devices are meant to last for decades in patients but virtually all of the clinical data covers much shorter time spans.

The safety data presented to the panel covered about 540 patients, but the effectiveness data was limited to 250 patients, about half of whom received the implant, which is called the Prestige ST.

Another challenge for the cervical disks is that cervical fusion surgery is generally considered far more likely to be successful than lumbar fusion. So doctors and patients may see less need for an alternative.

"Getting paid for this will be hard," said Glenn A. **Stiegman**, vice president of regulatory affairs for **Musculoskeletal Clinical** Regulatory Advisors, a consulting firm.

The advisory panel on Tuesday also recommended that Medtronic be barred from claiming that using

artificial disks to preserve a patient's range of motion could protect adjacent natural disks from degeneration. Although orthopedists believe that to be true, and believe that fusion surgery can speed degeneration, the panel said that published research did not support such a conclusion.

Medtronic's data for patients who were monitored for two years suggested that the disk had actually achieved results on a series of pain, motion and safety measures that the F.D.A. had agreed would allow it to claim the device superior to fusion surgery. The median period before disk patients returned to work was 45 days compared to 61 for fusion patients. But overall satisfaction rates in the two groups were nearly identical.

Medtronic said after the hearing that it intended to press the agency to reach a different conclusion. "We'll try to provide incremental data to prove the claim," said Peter L. Wehrly, the senior vice president who oversees Medtronic's spinal subsidiary.

Yesterday's review was complicated by the fact that the trial data was based on a slightly different form of the device than the one for which Medtronic is seeking approval. Based on feedback from surgeons, the company has slightly thickened one portion of the device and altered the position of the screws that hold the implant in place. The changes allow the company to make larger disks.

The panelists were also concerned that Medtronic had shown that small amounts of stainless steel particles can wear away from the device over time, but that when it tested their potential health impact in rabbits the company had been unable to track what happened to the bits of steel.

"I'm a bit dumbfounded why the particles were not found anywhere," said Dr. Sanjiv H. Naidu, a surgeon and material science expert from the Pennsylvania State College of Medicine in Hershey, Pa., who was one of the 10 panel members.

Similar particles caused inflammation in tissue recovered from four patients who had the device removed during the trial for various reasons. The panel recommended that the F.D.A. require additional animal studies and more research on how the device's end plates interact with the body.

Medtronic has also begun a clinical trial for another, more compact version of the Prestige that is made of a titanium ceramic and held in place by two raised ridges on each plate. A separate Medtronic trial is testing an entirely different disk called the Bryan that sandwiches metal plates around a dense plastic core. The stainless steel Prestige is intended for cases where only one disk is being replaced while the others are meant to work with multiple disk procedures.

Document NYTF000020060920e29k0003m