Medtronic Slips After Infuse Reviews Detailed

The Associated Press

Shares of Medtronic slipped Tuesday, a day after the medical device maker announced findings from independent reviews of studies of its Infuse bone graft.

THE SPARK: The Minneapolis company said the reviews, conducted through Yale University, concluded that clinical success rates with its Infuse product were equivalent to more traditional bone graft procedures in which bone is taken from the hip. Medtronic also said it believes that the data showed no link between Infuse and cancer development, but it is continuing to study this issue.

Medtronic had said in 2011 it would provide a $2.5 million grant to allow Yale to conduct two independent reviews of the safety and effectiveness of Infuse in the wake of criticism of the clinical trials it conducted to support the device. Medtronic provided Yale with clinical trial data and side effect reports provided to the Food and Drug Administration.

THE BIG PICTURE: Infuse contains a genetically engineered protein that can stimulate bone growth. It is used as an alternative to procedures like autologous grafting, where bone is taken from elsewhere in the patient's body.

The Food and Drug Administration approved Infuse in 2002 for use in spinal, oral and dental graft procedures, but it also is used off-label in neck surgeries and other procedures.

Medtronic's spinal business has been hurt by revelations about the company's handling of the studies and marketing of Infuse.

Last year, a Senate investigation concluded that the company helped write and edit medical journal articles about the graft that downplayed its risks. The Senate Finance Committee said Medtronic did not disclose its role in shaping key studies that helped turn Infuse into an $800-million a year product

THE ANALYSIS: The reviews uncovered no "smoking guns" linking Infuse to cancer or other issues, Jefferies analyst Raj Denhoy said in a research note. But they also showed that the material in the graft offers little clinical benefit and comes with a risk of increased harm compared to other grafts.

"On balance we view the papers as tilted to the negative and expect (Infuse) to continue to hemorrhage sales," Denhoy wrote.

Stifel analyst Rick Wise said in a separate note he also didn't feel the review uncovered any meaningful new concerns, and that could be seen as a slight positive. Even so, he expects Infuse sales to continue to slide in the United States.

SHARE ACTION: Medtronic shares started to slip before markets opened and were down 77 cents to $52.74 Tuesday midday while broader trading indexes rose slightly. The shares hit a 52-week high of $53.83 last month and have traded between that and $36.91 over the past year.

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