

Medtronic's Infuse bone graft product has been tied to a number of adverse reactions, some quite serious.

(PRLEAP.COM) November 21, 2013 - Parker Waichman LLP, a national law firm dedicated to protecting the rights of victims injured by defective drugs and medical devices, notes that Minneapolis-based medical device maker Medtronic Inc. reported today that its spinal division had quarterly revenue of \$746 million, marking a 3 percent reduction year-over-year, and a 2.5 percent reduction compared to last quarter, according to a Nov. 19 report in [The Memphis Daily News](#) . Of the division's key spinal products, the Infuse Bone Graft continues to be a difficult area for the company, the article noted.

Sales for Infuse declined worse than expected, 17 percent for the quarter, according to the Daily News report, which also noted that Medtronic was attributing this to some physicians who were continuing to reduce their usage of the product, through both patient selection and the use of smaller kits.

The Daily News further noted that Infuse Bone Graft sales have been suffering since the release of "revelations about the company's handling of studies and marketing" of its Infuse product, adding that: "Last year, a U.S. Senate investigation concluded Medtronic helped write and edit journal articles about [Infuse] that downplayed its risks," the article reported.

Medtronic has cut costs throughout the company this year, including employee layoffs, on increased pressure as U.S. hospitals push for lower prices, among other things, the article reported, highlighting the fact that this past May, Medtronic announced it would trim 230 employees from its global spinal products group, including 60 jobs cuts in Memphis.

"Medtronic's Infuse product appears to have become a drag on corporate earnings. One must consider whether this decline in performance is related to the company's handling of clinical studies and marketing," said Gary Falkowitz, Managing Attorney at Parker Waichman LLP.

As for the charges mentioned in the Senate investigation, Medtronic was named in a whistleblower lawsuit that alleged it had paid a spine surgeon, who also was an editor of a medical journal, to promote its Infuse Bone growth device. Joanne Hartwig filed the lawsuit to recover damages arising out of alleged false claims presented, and supposedly concealed, by Medtronic against Medicare, Medicaid and various health care programs administered by the

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United States. The lawsuit was filed on July 8, 2011, in the U.S. District Court for the Southern District of Mississippi, Jackson Division (Case No. 3:11-cv-00413-CWR-LRA), entitled USA Ex Rel. Joanne Hartwig vs. Medtronic, Inc. et.al.

On December 12, 2011, the U.S. Department of Justice [issued a statement](#) that revealed Medtronic had agreed to pay \$23.5 million to resolve allegations that it had violated the False Claims Act by using kickbacks to induce doctors to implant the company's devices. As part of the resolution, the whistleblowers received payments totaling more than \$3.96 million from the federal share of the recovery, the government said.

The False Claims Act provides whistleblowers with protection, as well as the opportunity, to be compensated for their efforts. The Act was passed in 1863 during the Civil War, but had amendments connected to it in 1986 that have helped incentivize whistleblowers to come forward. It did so primarily by raising the amounts for damages and penalties; whistleblowers therefore can today be awarded millions of dollars. Anyone who possesses proof that a pharmaceutical or medical device company has engaged in some form of fraudulent activity against the federal government is encouraged to contact us. Please view our Pharmaceutical Whistleblower page or call 1-800-LAW-INFO (1-800-529-4636).

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