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Medtronic Spine, Formerly Kyphon Inc., to Pay U.S. \$75 Million to Resolve Allegations of Defrauding Medicare

WASHINGTON – Medtronic Spine LLC, the corporate successor to Kyphon Inc., has agreed to pay the United States \$75 million to settle allegations that it caused the submission of false claims to Medicare, the Justice Department announced today. The government alleged that Kyphon caused the submission of fraudulent claims for its kyphoplasty procedure, which is a minimally-invasive surgery used to treat compression fractures of the spine caused by osteoporosis, cancer or benign lesions.

The United States alleged that Kyphon engaged in a seven-year marketing scheme that resulted in certain hospitals billing Medicare for certain kyphoplasties performed on an inpatient basis rather than less costly and clinically appropriate outpatient kyphoplasty treatment. This conduct resulted in the Medicare program paying more for certain inpatient kyphoplasty procedures.

"Today's settlement demonstrates our commitment to ensure that the Medicare Trust Fund is used to pay for necessary medical care and is not depleted as a result of aggressive marketing schemes intended to increase sales of unnecessary devices or procedures," said Gregory G. Katsas, acting Assistant Attorney General of the Justice Department's Civil Division.

This civil settlement resolves allegations against Kyphon that were filed in Buffalo, N.Y., by two former employees of Kyphon. Their action was filed under the qui tam provisions of the federal False Claims Act, which permits private citizens to bring lawsuits on behalf of the United States and receive a portion of the proceeds of a settlement or judgment awarded against a defendant. The private citizens in this action will receive a total of \$14.9 million as their statutory share of the proceeds of this settlement.

"The settlement further demonstrates the private-public partnership fostered through the False Claims Act involving whistleblowers working with the United States continues to result in the identification of waste, fraud, and abuse and the significant return to the taxpayers of ill-gotten gains," said Terrance P. Flynn, U.S. Attorney for the Western District of New York.

In conjunction with the \$75 million settlement, Kyphon has entered into a Corporate Integrity Agreement with the U.S. Department of Health and Human Services, Office of Inspector General. The Corporate Integrity Agreement contains measures to ensure compliance with Medicare regulations and policies in the future.

"Those who are complicit in causing the Medicare program to pay out unnecessary dollars will be pursued by OIG and our law enforcement partners," said Daniel R. Levinson, Inspector General of the Department of Health and Human Services. "This \$75 million settlement restores much-needed funding to the Medicare Trust Fund, as well as protecting the integrity of the program and its beneficiaries."

The settlement with Medtronic Spine LLC was the result of a coordinated effort among the Commercial Litigation Branch of the Justice Department's Civil Division; the U.S. Attorney's Office for the Western District of New York in Buffalo, Affirmative Civil Enforcement Unit; and the Department of Health and Human Services' Office of Inspector General and Office of Counsel to the Inspector General.

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