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Neurosurgeon and Two Affiliated Companies Agree to Pay $4.4 Million to Settle Healthcare Fraud Allegations

Each Defendant Excluded from Federal Healthcare Programs for Six Years

Neurosurgeon Wilson Asfora, M.D. of Sioux Falls, South Dakota, and two medical device distributorships that he owns, Medical Designs LLC and Sicage LLC, have agreed to pay $4.4 million to resolve False Claims Act allegations relating to illegal payments to Asfora to induce the use of certain medical devices, in violation of the Anti-Kickback Statute, as well as claims for medically unnecessary surgeries.

Medical Designs and Sicage agreed to pay an additional $100,000 in penalties to settle allegations that they violated the Open Payments Program by failing to report to the Centers for Medicare & Medicaid Services (CMS) Asfora's ownership interests and payments made to Asfora.

Under the terms of the settlement agreement, Asfora, Medical Designs, and Sicage each will be excluded from participation in federal healthcare programs for a period of six years.

"Physicians who accept kickbacks and perform unnecessary surgeries put their patients at risk and increase healthcare costs for everyone," said Acting Assistant Attorney General Brian M. Boynton of the Department of Justice's Civil Division. "We will continue to hold physicians and medical device companies accountable for unlawful financial arrangements that undermine the integrity of federal healthcare programs."

The settlement announced today resolves allegations that over the course of nearly a decade, Asfora, Medical Designs, and Sicage knowingly and willfully engaged in three kickback schemes to allow Asfora to profit from his use of over a dozen devices in his medical procedures. First, the United States alleged that Medical Designs and Sicage paid Asfora profit distributions in exchange for Asfora using Medical Designs' and Sicage's devices in his spine surgeries. Second, the United States alleged that Medical Designs acted as a distributor, reselling other manufacturers' spinal devices and splitting the profits with Asfora when he used those devices in surgeries. Third, the United States alleged that Asfora solicited and received kickbacks from medical device manufacturer Medtronic USA Inc. in exchange for using its SynchroMed II infusion pumps, which are implantable devices used to deliver medication to patients. At Asfora's request, Medtronic allegedly paid the kickbacks to Asfora through a restaurant he owned with his wife, called Carnaval Brazilian Grill, in the form of lavish meals and alcohol for Asfora and his friends, colleagues, and business partners.

In addition, the settlement resolves allegations that Asfora knowingly submitted false claims to federal healthcare programs for medically unnecessary procedures using the devices in which he had a financial interest. Despite receiving numerous warnings that he was performing medically unnecessary procedures – including warnings from his own physician colleagues – Asfora allegedly continued to perform such procedures while personally profiting from his use of devices sold by Medical Designs, Sicage, and Medtronic.

"Fraud in the healthcare arena is taken very seriously by the Department of Justice," said Acting U.S. Attorney Dennis R. Holmes for the District of South Dakota. "South Dakota is fortunate to have many honest and dedicated healthcare providers who strive daily to provide high quality services. Dr. Asfora and his companies violated the trust that so many others have worked hard to earn."

"Kickback dollars can corrupt the high quality medical care patients deserve and taxpayers fund," said Special Agent in Charge Curt L. Muller of the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG). "We have excluded Dr.

Asfora and his two medical distributorships from receiving Medicare, Medicaid, and other federal health program dollars."

This settlement also resolves Medical Designs' and Sicage's liability under CMS' Open Payments Program, which was established by the Affordable Care Act and requires medical device companies to disclose to CMS physician ownership interests and certain payments or other transfers of value to a physician.

The civil settlement includes the resolution of claims that Drs. Carl Dustin Bechtold and Bryan Wellman brought under the *qui tam* or whistleblower provisions of the False Claims Act against Asfora and Medical Designs. Under the *qui tam* provisions of the False Claims Act, a private party can file an action on behalf of the United States and receive a portion of any settlement. The *qui tam* case is captioned *United States ex rel. Bechtold, et al. v. Asfora, et al.*, No. 4:16-cv-04115-LLP (D.S.D.). The whistleblowers will receive $880,000 of the settlement proceeds.

This settlement was the result of a coordinated effort between the Civil Division's Commercial Litigation Branch, Fraud Section, and the U.S. Attorney's Office for the District of South Dakota, with assistance from HHS-OIG. As a result of its efforts, the United States has recovered a total of more than $33 million relating to conduct involving Asfora, including a False Claims Act settlement with Sanford Health entities for $20.25 million in October 2019 and a False Claims Act and Open Payments settlement with Medtronic for $9.21 million in October 2020. This matter and the related matters were investigated by Trial Attorneys Christopher Terranova and Harin C. Song and Assistant U.S. Attorneys Meghan K. Roche and Ellie J. Bailey.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

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