Department of Justice

U.S. Attorney's Office

Eastern District of Pennsylvania

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French Medical Device Manufacturer to Pay $2 Million to Resolve Alleged Kickbacks to Physicians and Related Medicare Open Payments Program Violations

PHILADELPHIA – Acting United States Attorney Jennifer Arbittier Williams announced today that Medicrea International, a French medical device manufacturer, and its American affiliate Medicrea USA Inc., have agreed to pay:

- $1 Million to the United States and participating states to resolve civil whistleblower allegations that the companies, by entertaining U.S.-based physicians during a 2013 conference in France, violated the Anti-Kickback Statute and, through resulting claims to federal healthcare programs, the False Claims Act and similar state statutes; and

- an additional $1 Million to the United States to resolve related allegations that the companies violated the physician Open Payments Program (formerly known as the "Sunshine Act") by failing to fully report those physician-entertainment expenses to the Centers for Medicare & Medicaid Services (CMS).

The Anti-Kickback Statute prohibits medical device manufacturers from directly or indirectly offering or paying anything of value to induce the referral of items or services, such as device orders or purchases, covered by Medicare, Medicaid, TRICARE, or other federal healthcare programs. The federal settlement resolves allegations that Medicrea (which Medtronic USA Inc., recently acquired) provided items of value in the form of meals, alcoholic beverages, entertainment, and travel expenses to U.S.-based physicians at events surrounding the Scoliosis Research Society's September 2013 Congress in Lyon, France. The United States alleged that Medicrea provided the benefits to induce the physicians to purchase or order Medicrea's spinal devices, and that this resulted in false payment claims to federal healthcare programs.

This settlement also resolves Medicrea's liability under CMS's Open Payments Program. As part of the Affordable Care Act, Congress created the Open Payments Program: (1) to provide greater transparency and protection to consumers, by requiring medical device manufacturers and others publicly to disclose certain payments and other transfers of value to physicians; and (2) with the goal of preventing, through such disclosures, payments and benefits from being used to induce physicians and hospitals to prescribe or buy products.

This is among the first settlements to resolve allegations under both the False Claims Act and the Open Payments Program. The settlement follows the Senate Finance Committee's March 2019 request that HHS-OIG and CMS investigate Open Payments Program non-compliance and pursue enforcement. Manufacturers must ensure accurate and timely Open Payments Program reporting to CMS of all applicable payments or transfers of value, including indirect payments.

The civil settlement includes the resolution of claims brought under the *qui tam* or whistleblower provisions of the False Claims Act statute. Under those provisions, a private party can file an action on behalf of the United States and receive a

portion of any recovery. The suit was filed in the Eastern District of Pennsylvania and is captioned *United States of America, et al., ex rel. Dory Frain v. Medicrea USA Corporation,* Civil Action No. 16-1986. The whistleblower's Philadelphia-based attorneys are Michael A. Filoromo, III of Katz, Marshall & Banks, LLP, and Ryan Allen Hancock of Willig Williams & Davidson.

"Kickbacks undermine the integrity of federal healthcare programs and increase costs to taxpayers," said Acting U.S. Attorney Williams. "This case demonstrates the Department of Justice's commitment to ensuring that medical device manufacturers do not use improper relationships to influence physician decision-making and are transparent about the benefits that they provide to physicians."

Williams added: "We thank the relator and relator's counsel for their contributions. Without information from citizens like the relator, detecting fraud and conserving government program funds would be much more difficult."

"Allegations of kickbacks are concerning as patients rely on their medical professionals to make health care decisions based on their individual medical needs," said Maureen R. Dixon, Special Agent in Charge for the Office of Inspector General of the U.S. Department of Health and Human Services (HHS-OIG). "We will continue working with the U.S. Attorney's Office, CMS and our Medicaid Fraud Control Units to protect patients and taxpayers."

The United States' investigation and resolution of this matter illustrates its focus on combating healthcare fraud. Tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement can be reported to the U.S. Department of Health and Human Services, at 800-HHS-TIPS (800-447-8477).

The settled claims are allegations only; there has been no determination of liability.

This case was investigated by the U.S. Department of Health and Human Services Office of the Inspector General, the U.S. Attorney's Office for the Eastern District of Pennsylvania, the Commercial Litigation Branch of the Justice Department's Civil Division, as well as the National Association of Medicaid Fraud Control Units (NAMFCU). For the U.S. Attorney's Office, the investigation and settlement were handled by Assistant United States Attorneys Landon Y. Jones III and Gerald B. Sullivan, and Auditor Dawn Wiggins.

Topic(s):
False Claims Act

Component(s):
USAO - Pennsylvania, Eastern

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