



Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Thursday, October 29, 2020

Medtronic to Pay Over \$9.2 Million To Settle Allegations of Improper Payments to South Dakota Neurosurgeon

Minnesota-based medical device maker Medtronic USA Inc. has agreed to pay \$8.1 million to resolve allegations that it violated the False Claims Act by paying kickbacks to induce a South Dakota neurosurgeon to use certain Medtronic products, the Department of Justice announced today.

Medtronic also agreed to pay an additional \$1.11 million to resolve allegations that it violated the Open Payments Program by failing to accurately report payments it made to the neurosurgeon to the Centers for Medicare & Medicaid Services (CMS).

“Kickbacks undermine the integrity of federal healthcare programs and increase costs borne by taxpayers,” said Acting Assistant Attorney General Jeffrey Bossert Clark of the Department of Justice’s Civil Division. “This case demonstrates the Department of Justice’s commitment to ensure that medical device manufacturers do not use improper financial relationships to influence physician decision-making.”

“We expect doctors to make medical decisions based on what is best for their patients, not what is best for their bank accounts,” said U.S. Attorney Ron Parsons for the District of South Dakota. “The quality of medical care is eroded – and patients and their families suffer – when companies and physicians enter into these sorts of under the table schemes to create illegal financial incentives to increase the use of medical devices.”

“Allegations of kickbacks are taken very seriously. Such actions threaten the integrity of federal healthcare systems,” said Curt L. Muller, 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 our law enforcement partners to protect patients and taxpayers.”

“CMS’ Open Payments Program is intended to promote transparency and accountability in the healthcare system. Manufacturers that misreport their financial relationships with healthcare providers erode the integrity of the Open Payments Program and will be held accountable,” said Brenna E. Jenny, HHS Deputy General Counsel and CMS Chief Legal Officer. “CMS looks forward to continued partnership with the Department of Justice to resolve allegations of manufacturers skirting their Open Payments obligations.”

The Anti-Kickback Statute prohibits directly or indirectly offering or paying anything of value to induce the referral of items or services covered by Medicare, Medicaid, TRICARE, and other federal healthcare programs.

The settlement announced today resolves allegations that Medtronic agreed to the requests of South Dakota neurosurgeon, Wilson Asfora, M.D., to pay for social events at Carnaval Brazilian Grill, a restaurant Medtronic knew Asfora owned, including scores of expensive meals. Medtronic allegedly made the payments to benefit Asfora and induce him to use Medtronic’s SynchroMed II intrathecal infusion pumps, which are implantable devices used to deliver medication to patients. The United States alleged that Medtronic’s sponsored events at Asfora’s restaurant were social gatherings for which Asfora selected and invited his social acquaintances, business partners, favored colleagues, and potential and existing referral sources, while Medtronic paid for their meals and drinks. Over a nine-year period, Medtronic allegedly paid for more than one hundred events at Asfora’s restaurant.

This settlement also resolves Medtronic’s liability under CMS’ Open Payments Program, which was established by the Affordable Care Act and requires medical device manufacturers like Medtronic to disclose to CMS certain payments or other transfers of value to a physician like Asfora. The United States alleged that Medtronic made payments to Asfora’s restaurant at his request, knowing that Asfora owned the restaurant, but underreported those payments to CMS.

Asfora and two of his other companies are defendants in a separate FCA lawsuit in which the United States filed a complaint in November 2019, alleging that Asfora received kickbacks to use certain implants in his spinal surgeries. That pending case is captioned *United States ex rel. Bechtold, et al. v. Asfora, et al.*, No. 4:16-cv-04115-LLP (D.S.D.).

The government's pursuit of these matters illustrates the government's emphasis on combating healthcare fraud. One of the most powerful tools in this effort is the False Claims Act. Tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement can be reported to the Department of Health and Human Services, at 800-HHS-TIPS (800-447-8477).

The settlement was the result of an investigation by the Department of Justice's Civil Division, the U.S. Attorney's Office for the District of South Dakota, and HHS-OIG. As part of the settlement, Medtronic agreed to cooperate with the Department's investigations of and litigation against other parties, and the device maker took remedial action once it learned of the wrongdoing, including terminating a sales representative and sales manager and disciplining twelve other employees involved in the alleged misconduct.

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

Attachment(s):

[Download Medtronic Settlement Agreement](#)

Topic(s):

False Claims Act

Component(s):

[Civil Division](#)

Press Release Number:

20-1183

Updated October 29, 2020