Company Selling Migraine Treatment Device Agrees to Resolve Alleged False Claims Act Violations

by Dan Brannan, Content Director
December 11 2023 3:51 PM

FAIRVIEW HEIGHTS – Utah-based Dolor Technologies, LLC (“Dolor) has entered into a settlement agreement with the United States to resolve Dolor’s civil liability relating to a device it sold and marketed to treat migraines, the Department of Justice announced today.

This resolution requires Dolor to make monetary payments to the U.S. based upon its ability to pay. The government alleges that, between July 2013 through July 2017, Dolor violated the False Claims Act (FCA) by causing medical providers to submit false claims to the Medicare Program for procedures using a device called the SphenoCath. The SphenoCath was intended to treat migraine headaches by administering nerve blocks to the sphenopalatine ganglion (SPG), a collection of nerves located deep in the midface of the skull.

The government alleged the SphenoCath was not approved or authorized by the FDA for use in SPG nerve blocks for the treatment of headaches. The government also alleged Dolor instructed, coached, and encouraged medical providers to submit improper billing codes to Medicare for reimbursement of services using the SphenoCath device. “Device companies that evade the FDA approval process and improperly promote their products undermine the health of patients and the financial integrity of federal health care programs,” said U.S. Attorney Rachelle Aud Crowe for the Southern District of Illinois.

“This settlement demonstrates the commitment of our office and investigative partners to combat health care fraud against the Medicare Program.”

In a related criminal matter, Dolor’s former chief executive officer, Mark Wright, pleaded guilty on Oct. 11, 2023, in the U.S. District Court for the District of Utah to misdemeanor charges of causing the introduction of misbranded and adulterated devices into interstate commerce. As part of his guilty plea, Wright admitted that Dolor did not seek approval or clearance from the Food and Drug Administration to distribute the SphenoCath for the intended use of treating headaches. “U.S. consumers rely on FDA oversight to ensure that medical devices are safe and effective. Device manufacturers who disregard FDA’s oversight and misdirect the use of medical devices put consumers at risk,” said Special Agent in Charge George A. Scavdis, FDA Office of Criminal Investigations Metro Washington Field Office.

“We will continue to investigate and bring to justice companies that jeopardize the public health.” Wright also admitted that, while FDA had recommended in April 2014 that Dolor proceed with investigational studies regarding the SphenoCath’s safety and effectiveness, Dolor never conducted any such study. Instead, Wright and Dolor continued to market the SphenoCath with the intention that it be used to treat migraine headaches by administering SPG nerve blocks. “The submission of false claims to Medicare undermines the solvency of our federal health care programs and wastes valuable taxpayer dollars,” said Special Agent in Charge Mario M. Pinto of the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG).

“Our agency, working with our law enforcement partners, is committed to holding accountable those who seek to defraud federally funded health care programs.” The civil settlement resolves claims brought under the qui tam or whistleblower provisions of the FCA by Ronald Michael, M.D. The act permits private parties to sue for false claims on behalf of the United States and to share in any recovery. The qui tam case is captioned U.S. ex rel. Ronald Michael, M.D. v. Dolor Technologies, LLC, et al., No. 15-cv-1004 (S.D. Ill.), which also resulted in a civil settlement with device companies Jet Medical, LLC and Medical Components, Inc. Dr. Michael will receive a share of the proceeds from the FCA settlements.

The government’s resolution of this matter illustrates the government’s emphasis on combating health care fraud. The FCA is one of the most powerful tools in this effort. 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 900-HHS-TIPS (800-447-8477).

The government is represented in the civil case by Assistant U.S. Attorney Laura Barke of the U.S. Attorney’s Office for the Southern District of Illinois. The investigation was conducted by the FDA’s Office of Criminal Investigations and the U.S. Department of Health and Human Services Office of Inspector General. The claims settled by the civil agreement are allegations only and there has been no determination of civil liability.