PRESS RELEASE

Pharmaceutical Manufacturer Assertio Therapeutics, Inc. to Pay $3.6 Million to Resolve Allegations that It Violated the False Claims Act in Connection with Marketing its Fentanyl Product

Friday, May 9, 2025

For Immediate Release

U.S. Attorney's Office, District of Columbia

USADC.Media@usdoj.gov

The Justice Department announced on May 5, 2025, that Assertio Therapeutics, Inc., formerly known as Depomed, Inc., a pharmaceutical company headquartered in Lake Forest, Illinois, has agreed to pay $3.6 million to resolve claims that Assertio violated the False Claims Act by causing the submission of false claims for the transmucosal immediate-release fentanyl drug Lazanda for individuals who did not have breakthrough cancer pain.

The settlement was announced by U.S. Attorney Edward R. Martin, Jr., Acting Assistant Attorney General Yaakov Roth of the Justice Department's Civil Division, Deputy Inspector General Christian J. Schrank of the Department of Health and Human Services Office of Inspector General, and FBIActing Assistant Director Darren Cox of the Criminal Investigative Division.

Lazanda, a fentanyl nasal spray, is approved by the FDA solely for break-through cancer pain in patients who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. The United States alleges that between 2013 and 2017, Assertio caused the submission of false claims to the Medicare and TRICARE programs by focusing its marketing on pain specialists who were prescribing high volumes of transmucosal immediate-release fentanyl, known as TIRF products, including those who were flagged for diversion or who were later indicted.

The United States further alleges that Assertio placed high-volume TIRF prescribers on its speakers' bureau and advisory boards and developed its "Signature Support Program" to ensure that Lazanda prescriptions would be approved by insurance companies, including Medicare Part D plans. The United States contends that, as a result of Assertio's marketing, prescribers wrote Lazanda prescriptions for Medicare and TRICARE beneficiaries who did not have breakthrough cancer pain and that Assertio therefore caused false claims to be submitted to Medicare and TRICARE from high-volume thirteen prescribers.

"This company took steps to boost its profits despite the risk of boosting the deadly opioid epidemic," said U.S. Attorney Martin. "My office will continue to seek out violations like this that demonstrate a brazen disregard for the safety of the public."

"The Department is committed to pursuing companies that contributed to the tragic opioid epidemic," said Acting Assistant Attorney General Roth. "This resolution demonstrates that companies that recklessly marketed powerful opioids, like fentanyl, will be held accountable for their role in the opioid crisis, which continues to plague our country today."

"As today's settlement demonstrates, the FBI and our law enforcement partners remain committed to investigating violations of the False Claims Act," said FBI Assistant Director in Charge Steven J. Jensen of the Washington Field Office. "We will continue holding companies accountable for fraudulent marketing that puts patients at risk."

"Violations of the False Claims Act such as the illegal prescribing practices alleged in this settlement are especially egregious considering the opioid epidemic," said Deputy Inspector General Schrank. "HHS-OIG will continue to work with our law enforcement partners to ensure health care providers and corporations involved in schemes that threaten patient safety are held accountable."

The civil settlement includes the resolution of claims brought in 2017 under the *qui* tam, or whistleblower, provisions of the FCA by Noelle Webb and Nicole Novellino, who previously worked at Depomed as sales representatives. The FCA authorizes private parties to sue on behalf of the United States for false claims and share in any recovery. The *qui tam* case is captioned *United States ex rel. Webb et al. v. Assertio Therapeutics, Inc., f/k/a Depomed, Inc.*, No. 1:17-02309 (D.D.C.). The relators' share of these proceeds has not yet been determined.

The Justice Department's Civil Division, Commercial Litigation Branch - Fraud Section, and the U.S. Attorney's Office for the District of Columbia handled this matter. The FBI, led by its Washington Field Office; the FDA's Office of Criminal Investigations; and the Department of Health and Human Services Office of Inspector General provided substantial assistance in the investigation and resolution.

Today's settlement illustrates the government's emphasis on combating healthcare fraud. One of the most powerful tools in this effort is the FCA. 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 Justice Department is committed to holding responsible those who have fueled the opioid crisis by violating the law.

This case is being handled by Assistant U.S. Attorney Darrell Valdez for the District of Columbia, Senior Trial Counsel Sarah Arni, Trial Attorney Matthew Arrow, and Assistant Director Natalie Waites of the Civil Division's Fraud Section.

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

Contact

USADC.Media@usdoj.gov

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Topic

HEALTHCARE FRAUD

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