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## Department of Justice

U.S. Attorney's Office

District of Massachusetts

FOR IMMEDIATE RELEASE

Tuesday, November 9, 2021

**Kaléo, Inc. Agrees to Pay \$12.7 Million to Resolve Allegations of False Claims for Anti-Overdose Drug**

BOSTON – A Virginia-based pharmaceutical manufacturer, kaléo, Inc., has agreed to resolve allegations that it caused the submission of false claims for the drug Evzio and provided kickbacks to prescribers.

kaléo manufactured and sold Evzio, a naloxone hydrochloride product used for the rapid reversal of an opioid overdose. Evzio was the highest-priced version of naloxone on the market, and insurers frequently required the submission of prior authorization requests before they would approve coverage for Evzio.

The United States contends that, between March 14, 2017 and April 30, 2020, kaléo directed doctors prescribing Evzio to send prescriptions to certain preferred pharmacies that in turn submitted false claims for Evzio to Medicare, the TRICARE program and the Federal Employees Health Benefits Program. In particular, the pharmacies allegedly submitted false and misleading prior authorization requests for Evzio and dispensed Evzio without collecting or attempting to collect co-pays from government beneficiaries. The United States contends that kaléo knew of, or deliberately ignored, this pharmacy misconduct but nevertheless kept directing business to these pharmacies.

The settlement also resolves allegations that kaléo provided illegal remuneration in the form of kickbacks to prescribing physicians and their office staff to induce and reward their prescribing of Evzio. Specifically, the government alleges that Evzio sales representatives provided doctors' offices with frequent deliveries of food and beverages, as well as occasional holiday gifts, even when there was no connection to any educational or other business event.

"When a pharmaceutical manufacturer knowingly engages with bad actors, they hurt the federal healthcare system — and they can expect us to see it," said Acting United States Attorney Nathaniel R. Mendell. "Today's settlement is our latest signal to pharmaceutical manufacturers that my office does not tolerate health care fraud and will continue to pursue enforcement."

"Truthful and accurate documentation is essential to the integrity of federal healthcare programs," said Acting Assistant Attorney General Brian M. Boynton of the Justice Department's Civil Division. "Today's settlement demonstrates that the department will hold to account those who undermine these programs by causing false claims to be submitted to the government."

"The American people, as both taxpayers and consumers, expect pharmaceutical companies like kaléo to abide by relevant laws and regulations," said Phillip M. Coyne, Special Agent in Charge of the U.S. Department of Health and Human Services, Office of the Inspector General. "When a pharmaceutical company participates in fraud in order to boost profits, it erodes public confidence in the health care system, can compromise the patient-physician relationship and wastes valuable government health care program funds. We will continue to investigate allegations of fraud in close cooperation with our law enforcement partners."

"Today's settlement resolves allegations that kaléo used gifts to incentivize and reward providers for prescribing the company's pricey anti-overdose drug, while turning a blind eye to pharmacies' fraudulent practices that fleeced taxpayer-funded health care programs — programs that all of us pay for and depend on," said Joseph R. Bonavolonta, Special Agent in Charge of the Federal Bureau of Investigation, Boston Division. "These unsavory tactics only fuel the FBI's and our law enforcement partners' commitment to aggressively root out those who seek to boost their bottom line at the expense of hard-working taxpayers."

"False claims undermine the integrity of the Federal Employees Health Benefits Program," said Norbert E. Vint, Deputy Inspector General Performing the Duties of the Inspector General of the U.S. Office of Personnel Management, Office of the Inspector General (OPM OIG). "The OPM OIG is committed to protecting the Federal health care programs from deceptive schemes that increase the cost of medical care and waste taxpayer dollars."

"Protecting TRICARE, the health care system for military members and their dependents, is a top priority for the Department of Defense Office of Inspector General Defense Criminal Investigative Service (DCIS)," said Patrick J. Hegarty, Special Agent in Charge of DCIS, Northeast Field

Office. "When companies submit false authorizations for high-priced medical goods and services, they undermine the integrity of TRICARE and place an unnecessary financial burden on the program. The settlement agreement announced today is the result of a joint effort and demonstrates the DCIS' ongoing commitment to work with our law enforcement partners to investigate health care fraud."

Under the terms of the settlement agreement, kaléo will pay the government \$12.743 million. The settlement resolves allegations originally brought in a lawsuit filed by a whistleblower under the qui tam provisions of the False Claims Act, which allow private parties, known as relators, to bring suit on behalf of the government and to share in any recovery.

Acting U.S. Attorney Mendell, Acting AAG Boynton, HHS OIG SAC Coyne, FBI SAC Bonavolonta, OPM OIG Deputy Inspector General Vint, DCIS SAC Hegarty, and Matthew Modafferi, Special Agent in Charge of the U.S. Postal Service, Office of Inspector General, Northeast Area Field Office, made the announcement today. Assistant U.S. Attorneys David J. Derusha and Abraham R. George of Mendell's Affirmative Civil Enforcement Unit and Trial Attorney Sarah Arni of the Justice Department's Civil Division handled the matter.

**Attachment(s):**  
[Download Kaleo Settlement Agreement.pdf](#)

**Component(s):**  
[USAO - Massachusetts](#)

**Topic(s):**  
Health Care Fraud