PRESS RELEASE

Walgreens Agrees to Pay Up to \$350M for Illegally Filling Unlawful Opioid Prescriptions and for Submitting False Claims to the Federal Government

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For Immediate Release

Office of Public Affairs

Note: <u>View settlement here.</u>

The Justice Department, together with the Drug Enforcement Administration (DEA) and Department of Health and Human Services Office of Inspector General (HHS-OIG), today announced a \$300 million settlement with Walgreens Boots Alliance, Walgreen Co., and various subsidiaries (collectively, Walgreens) to resolve allegations that the national chain pharmacy illegally filled millions of invalid prescriptions for opioids and other controlled substances in violation of the Controlled Substances Act (CSA) and then sought payment for many of those invalid prescriptions by Medicare and other federal health care programs in violation of the False Claims Act (FCA). The settlement amount is based on Walgreens's ability to pay. Walgreens will owe the United States an additional \$50 million if the company is sold, merged, or transferred prior to fiscal year 2032.

The government's complaint, filed on Jan. 16 and amended April 18 in the U.S. District Court for the Northern District of Illinois, alleges that from approximately August 2012 through March 1, 2023, Walgreens, one of the nation's largest pharmacy chains, knowingly filled millions of unlawful controlled substance prescriptions. These unlawful prescriptions included prescriptions for excessive quantities of opioids, opioid prescriptions filled significantly early, and prescriptions for the especially dangerous and abused combination of three drugs known as a "trinity." Walgreens pharmacists allegedly filled these prescriptions despite clear red flags indicating a high likelihood that the prescriptions were invalid because they lacked a legitimate medical purpose or were not issued in the usual course of professional practice.

The complaint further alleges that Walgreens pressured its pharmacists to fill prescriptions quickly and without taking the time needed to confirm that each prescription was lawful. Walgreens's compliance officials also allegedly ignored substantial evidence that its stores were dispensing unlawful prescriptions and even intentionally deprived its own pharmacists of crucial information, including by refusing to share internal data regarding prescribers with pharmacists and preventing pharmacists from warning one another about certain problematic prescribers.

In light of Friday's settlement, the United States has moved to dismiss its complaint. Walgreens will also move to dismiss a related declaratory judgment action filed in U.S. District Court for the Eastern District of Texas.

"Pharmacies have a legal responsibility to prescribe controlled substances in a safe and professional manner, not dispense dangerous drugs just for profit," said Attorney General Pamela Bondi. "This Department of Justice is committed to ending the opioid crisis and holding bad actors accountable for their failure to protect patients from addiction."

"This settlement resolves allegations that, for years, Walgreens failed to meet its obligations when dispensing dangerous opioids and other drugs," said Deputy Assistant Attorney General Michael Granston of the Justice Department's Civil Division. "We will continue to hold accountable those entities and individuals whose actions contributed to the opioid crisis, whether through illegal prescribing, marketing, dispensing or distributing activities."

"Importantly, Walgreens's agreements with the DEA and HHS-OIG provide swift relief in the form of monitoring and claims review that will improve Walgreens's practices immediately," said U.S. Attorney Andrew S. Boutros for the Northern District of Illinois. "Our office will continue to work with our law enforcement partners to ensure that opioids are properly dispensed and that taxpayer funds are only spent on legitimate pharmacy claims."

"This landmark civil settlement is the largest Controlled Substances Act resolution in our district's history and once again confirms the high priority our office has placed upon confronting those responsible for the opioid crisis here," said U.S. Attorney Gregory W. Kehoe for the Middle District of Florida. "We are grateful for the energy and collaborative spirit brought to this effort by our colleagues in the DEA, the Department of Justice Civil Frauds Section and Consumer Protection Branch, and the United States Attorneys' Offices for the Northern District of Illinois, District of Maryland, Eastern District of New York, and Eastern District of Virginia."

"With the power to dispense potentially harmful substances comes the responsibility to ensure that every prescription is legitimate before it is filled," said U.S. Attorney Kelly O. Hayes for the District of Maryland. "When pharmacies fail that responsibility, this office will work with others across the country to hold accountable those who put patients and communities at risk."

"This settlement holds Walgreens accountable for failing to comply with its critical responsibility to prevent the diversion of opioids and other controlled substances," said U.S. Attorney John J. Durham for the Eastern District of New York. "The settlement also underscores our office's continued commitment to ensure that all persons and businesses that fill controlled-substance prescriptions adhere to the requirements of the Controlled Substances Act that are designed to prevent highly addictive medications from being used for illegitimate purposes."

"Strict compliance with the law is essential to safeguarding the public, who rely on carefully considered and limited prescriptions for their health and wellbeing," said U.S. Attorney Erik S. Siebert for the Eastern District of Virginia. "Those companies and individuals authorized to provide controlled substances have a professional responsibility to ensure that the prescriptions they fill are within the course of professional practice and regulations. Medically unnecessary prescriptions are a cost ultimately borne by the taxpayers and consumers. As we continue to address the opioid crisis here in Virginia and across the nation, we are determined to ensure pharmacies and pharmacists operate within the law."

In addition to the monetary payments announced today, Walgreens has entered into agreements with DEA and HHS-OIG to address its future obligations in dispensing controlled substances. Walgreens and DEA entered into a memorandum of agreement that requires the company to implement and maintain certain compliance measures for the next seven years. Walgreens must maintain policies and procedures requiring pharmacists to confirm the validity of controlled substance prescriptions prior to dispensing controlled substances, provide annual training to pharmacy employees regarding their legal obligations relating to controlled substances, verify that pharmacy staffing is sufficient to enable pharmacy employees to comply with those legal obligations, and maintain a system for blocking prescriptions from prescribers whom Walgreens becomes aware are writing illegitimate controlled substance prescriptions. Walgreens has also entered into a five-year Corporate Integrity Agreement with HHS-OIG, which further requires Walgreens to establish and maintain a compliance program that includes written policies and procedures, training, board oversight, and periodic reporting to HHS-OIG related to Walgreens's dispensing of controlled substances.

"Pharmacies have an obligation to ensure that every prescription for highly addictive controlled substances is legitimate and issued responsibly in compliance with the Controlled Substances Act," said DEA Acting Administrator Derek Maltz. "When one of the nation's largest pharmacies fails at this obligation, they jeopardize the health and safety of their customers and place the American public in danger. The DEA remains committed to protecting all Americans from unscrupulous practices that prioritize profit over patient safety."

"Pharmacies that neglect their legal duties and their critical role in delivering safe and appropriate medications to enrollees of federal health care programs, and instead exploit these programs for market advantage, squander taxpayer dollars and put patient safety at risk," said Acting Inspector General Juliet T. Hodgkins of HHS-OIG. "HHS-OIG and our law enforcement partners will use every tool in our arsenal to prevent these outcomes. This settlement and corporate integrity agreement reflect HHS-OIG's commitment to ensuring compliance, correcting failures in oversight, and protecting the foundation of federally-funded health care."

"In the midst of the opioid crisis that has plagued our nation, we rely on pharmacies to prevent not facilitate the unlawful distribution of these potentially harmful substances," said Norbert E. Vint, Deputy Inspector General Performing the Duties of the Inspector General at OPM OIG. "We applaud our investigative staff, law enforcement partners, and partners at the Department of Justice for their hard work and unwavering commitment to protecting patients from harm."

The civil settlement resolves four cases brought under the *qui tam*, or whistleblower, provisions of the FCA by former Walgreens employees. The FCA authorizes whistleblowers to sue on behalf of the United States and receive a share of any recovery. It also permits the United States to intervene and take over such lawsuits, as it did here. The relators will receive a 17.25% share of the government's FCA recovery in this matter.

The United States' pursuit of this matter underscores the government's commitment to combating health care 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 HHS-OIG, at 800-HHS-TIPS (800-447-8477).

The DEA, HHS-OIG, Defense Criminal Investigative Service, Defense Health Agency (DHA), Office of Personnel Management (OPM), Department of Labor (DOL) Office of Inspector General, Department of Veterans Affairs (VA), Office of Inspector General, FBI Chicago Field Office, and the U.S. Attorneys' Offices for the District of Colorado, Southern District of California, Eastern District of California, Northern District of California, Southern

District of Illinois, Central District of Illinois, District of Arizona, Western District of Texas, Northern District of Texas, District of Puerto Rico, and Eastern District of Louisiana provided substantial assistance in the investigation.

The United States is represented in this matter by attorneys from the Justice Department's Civil Division Consumer Protection Branch (Assistant Director Amy DeLine and Trial Attorney Nicole Frazer) and Commercial Litigation Branch, Fraud Section (Assistant Director Natalie Waites and Trial Attorney Joshua Barron), as well as from the U.S. Attorneys' Offices for the Northern District of Illinois (Assistant U.S. Attorney Valerie R. Raedy), Middle District of Florida (Chief of the Civil Division Randy Harwell and Assistant U.S. Attorney Carolyn Tapie), District of Maryland (Chief of the Civil Division Thomas Corcoran), Eastern District of New York (Assistant U.S. Attorney Elliot M. Schachner) and Eastern District of Virginia (Assistant U.S. Attorney John Beerbower). Fraud Section senior financial analyst Karen Sharp provided support for the matter.

The claims asserted against defendants are allegations only and there has been no determination of liability.

Additional information about the Consumer Protection Branch and its enforcement efforts can be found at www.justice.gov/civil/consumer-protection-branch. Additional information about the Fraud Section of the Civil Division and its enforcement efforts can be found at www.justice.gov/civil/fraud-section.

For information about the U.S. Attorneys' Offices, visit:

- Middle District of Florida, <u>www.justice.gov/usao-mdfl</u>;
- Northern District of Illinois, www.justice.gov/usao-ndil;
- District of Maryland, www.justice.gov/usao-md;
- Eastern District of New York, www.justice.gov/usao-edny; and
- Eastern District of Virginia, www.justice.gov/usao-edva.

For information about the federal agencies involved in this investigation and their work to combat the opioid crisis and federal healthcare fraud, visit:

- DEA at <u>www.dea.gov</u>;
- FBI at <u>www.fbi.gov</u>;
- HHS-OIG at <u>www.oig.hhs.gov</u>;
- DHA at www.health.mil/About-MHS/OASDHA/Defense-Health-Agency;
- OPM at www.opm.gov; and
- DOL at www.dol.gov.

Topic

FALSE CLAIMS ACT

Components

Office of the Attorney General

Civil Division

Drug Enforcement Administration (DEA)

USAO - Florida, Middle

USAO - Illinois, Northern

USAO - Maryland

USAO - New York, Eastern

USAO - Virginia, Eastern

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