

JUSTICE NEWS

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United States Files False Claims Act Complaint Against Two Compounding Pharmacies and Their Owner For Submitting Inflated Claims and Improperly Waiving Patient Copayments

The Department of Justice announced today that the United States has filed a complaint in intervention against Smart Pharmacy Inc., and SP2 LLC, two compounding pharmacies located in Jacksonville, Florida. The complaint alleges that the pharmacies improperly included the drug aripiprazole, an atypical antipsychotic drug, in compounded pain creams in order to boost the pharmacies' reimbursement for the prescriptions and that the pharmacies routinely waived patient copayment obligations. The government has also brought claims against Gregory Balotin, a co-owner of the pharmacies, for his involvement in the alleged schemes.

Aripiprazole, which is sold under the brand names Abilify, Abilify Maintena, and Aristada, is approved by the U.S. Food and Drug Administration to treat a number of psychological conditions such as schizophrenia, Tourette's disorder, irritability associated with autistic disorder, and manic and mixed episodes associated with Bipolar I. The complaint alleges that the defendants crushed pills of aripiprazole and included them in compounded creams used topically for pain treatment while knowing that there was not an adequate clinical basis for adding aripiprazole to the compound. The complaint alleges that, by including the drug in the pain creams, the defendants substantially increased their reimbursement for prescriptions for the creams from Medicare Part D and TRICARE, the federal health care program for active duty military personnel, retirees, and their families.

The government's complaint also alleges that the defendants improperly waived patient copayments. While copayments may be waived in certain unique circumstances, such as on the basis of financial hardship of the patient, the defendants are alleged to have routinely waived patient copayments without regard for whether a waiver was warranted.

"The Department of Justice will hold accountable health care providers that manipulate the system to improperly enrich themselves at the taxpayers' expense," said Assistant Attorney General Jody Hunt for the Department of Justice's Civil Division. "Dispensing drugs for unproven uses and improperly waiving patient copayments erodes public trust in the health care system and increases the costs borne by federal health care programs."

"This complaint addresses alarming misconduct by some of the largest compounding pharmacies in our district," said U.S. Attorney for the Middle District of Florida Maria Chapa Lopez. "We intend to hold providers accountable under the False Claims Act when they put their own economic interests ahead of the medical needs of federal health program beneficiaries."

"Fraud in government health programs may result in harm to vulnerable populations and needless taxpayer expense," said Shimon R. Richmond, Special Agent in Charge of the Office of Inspector General for the U.S. Department of Health and Human Services. "All available resources will be used to aggressively investigate these allegations."

"I applaud the Department of Justice for its continued efforts to hold compounding pharmacies accountable to the American taxpayer," said Vice Adm. Raquel Bono, director of the Defense Health Agency. "The efforts of the Department of Justice safeguard the health care benefit for our service members, veterans and their families. The Defense Health Agency will continue working closely with the Justice Department, and other state and federal agencies to investigate all those who participated in fraudulent practices."

"It is of utmost importance to protect the integrity of DoD programs by rooting out fraud, waste, and abuse that diverts and wastes precious American taxpayer dollars intended for our Warfighters, and their families. Allegations of providers unjustly enriching themselves will be met with a coordinated effort amongst all affected agencies to hold those accountable," said the Defense Criminal Investigative Service Special Agent in Charge Cynthia Bruce, Southeast Field Office.

The lawsuits, *United States ex rel. Sanchez v. Smart Pharmacy, Inc., et al.*, No. 14-cv-1453 (M.D. Fla.), and *United States ex rel. Kohli v. Smart Pharmacy, Inc., et al.*, No. 16-cv-387 (M.D. Fla.), were originally filed in the U.S. District Court for the Middle District of Florida by Amy Sanchez and Ashok Kohli, two former employees of Smart Pharmacy. The lawsuits were filed under the *qui tam* or whistleblower provisions of the False Claims Act, which permit private parties to sue on behalf of the United States for false claims and to receive a share of any recovery. The Act permits the United States to intervene in such lawsuits, as the United States has done in these cases.

This matter is being handled by the Civil Division's Commercial Litigation Branch and the U.S. Attorney's Office for the Middle District of Florida, with assistance from the Defense Criminal Investigative Service, the Department of Health and Human Services Office of Inspector General, the Department of Veterans Affairs Office of Inspector General, the Department of Labor Office of Inspector General, and the Office of Personnel Management Office of Inspector General.

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

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Component(s):

Civil Division

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