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Two Jacksonville Compounding Pharmacies and Their Owner Agree to Pay at Least \$7.4 Million to Resolve False Claims Act Allegations

The Justice Department announced today that Smart Pharmacy, Inc., SP2, LLC, and owner Gregory Balotin have agreed to pay at least \$7.4 million to resolve lawsuits filed in Jacksonville, Florida, alleging they violated the False Claims Act by adding the antipsychotic drug aripiprazole to topical compounded pain creams to boost reimbursement and by routinely waiving patient copayment obligations. The settlement amount is based on the defendants' ability to pay.

"When pharmacies inflate their revenue with medically unsupported prescription ingredients, they compromise the quality of patient care and waste taxpayer dollars," said Principal Deputy Assistant Attorney General Brian M. Boynton, head of the Justice Department's Civil Division. "The department will hold accountable those who undermine the integrity of federal healthcare programs for personal profit."

"A primary mission of the U.S. Attorney's Office is protecting the Medicare and TRICARE programs from fraud," said U.S. Attorney Roger Handberg for the Middle District of Florida. "This case exemplifies our commitment to pursue pharmacies and pharmacists who abuse federal healthcare programs at the expense of the taxpayers."

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 and Tourette's disorder. The United States alleged that the defendants crushed aripiprazole pills approved for oral use and included them in compounded creams used topically for pain treatment, while knowing that there was not an adequate clinical basis to do so. The defendants allegedly included the drug in the pain creams to increase their profits on prescriptions paid for by Medicare Part D and TRICARE, the federal health care program for active duty military personnel, retirees, and their families. Both Medicare Part D and TRICARE reimburse pharmacies for the individual ingredients included in compounded drugs, thus defendants increased their reimbursement by adding aripiprazole to the combination of drugs used in their pain creams.

The government also alleged that the defendants improperly waived patient copayments to induce patients to accept the pain cream prescriptions. Although copayments may be waived in certain unique circumstances, such as on the basis of an individualized assessment of a patient's financial hardship, the defendants allegedly routinely waived copayments without regard to patient need.

In connection with the settlement, Gregory Balotin has agreed to enter into a three-year integrity agreement with the Department of Health and Human Services Office of Inspector General (HHS-OIG), which includes an annual claims review by an independent review organization.

"Pharmacies participating in Medicare are obligated to obey laws designed to protect both the integrity of this program and the quality of care provided to patients," said Special Agent in Charge Omar Pérez Aybar of HHS-OIG. "With our law enforcement partners, our agency is committed to investigating alleged health care fraud to protect both federal health care programs as well as the individuals served by those programs."

"We are grateful to the U.S. Department of Justice, the U.S. Attorney's Office, and other state and federal officials for their unwavering commitment to protect taxpayer dollars and safeguard the TRICARE pharmacy benefit," said Chief Edward C. Norton Jr. of the Defense Health Agency's Pharmacy Operations Division. "Their efforts ensure our service members, veterans, and their families continue to receive the highest-quality pharmacy benefit commensurate with the service and sacrifice they make for our nation."

“Health care providers and suppliers that serve our nation’s active duty service members, military retirees, and their families are expected to meet the highest standards of ethical and professional behavior,” said Special Agent in Charge Darrin K. Jones of the Department of Defense (DoD) Office of Inspector General, Defense Criminal Investigative Service (DCIS), Southeast Field Office. “DCIS and its law enforcement partners will continue to investigate unprincipled health care providers that undermine the integrity of the DoD’s TRICARE program.”

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 share in any recovery. The Act permits the United States to intervene and take over such lawsuits, which the United States did here, in part. The share to be awarded in this case has not been determined.

This matter was 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 HHS-OIG, DCIS, 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.

Assistant U.S. Attorneys Collette Cunningham and Holly Snow for the Middle District of Florida and Trial Attorneys Nicholas Perros, Jessica Sievert, and Andrew Jaco of the Civil Division are prosecuting the case.

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

Component(s):

[Civil Division](#)
[USAO - Florida, Middle](#)

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