JUSTICE NEWS

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Justice Department Files Complaint Against Professional Compounding Centers of America Inc. for Reporting Fraudulent Pricing Information for Ingredients Sold to Pharmacies

The Justice Department has filed a complaint under the False Claims Act against Professional Compounding Centers of America Inc. (PCCA), a Houston-based company that sells active pharmaceutical ingredients and other products and services to compounding pharmacies. The complaint alleges that PCCA reported fraudulent and inflated Average Wholesale Prices (AWPs) for its ingredients that bore no relationship to the actual prices at which it sold those ingredients to its pharmacy customers, thereby causing those pharmacies to submit inflated compound prescription claims to TRICARE, the federal health care program providing insurance for active duty military personnel, military retirees and military dependents.

Compounding pharmacies purchase ingredients for use in compound drugs from ingredient suppliers such as PCCA, which establish and report AWPs for their ingredients to pricing compendia used by federal health care programs and commercial health insurance companies. TRICARE determines the level of reimbursement for compound prescription claims based in part on the reported AWP for each of the ingredients in a compound drug. The complaint alleges that PCCA knowingly established and reported AWPs for its ingredients that were greatly inflated above their actual selling prices. For example, in 2014, PCCA typically sold the chemical Fluticasone Propionate to its top customers for between approximately \$135 and \$197 per gram, but it reported an AWP for that ingredient of \$3,630.90 per gram – approximately 18 to 27 times the actual selling price. That same year, PCCA typically sold the ingredient Resveratrol to its top customers for under \$2 per gram but reported an AWP of \$818.68 per gram, more than 400 times the actual selling price of the ingredient.

"The fraudulent reporting and marketing of drug prices to solicit business will not be tolerated," said Deputy Assistant Attorney General Michael D. Granston of the Justice Department's Commercial Litigation Branch in the Civil Division. "We will continue to hold accountable those who take improper advantage of federal health care programs."

"We diligently investigate fraud on the federal healthcare system, especially where it impacts our veterans and their families," said U.S. Attorney Ashley Hoff for the Western District of Texas. "We will continue to guard the system so patients receive the care they deserve and federal taxpayer dollars are not wasted."

"The practices we confront in this case created a major threat to the viability of the TRICARE program, a critically important public healthcare program that serves the needs of our military," said Acting U.S. Attorney Karin Hoppmann for the Middle District of Florida. "This effort demonstrates our district's resolve in the struggle against fraud schemes that prey on the nation's military personnel and their families."

"As the investigative arm of the Department of Defense Office of the Inspector General, the Defense Criminal Investigative Service (DCIS) will aggressively pursue all allegations of fraud perpetrated against the Department of Defense," said Special Agent in Charge Michael C. Mentavlos of the DCIS Southwest Field Office. "DCIS will continue to partner with the Defense Health Agency and the Department of Justice to hold companies like PCCA accountable for their actions, protect the TRICARE program and recover valuable taxpayer resources."

The complaint alleges that PCCA marketed its inflated AWPs, the resulting profit potential and compound formulas containing high AWP ingredients as inducements to pharmacies to purchase PCCA ingredients. PCCA's actions caused its pharmacy customers to submit tens of thousands of false and fraudulently inflated compound prescription claims containing PCCA ingredients to TRICARE, costing the program hundreds of millions of dollars in excess reimbursement.

The complaint also alleges that PCCA offered additional inducements to pharmacy customers, such as annual all-inclusive travel packages, in exchange for ingredient purchases and purchase commitments.

The United States filed its complaint in a lawsuit originally brought under the *qui tam* or whistleblower provisions of the False Claims Act by Peter Hueseman. Hueseman was formerly a part owner and pharmacist at a pharmacy that purchased compound ingredients from PCCA. Under the act, a private party can file an action on behalf of the United States and receive a portion of any recovery. The act permits the United States to intervene in such lawsuits, as it has done in this case. The *qui tam* case is captioned *United States ex rel. Hueseman v. Professional Compounding Centers of America, Inc.*, No. 5:14-cv-212 (W.D. Tex.). In November 2019, the United States reached settlements with Freedom Pharmaceuticals Inc., and Pharmacy Services Inc., which were also defendants in this matter. See <u>https://www.justice.gov/opa/pr/compound-ingredient-supplier-fagron-holding-usa-llc-pay-2205-million-resolve-allegations.</u>

The investigation of this matter was the result of a coordinated effort between the Civil Division's Commercial Litigation Branch (Fraud Section) and the U.S. Attorneys' Offices for the Western District of Texas and Middle District of Florida, with assistance from DCIS, FBI, the U.S. Postal Service Office of Inspector General, the Department of Labor Office of Inspector General, and the Drug Enforcement Agency.

The United States' intervention in this matter illustrates the government's emphasis on combating healthcare 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 the Department of Health and Human Services at 800-HHS-TIPS (800-447-8477).

This matter is being handled by Fraud Section Attorneys Sanjay Bhambhani, Danielle Sgro and Nathan Green and Assistant U.S. Attorneys Mary Kruger, John Deck, and Collette Cunningham.

The claims in the complaint are allegations only, and there has been no determination of liability.

Attachment(s): Download PCCA Complaint.pdf

Topic(s): False Claims Act Component(s): Civil Division USAO - Florida, Middle USAO - Texas, Western

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