

Department of Justice

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Eastern District of Pennsylvania

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Three Generic Pharmaceutical Companies Agree to Pay Almost Half a Billion Dollars to Resolve Alleged False Claims Act Liability, Bringing Total Payments for Price-Fixing to Nearly \$900 Million

PHILADELPHIA – Acting U.S. Attorney Jennifer Arbittier Williams announced that three generic pharmaceutical manufacturers, Taro Pharmaceuticals U.S.A., Inc., Sandoz Inc., and Apotex Corporation, have agreed to pay a total of \$447.2 million to resolve alleged violations of the False Claims Act arising from conspiracies to fix the price of various generic drugs. These conspiracies allegedly resulted in higher drug prices for federal health care programs according to the Justice Department. These civil recoveries follow criminal deferred prosecution agreements, under which the three companies previously paid a total of \$424.7 million.

The government further alleges that between 2013 and 2015, all three companies paid and received remuneration prohibited by the Anti-Kickback Statute through arrangements on price, supply, and allocation of customers with other pharmaceutical manufacturers for certain generic drugs manufactured by the companies.

Taro Pharmaceuticals U.S.A., Inc., headquartered in New York, has agreed to pay \$213.2 million. The Taro drugs allegedly implicated in this scheme address a wide variety of health conditions and include etodolac, a nonsteroidal anti-inflammatory drug used to treat pain and arthritis, and nystatin-triamcinolone cream and ointment, a combination of an antifungal medicine and steroid used to treat certain kinds of skin infections.

Sandoz Inc., headquartered in New Jersey, has agreed to pay \$185 million. The Sandoz drugs at issue include benazepril HCTZ, used to treat hypertension, and clobetasol, a corticosteroid used to treat skin conditions.

Apotex Corporation, headquartered in Florida, has agreed to pay \$49 million in connection with its sale of pravastatin, a drug used to treat high cholesterol and triglyceride levels.

"This series of civil settlements should serve as a wake-up call for the generic drug industry. Generic drug companies must and will be held accountable for price-fixing schemes which not only cause massive financial harm to federal health care programs, but also may impact the care available to patients," said Acting U.S. Attorney Williams. "We will continue to aggressively pursue these violations of the Anti-Kickback Statute and the False Claims Act and obtain significant recoveries."

"Illegal collaboration on the price or supply of drugs increases costs both to federal health care programs and beneficiaries," said Acting Assistant Attorney General Brian M. Boynton of the Justice Department's Civil Division. "The Department will use every tool at its disposal to prevent such conduct and to protect these taxpayer-funded programs."

"Conspiring to raise prices on generic medications is illegal and could prevent patients from being able to afford their needed prescription drugs. Americans have the right to purchase generic drugs set by fair and open competition, not collusion," said Maureen R. Dixon, Special Agent in Charge of the Philadelphia Regional Office of the Inspector General, Department of Health and Human Services (HHS-OIG). "HHS-OIG along with our law enforcement partners will continue to investigate allegations of companies engaging in actions that put the public and the Medicare program at risk."

In connection with its settlement agreement, each company also entered a five-year corporate integrity agreement (CIA) with OIG. The CIAs include unique internal monitoring and price transparency provisions. They also require the companies to implement compliance measures including risk assessment programs, executive recoupment provisions, and compliance-related certifications from company executives and Board members.

"These kickback schemes harm Medicare, Medicaid, and patients," said Gregory E. Demske, Chief Counsel to the Inspector General at the U.S. Department of Health and Human Services. "The CIAs promote transparency and accountability by requiring the companies to report price-related information to OIG and mandating individual certifications by key executives involved in pricing and contracting functions."

“Protecting TRICARE, the healthcare system for U.S. military members and their dependents, is a top priority for the Department of Defense, Office of Inspector General, Defense Criminal Investigative Service (DCIS),” stated Special Agent in Charge Patrick J. Hegarty, DCIS Northeast Field Office. “When pharmaceutical corporations artificially inflate prices, they undermine the integrity of TRICARE and place an unnecessary financial burden on the program. The settlement agreements announced today are the result of a joint effort and demonstrate the ongoing commitment of DCIS to work with our law enforcement partners, DOJ Civil Frauds and the USAO-EDPA, to investigate healthcare fraud.”

The Anti-Kickback Statute prohibits companies from receiving or paying remuneration in return for arranging the sale or purchase of items such as drugs for which payment may be made by a federal health care program. These provisions are designed to ensure that the supply and price of health care items are not compromised by improper financial incentives. These settlements reflect the important role of the False Claims Act to ensure that the United States is fully compensated when it is the victim of kickbacks paid to further anticompetitive conduct.

All three companies previously entered into deferred prosecution agreements with the Antitrust Division to resolve related criminal charges. Taro paid a criminal penalty of \$205.6 million and admitted to conspiring with two other generic drug companies to fix prices on certain generic drugs. Sandoz paid a criminal penalty of \$195 million and admitted to conspiring with four other generic drug companies to fix prices on certain generic drugs. Apotex paid a criminal penalty of \$24.1 million and admitted to conspiring to increase and maintain the price on pravastatin. The civil settlement payments announced today are in addition to the criminal penalties paid by the companies.

Today’s civil settlements are the third, fourth, and fifth arising from this investigation and were handled by the U.S. Attorney’s Office for the Eastern District of Pennsylvania in conjunction with the Civil Division’s Commercial Litigation Branch (Fraud Section), with investigative support from the HHS-OIG, DCIS, the Defense Health Agency Program Integrity Office, and the Office of Inspector General for the Department of Veterans Affairs. The matters were handled by Assistant U.S. Attorneys Landon Y. Jones III, Rebecca S. Melley and Anthony D. Scicchitano, in conjunction with Senior Trial Counsels Jennifer L. Cihon and Laurie A. Oberembt of the Civil Fraud Section.

Except for those facts admitted to in the deferred prosecution agreements, the claims resolved by the civil settlements are allegations only, and there has been no determination of liability.

Topic(s):

False Claims Act

Component(s):

[USAO - Pennsylvania, Eastern](#)

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