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Pharmaceutical Company Admits to Price Fixing in Violation of Antitrust Law, Resolves Related False Claims Act Violations

Heritage Pharmaceuticals Agrees to Pay More than \$7 Million in Criminal Penalty and Civil Damages and to Cooperate with Ongoing Parallel Investigations in the Generics Industry

Heritage Pharmaceuticals Inc., a generic pharmaceutical company headquartered in Eatontown, New Jersey, was charged for conspiring with its competitors to fix prices, rig bids, and allocate customers, the Department of Justice announced today.

According to a one-count felony charge filed yesterday in the United States District Court for the Eastern District of Pennsylvania in Philadelphia, from about April 2014 until at least December 2015, Heritage participated in a criminal antitrust conspiracy with other companies and individuals engaged in the production and sale of generic pharmaceuticals, a purpose of which was to fix prices, rig bids, and allocate customers for glyburide, a medicine used to treat diabetes. This charge is the third in the Department of Justice's Antitrust Division's ongoing investigation; Heritage's former CEO and its former president were previously charged.

The Antitrust Division also announced a deferred prosecution agreement resolving the charge, under which Heritage admits that it conspired to fix prices, rig bids, and allocate customers for glyburide. Under the agreement's terms, Heritage will pay a \$225,000 criminal penalty and cooperate fully with the ongoing criminal investigation. The United States will defer prosecuting Heritage for a period of three years to allow the company to comply with the agreement's terms. The agreement will not be final until accepted by the court.

"American consumers have the right to generic drugs sold at prices set by competition, not collusion," said Assistant Attorney General Makan Delrahim of the Department of Justice's Antitrust

Division. “It is particularly galling that, when healthcare prices in the United States are already high, certain generic pharmaceutical companies and executives engaged in collusive conduct at the expense of individuals who depend on critical medications. Heritage and its co-conspirators cheated and exploited vulnerable American patients to pad their bottom line.” Delrahim continued, “this resolution — requiring an admission of guilt, a criminal penalty, and cooperation in the ongoing investigation — sends a clear message to generic pharmaceutical companies and their executives that this conduct will not be tolerated. The Division and its law enforcement partners, including the FBI and the U.S. Postal Service Office of Inspector General, will continue to hold companies and individuals accountable for collusion that undermines the integrity of the market for drugs.”

The Antitrust Division entered into the deferred prosecution agreement with Heritage based on the individual facts and circumstances of this case. Among those facts and circumstances, the agreement specifically identifies the company’s substantial and ongoing cooperation with the investigation to date, including its disclosure of information regarding criminal antitrust violations involving drugs other than those identified in the criminal charge and the agreement. According to the agreement, this cooperation has allowed the United States to advance its investigation into criminal antitrust conspiracies among other manufacturers of generic pharmaceuticals. Other facts and circumstances identified in the agreement include: Heritage has agreed to resolve all civil claims relating to federal health care programs arising from its conduct; and a conviction (including a guilty plea) would likely result in the Office of the Inspector General of the Department of Health and Human Services imposing mandatory exclusion of Heritage from all federal health care programs under 42 U.S.C. § 1320a-7 for a period of at least five years, which would result in substantial consequences, including to American consumers. The agreement can ensure that integrity has been restored to Heritage’s operations and preserve its financial viability while preserving the United States’ ability to prosecute it should material breaches occur.

“Price fixing, bid rigging and market allocation promote an environment antithetical to free and open competition in the marketplace. When this occurs, the consumer is not guaranteed the best products at the lowest prices,” said Special Agent in Charge Scott Pierce, U.S. Postal Service Office of Inspector General. “The U.S. Postal Service spends hundreds of millions of dollars every year on health care associated costs, including expenses related to prescription drugs. Along with the Department of Justice and our federal law enforcement partners, the USPS Office of Inspector General will aggressively investigate those who would engage in this type of harmful conduct.”

“The availability of generic medications should be a boon to the public, giving them access to proven drugs at lower prices,” said Michael T. Harpster, Special Agent in Charge of the FBI’s Philadelphia Division. “When generic pharmaceutical firms engage in price fixing and bid rigging in order to pad their profits, they not only disrupt the free market but do so on the backs of the folks who depend on

these drugs. The FBI will continue to investigate and hold accountable companies engaged in such illegal and anticompetitive acts.”

In a separate civil resolution, Heritage has agreed to pay \$7.1 million to resolve allegations under the False Claims Act related to the price-fixing conspiracy. The government alleged that between 2012 and 2015, Heritage paid and received remuneration through arrangements on price, supply, and allocation of customers with other pharmaceutical manufacturers for certain generic drugs in violation of the Anti-Kickback Statute, and that its sale of such drugs resulted in claims submitted to or purchases by federal healthcare programs. The drugs allegedly implicated in this scheme address a wide variety of health conditions, and include hydralazine, used to treat high blood pressure, theophylline, used to treat asthma and other respiratory problems, and glyburide.

“Price fixing of generic drugs harms federal health care programs and the beneficiaries those programs serve,” said Assistant Attorney General Jody Hunt of the Department of Justice’s Civil Division. “The Department of Justice will use every tool at its disposal to hold generic drug manufacturers accountable for wrongdoing.”

“My Office is proud to announce both the civil healthcare fraud settlement with the Civil Division and the deferred prosecution agreement with the Antitrust Division,” said U.S. Attorney McSwain. “Price fixing and market allocation in generic drugs will not be tolerated, especially when such actions artificially inflate prices and negatively impact federal healthcare programs like Medicare and Medicaid. This resolution with Heritage is an important milestone, and my Office will continue to investigate and pursue illegal conduct regarding generic drugs.”

“Plotting to raise prices on generic medications is illegal and may result in patients’ inability to afford vital medicines,” said Maureen R. Dixon, Special Agent in Charge of the Philadelphia Regional Office of the Inspector General, Department of Health and Human Services. “Along with our law enforcement partners at the DOJ, FBI, and Postal-OIG, we will continue to investigate allegations of companies engaging in actions that put the public and the Medicare program at risk.”

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. This settlement reflects 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.

The criminal charge is the result of an ongoing federal antitrust investigation into price fixing, bid rigging, and other anticompetitive conduct in the generic pharmaceutical industry, which is being conducted by the Antitrust Division with the assistance of the FBI’s Philadelphia Division, the FBI

headquarters' International Corruption Unit, the United States Postal Service Office of Inspector General, and the U.S. Attorney's Office for the Eastern District of Pennsylvania. Anyone with information on market allocation, price fixing, bid rigging and other anticompetitive conduct related to the generic pharmaceutical industry should contact the Antitrust Division's Citizen Complaint Center at 1-888-647-3258, visit www.justice.gov/atr/contact/newcase.html or call the FBI's Philadelphia Division at 215-418-4000.

The civil settlement was handled by the Civil Division's Commercial Litigation Branch and the U.S. Attorney's Office for the Eastern District of Pennsylvania with support from the Department of Health and Human Services Office of the Inspector General, Defense Health Agency Program Integrity, and the Office of Inspector General for the Department of Veterans Affairs. Except for those facts admitted to in the deferred prosecution agreement, the claims resolved by the civil settlement are allegations only, and there has been no determination of liability.

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