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DRUG MAKER UNITED THERAPEUTICS AGREES TO PAY \$210 MILLION TO RESOLVE FALSE CLAIMS ACT LIABILITY FOR PAYING KICKBACKS

Pharmaceutical company United Therapeutics Corporation (UT), based in Silver Spring, Maryland, has agreed to pay \$210 million to resolve claims that it used a foundation as a conduit to pay the copays of Medicare patients taking UT's pulmonary arterial hypertension drugs, in violation of the False Claims Act, the Justice Department announced today.

When a Medicare beneficiary obtains a prescription drug covered by Medicare Part B or Part D, the beneficiary may be required to make a partial payment, which may take the form of a copayment, coinsurance, or deductible (collectively "copays"). These copay obligations may be substantial for expensive medications. Congress included copay requirements in these programs, in part, to encourage market forces to serve as a check on health care costs—including the prices that pharmaceutical manufacturers can demand for their drugs. Under the Anti-Kickback Statute, a pharmaceutical company is prohibited from offering or paying, directly or indirectly, any remuneration—which includes money or any other thing of value—to induce Medicare patients to purchase the company's product.

UT sells a number of pulmonary arterial hypertension drugs, including Adcirca, Remodulin, Tyvaso, and Orenitram (the "Subject Drugs"). The government alleged that UT used a foundation, which claims 501(c)(3) status for tax purposes, as a conduit to pay the copay obligations of thousands of Medicare patients taking the Subject Drugs. In particular, from 2010 to 2014, UT allegedly made donations to the foundation, which, in turn, used those donations to pay copays for the Subject Drugs to induce patients to purchase these drugs. The government alleged that UT routinely obtained data from the foundation detailing how much the foundation had spent for patients on each Subject Drug and that this data was used by UT to decide how much to donate to the foundation. The Government also alleged that UT had a policy of not permitting needy Medicare patients to participate in its free drug program, which was open to other financially needy patients, and instead referred Medicare patients to the foundation, which allowed claims to be submitted to Medicare.

“While we support efforts to provide patients with access to needed medications, such assistance must comply with federal law. Today’s settlement shows that the government will hold accountable drug companies that attempt to use illegal kickbacks to defeat mechanisms Congress designed to act as a check on drug pricing and healthcare costs,” said Acting Assistant Attorney General Chad A. Readler of the Justice Department’s Civil Division.

UT has also entered into a corporate integrity agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG). The five-year CIA requires, among other things, that UT implement measures designed to ensure that arrangements and interactions with third-party patient assistance programs are compliant with the law. In addition, the CIA requires reviews by an independent review organization, compliance-related certifications from company executives and Board members, and the implementation of a risk assessment and mitigation process.

“Our corporate integrity agreement requires United Therapeutics to implement controls and monitoring designed to promote true independence from any patient assistance programs to which it donates,” said Gregory E. Demske, Chief Counsel to the Inspector General for the U.S. Department of Health and Human Services. “Without true independence, a drug company can use a foundation as a conduit for improper payments that expose the taxpayer-funded Medicare program to the risk of abuse.”

“UT used a third party to do exactly what it knew it could not lawfully do itself,” said Acting United States Attorney William D. Weinreb. “According to the allegations in today’s settlement agreement, UT understood that the third-party foundation used UT’s money to cover the co-pays of patients taking UT drugs. UT’s payments to the foundation were not charity for PAH patients generally, but rather were a way to funnel money to patients taking UT drugs. The Anti-Kickback Statute exists to protect Medicare, and the taxpayers who fund it, from schemes like these that leave Medicare holding the bag for the costs of expensive drugs.”

The government’s resolution of 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).

The investigation was conducted by the Justice Department's Civil Division and the U.S. Attorney's Office for the District of Massachusetts, in conjunction with the Department of Health and Human Services, Office of Inspector General; the Federal Bureau of Investigation; the Department of Veterans Affairs, Office of Inspector General; and the United States Postal Inspection Service.

The claims resolved by the settlement are allegations only; there has been no determination of liability.