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Thursday, May 24, 2018

## **DRUG MAKER PFIZER AGREES TO PAY \$23.85 MILLION TO RESOLVE FALSE CLAIMS ACT LIABILITY FOR PAYING KICKBACKS**

Pharmaceutical company Pfizer, Inc. (Pfizer), based in New York, NY, has agreed to pay \$23.85 million to resolve claims that it used a foundation as a conduit to pay the copays of Medicare patients taking three Pfizer 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). Congress included copay requirements in the Medicare program, 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, directly or indirectly, any remuneration—which includes paying patients' copay obligations—to induce Medicare patients to purchase the company's drugs.

As part of today's settlement, the government alleged that Pfizer used a foundation as a conduit to pay the copay obligations of Medicare patients taking three Pfizer drugs: Sutent and Inlyta, which both treat renal cell carcinoma, and Tikosyn, which treats arrhythmia in patients with atrial fibrillation or atrial flutter. The government alleged that, in order to generate revenue, and instead of giving Sutent and Inlyta to Medicare patients who met the financial qualifications of Pfizer's existing free drug program, Pfizer used a third-party specialty pharmacy to transition certain patients to the foundation, which covered the patients' Medicare copays. Pfizer allegedly made donations to the foundation to enable it to cover the copays of these patients and received confirmation from the foundation, via the specialty pharmacy, that the foundation funded the copays.

With respect to Tikosyn, Pfizer raised the wholesale acquisition cost of a package of forty .125 mg capsules of the drug by over 40 percent in the last three months of 2015. Pfizer allegedly knew that the price increase would also increase Medicare beneficiaries' copay obligations for Tikosyn, and potentially prevent some patients from being able to afford the drug. Pfizer allegedly worked with the foundation to create and finance a fund for Medicare patients suffering from the condition treated by Tikosyn, coordinated the opening of the fund with the implementation of its price increase for the drug, and referred patients to the fund. For the next nine months, Tikosyn patients accounted for virtually all of the beneficiaries whose copayments were paid by the fund.

“Kickbacks undermine the independence of physician and patient decision-making, and raise healthcare costs,” said Acting Assistant Attorney General Chad A. Readler of the Justice Department’s Civil Division. “As today’s settlement makes clear, the Department will hold accountable drug companies that pay illegal kickbacks—whether directly or indirectly—to undermine taxpayer funded healthcare programs, including Medicare.”

“Pfizer used a third party to saddle Medicare with extra costs,” said United States Attorney Andrew E. Lelling. “According to the allegations in today’s settlement agreement, Pfizer knew that the third-party foundation was using Pfizer’s money to cover the co-pays of patients taking Pfizer drugs, thus generating more revenue for Pfizer and masking the effect of Pfizer’s price increases. The Anti-Kickback Statute exists to protect Medicare, and the taxpayers who fund it, from schemes like these. At the same time, we commend Pfizer for stepping forward to resolve these issues in a responsible manner.”

“Today’s settlement demonstrates the FBI’s commitment to making sure patients receive, and the government pays for, health care that is not compromised by kickbacks,” said Harold H. Shaw, Special Agent in Charge, FBI Boston Division. “What Pfizer is accused of doing in this case—masking charitable contributions to increase company profits—violates the basic trust patients extend to the healthcare system and threatens the financial integrity of the Medicare program.”

Pfizer 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 Pfizer 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 promotes independence between Pfizer and any patient assistance programs to which it may donate,” said Gregory E. Demske, Chief Counsel to the Inspector General for the United States Department of Health and Human Services. “Without true independence, as we have seen in this case, drug companies may use patient assistance programs as conduits for improper payments that harm Medicare.”

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.