

# Pharmaceutical Fraud

Whistleblowers acting under the Federal False Claims Act (“FCA”) and Texas Medicaid Fraud and Prevention Act (“TMFPA”) are critical to exposing pharmaceutical fraud and recovering substantial funds owed by pharmaceutical companies to federal and state governments. Whistleblower cases brought under the FCA and TMFPA have been particularly effective in combating fraudulent claims by pharmaceutical manufacturers. Some of the schemes that pharmaceutical companies have commonly used that may be violations of FCA and TMFPA include:

- **Off-Label Marketing**

Pharmaceuticals and other drugs are highly regulated by numerous federal and state laws and regulations. Before any drug can be approved for use in the United States, it must first be approved by the FDA. The FDA determines which medical conditions a drug may be used to treat, known as the drug’s “label”. Federal law restricts pharmaceutical companies to marketing drugs only for the uses or indications approved by the FDA. On the other hand, Physicians may in some circumstances prescribe drugs to treat numerous medical conditions even if the drug has not been approved by the FDA to treat those conditions. This practice is known as “off-label” use of a drug because it goes beyond those uses specifically approved by the FDA. One common scheme that violates the TMFPA and FCA by pharmaceutical manufacturers has been to market their drugs to physicians for an off-label use.

## **Improper Billing**

Medicare and other government health care program laws and regulations set rules about when an approved drug is eligible to be reimbursed for a patient. Claims submitted to the government for payment that violate these rules give rise to FCA and TMFPA violations. The most basic reimbursement requirement is that the drug must be reasonable and necessary for the diagnosis or treatment of illness or injury. The FCA and TMFPA prohibit the following common fraud schemes:

- multiple billing for the same drug dose.
- billing for a drug that was not actually provided to the patient.
- billing the incorrect price for the drug.

- misrepresenting the patient's condition to make it appear that the drug is reasonable and necessary.

### **Kickbacks:**

One common scheme has been for pharmaceutical companies to provide payments or other financial incentives to hospitals and/or physicians in order to induce them to prescribe their drugs to patients. Examples of such payments or financial inducements are as follows

- Payments for attending conferences;
- Phony or sham drug trials;
- Free samples of drugs;
- Bonus payments to physicians and hospitals;
- Free vacations;
- Lavish meals;
- Tickets to sporting events;
- Gifts

These and other financial inducements can be a violation of the FCA and Anti-Kickback statute, 42 U.S.C. §1328-7b(b).

- **Inflating the Price of Pharmaceuticals:**

One common type of fraud has been for pharmaceutical manufacturers to inflate the average wholesale price ("AWP") of their drugs and to use that inflated cost to provide a financial inducement for Pharmacists and Insurers to prescribe their drugs. As a financial inducement to prescribe their drugs, pharmaceutical manufacturers have inflated the AWP, thereby increasing the spread between the actual cost of the drug and the amount that the Government pays for that drug.

- **Best Price for Medicaid**

In order for a pharmaceutical manufacturer to sell its drugs to the Medicaid Program, it must agree to charge the program the lowest price at which the manufacturer sells to drug wholesalers, pharmacists, and other private sector customers. In order to induce these pharmacists and

businesses to purchase and prescribe their drugs, pharmaceutical manufacturers have offered their drugs at prices below the best price offered to Medicaid. The pharmaceutical companies conceal these discounts so as to avoid having to provide rebates to Medicaid to match the discounted price they are providing to pharmacists and businesses. This violation of the Medicaid Best Price requirement can be a violation of the FCA and/or the TMFPA.

## **Examples of Whistleblower recoveries in Pharmaceutical Fraud Cases alleging violations of the FCA:**

In September of 2019, three **whistleblowers received more than \$17.7 Million** as a Relator share when a pharmaceutical company was charged for paying kickbacks to a health care provider to prescribe the company's drug to beneficiaries of federal health care programs. The company agreed to pay more than **\$108 million** in criminal penalties, forfeiture, and civil damages. DOJ alleged that the pharmaceutical company paid kickbacks in the form of money, honoraria, travel, and meals to health care providers of elderly patients at long-term care facilities to induce them to prescribe the company's drug for behaviors associated with dementia patients, which is not an approved use of the drug. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Pharmaceutical Company Targeting Elderly Victims Admits to Paying Kickbacks, Resolves Related False Claims Act Violations (Sept. 26, 2019), <https://www.justice.gov/opa/pr/pharmaceutical-company-targeting-elderly-victims-admits-paying-kickbacks-resolves-related>.

The **whistleblower** received a **Relator Fee** of approximately **\$93 million** of the **\$260 million settlement** in October of 2018, in a case where Amerisource Bergen Corporation agreed to resolve allegations that they improperly repackaged and distributed overfill oncology drugs and allegedly provided kickbacks to induce physicians to purchase the repackaged drugs. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, AmerisourceBergen Corporation Agrees to Pay \$625 Million to Resolve Allegations That it Illegally Repackaged Cancer-Supportive Injectable Drugs to Profit from Overfill (Oct. 1, 2018), <https://www.justice.gov/opa/pr/amerisourcebergen-corporation-agrees-pay-625-million-resolve-allegations-it-illegally>.

## **Blow the Whistle on Pharmaceutical Fraud**

Individuals with knowledge of fraud committed by pharmaceutical companies may be able to blow the whistle on this kind of fraud using the FCA, the TMFPA and other whistleblower reward programs. Whistleblowers play a critical role in bringing this type of pharmaceutical fraud to light and holding wrongdoers accountable when they try to cheat the system.

To talk with me about your pharmaceutical fraud case, call my Dallas law offices at 214-505-0097 or contact me online. Consultations with a Dallas County Pharmaceutical Fraud attorney are free and confidential. I handle these types of cases on a contingent fee basis, meaning you owe me no legal fees or expenses unless I obtain a recovery for you.