KESSLERTOPAZ MELTZERCHECK LLP

PHARMACEUTICAL INDUSTRY FRAUD

The FDA regulates the sales and marketing of prescription drugs and medical devices in the U.S. market, and requires drugs and devices to contain labels which describe their approved uses. Although physicians are free to prescribe drugs off-label, drug and medical device companies are only allowed to promote or market drugs or devices for approved, on-label uses.

Whistleblowers have achieved great successes in identifying fraudulent business practices of the pharmaceutical and medical device industries. Indeed, in the 2020 fiscal year alone, False Claims Act cases against healthcare entities, including pharmaceutical and medical device companies, resulted in over $1.8 billion in recovered funds. Major types of fraud in in the pharmaceutical and medical device industries include:

Off-Label Marketing – Off-label marketing occurs when a pharmaceutical or medical device company markets a drug or device for uses that are not approved by the FDA in order to increase its profits. Since the FCA was amended in 1986, whistleblowers have recovered billions of dollars from drug and medical device companies that illegally promoted off-label uses for products which were ultimately reimbursed by federal and state healthcare programs.

Illegal Kickbacks – Another major type of fraud in the pharmaceutical and medical device industries involves the payment of kickbacks to healthcare providers, hospitals, and physicians in order to induce them to prescribe drugs or use certain medical devices for patients covered by federal or state healthcare programs. Such payments or financial inducements can come in many forms, including:

- Excessive payments to physicians to serve as a paid-speaker for a drug or medical device;
- Research funding and unrestricted educational grants;
- Bonus payments to physicians and hospitals;
- Lavish dinners and lunches;
- Gifts;
- Payments for attending conferences, lectures or other meetings;
- Joint business ventures between pharmaceutical or medical device companies and hospitals or physicians;

- Sham drug or medical device trials; and
- Free samples of drugs, which physicians then sell to patients.

Medicare Part D Fraud – Since coverage began in 2006, Medicare's outpatient prescription drug program, known as Medicare Part D, has been affected by fraud and abuse. The False Claims Act has successfully been used to combat fraud on the Medicare Part D program by drug companies as well as the entities which contract with CMS to provide coverage to beneficiaries (Part D Sponsors), the entities which administer and process prescription drug claims (pharmacy benefit managers), and pharmacies. Common types of fraud on the Medicare Part D program include:

- Improper waiver of a beneficiaries' cost-sharing obligations;
- Billing for non-existent prescriptions;
- Manipulation of a beneficiary's true out-of-pocket costs in order to reach catastrophic coverage;
- Bait and switch drug pricing;
- Improper prescription drug switching;
- Failure to provide negotiated prices of a drug to a beneficiary;
- Improper payments for excluded or non-covered drugs;
- Inaccurate or false prescription drug event ("PDE") data submission.
- Illegal marketing schemes;
- Billing for brand name drugs even though generic drugs are dispensed

If you are aware of pharmaceutical or medical device industry fraud or fraud on the Medicare Part D program and would like to speak with an attorney in our whistleblower practice group, please email us at wbinfo@ktmc.com or call us at (610) 667-7706. All case evaluations are confidential and free.