

Fraud on the FDA

The Food and Drug Administration (FDA) is the federal agency that regulates drugs, medical devices, and various other types of health and safety products. A whistleblower with knowledge of misconduct involving the FDA that affects government healthcare programs (such as Medicare and Medicaid) may be able to pursue *qui tam* claims under the federal False claims Act or State False Claims Acts and share in any recovery.

The FDA oversees a comprehensive regulatory framework for medical devices and drugs. Most significantly, new drugs and medical devices go through a mandatory and rigorous approval process with the FDA, which is designed to ensure that the products are safe and effective before they are used on patients. The FDA continues to monitor the safety and effectiveness of the products after they are initially approved. As part of this process, the FDA requires manufacturers to report certain “adverse events” and other information to the agency.

Both before and after a product’s approval, there are various forms of misconduct that a company can commit with the FDA. This can include both omissions (such as failing to disclose unfavorable information to the FDA) or affirmative misrepresentation (such as making false or misleading statements to the FDA). For example, companies attempting to obtain FDA approval of a new product often submit information from human trials of the product. To avoid a delay in approval or outright rejection by the FDA, a company that receives unfavorable information from a human trial might fail to disclose that information to the FDA or lie to the FDA about the scope or significance of the problem.

Where there is a connection between misconduct on the FDA and the government’s expenditure of money, this misconduct can form the basis for a *qui tam*. For example, Medicare only covers products and procedures that are approved by the FDA. Thus, if a pharmaceutical or medical device company fraudulently induces the FDA into approving a product and Medicare then pays for the product, the company may be liable under the False Claims Act.

To schedule a free and confidential consultation call 888.384.2588 or [click here](#).