

# Mass Torts and Whistleblowing Converge as a Multisided Die

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When a pharmaceutical or medical device is implicated in harming patients, it is easy to overlook what may involve multifaceted litigation. While medical mass torts can proceed without a whistleblower who may have witnessed wrongdoing leading to patient harm, there may be a whistleblower who recognizes that the government also compensated or overpaid potential defendants for drugs or devices that would not otherwise have been covered by state-funded benefits.

## Medical Mass Torts

“Mass tort litigation emerges when an event or series of related events allegedly injure a large number of people or damage their property, giving rise to a large number of cases.” *Report on Mass Tort Litigation*, 187 F.R.D. 293, 300 (1999). A common mass tort lawsuit involves plaintiffs who suffered injuries as a result of a defective drug or medical device. Plaintiffs may sue the drug or medical device manufacturer for personal injuries or wrongful death resulting from using the product. When there are many such lawsuits, coordinating the individual personal injury lawsuits into a mass tort litigation allows one court to resolve factual and legal questions common to all the injury cases in a more cost-efficient and timely manner. Although the plaintiffs in a mass tort lawsuit each bring a case against the same defendant, the injuries each plaintiff has suffered and the amount of compensation sought for injuries may differ.

## Whistleblowing under the False Claims Act

The federal False Claims Act (FCA), 31 U.S.C. § 3730, allows whistleblowers, called relators, to file a lawsuit (referred to as a *qui tam* case) on behalf of the government against companies and individuals who submit false claims to the government. Those who violate the FCA are subject to treble damages and civil penalties of up to \$11,000 for each false claim (an amount that may be adjusted periodically for inflation). Cases brought under the FCA are filed under seal. Whistleblowers are not allowed to discuss the case with anyone other than their attorneys or the government while the case is sealed. Some cases may be sealed for years while the government decides whether to intervene in the case or not. Under the FCA, the whistleblower may receive 15 to 25 percent of the recovery if the government intervenes and up to 30 percent of the recovery if the government does not intervene.

The most common type of state false claims act cases involves Medicaid because Medicaid is jointly funded by the federal and state governments. State false claims acts are often similar to the federal FCA but include important distinctions; for instance, many state false claims acts are limited to Medicaid cases only. Frequently, whistleblowers will bring a claim under the federal FCA and then include related state false claims act counts.

## Who Are False Claims Act Whistleblowers?

Most whistleblowers are from the health care industry because the most common types of whistleblower cases involve Medicare and Medicaid. Whistleblowers have settled cases against hospitals, pharmacies, laboratories, nursing homes, home health care agencies, individual physicians, dental practices, dialysis companies, medical equipment manufacturers, and pharmaceutical companies. Pharmaceutical companies have paid large settlements for marketing drugs and devices for uses that have not been approved by the FDA (referred to as off-label marketing) and for paying kickbacks to pharmacies and physicians. Typically, a whistleblower is a current or former employee of a company that is committing fraud. Examples of successful whistleblowers are current and former pharmaceutical sales representatives because they often have knowledge of off-label marketing and kickback schemes. Whistleblowers may be competitors of companies that are committing fraud. There also have been successful FCA cases brought by patients. The federal FCA and state false claims acts include provisions that provide remedies for whistleblowers who are terminated or otherwise retaliated against for reporting false claims. Sometimes whistleblowers (particularly in the pharmaceutical industry) are fearful of being blackballed in their profession. This adds yet another side of potential litigation because the FCA includes a cause of action for retaliation.

## Why and How Medical Mass Torts and Whistleblowing Converge

A number of examples of settled FCA cases involve pharmaceuticals and medical devices that had implications in the mass tort context:

- In 2009, Pfizer paid \$2.3 billion to resolve allegations that it illegally promoted certain drugs and paid illegal kickbacks (see [www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history](http://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history)).
- Abbott Laboratories paid \$1.5 billion to resolve allegations that it illegally promoted the drug Depakote for off-label uses (see [www.justice.gov/opa/pr/2012/May/12-civ-585.html](http://www.justice.gov/opa/pr/2012/May/12-civ-585.html)).
- In 2013, Johnson & Johnson paid \$2.2 billion in civil and criminal penalties to resolve allegations that it paid illegal kickbacks and engaged in off-label marketing for Risperdal, Invega, and Natrecor (see [www.justice.gov/opa/pr/2013/November/13-ag-1170.html](http://www.justice.gov/opa/pr/2013/November/13-ag-1170.html)).

FCA cases also have been brought against pharmaceutical companies involving violations of FDA good manufacturing standards. Glaxo-SmithKline paid \$650 million over allegations that it violated FDA good manufacturing standards and sold drugs to the government that were adulterated (see [www.nytimes.com/2010/10/27/business/27drug.html?pagewanted=all&\\_r=2](http://www.nytimes.com/2010/10/27/business/27drug.html?pagewanted=all&_r=2)). Additionally, there have been significant settlements involving nursing home facilities, such as Omnicare, which paid a \$124 million settlement regarding allegations that it offered kickbacks to nursing facilities in exchange for the facilities selecting Omnicare to supply drugs to the facilities' Medicare and Medicaid patients (see [www.justice.gov/opa/pr/nation-s-largest-nursing-home-pharmacy-company-pay-124-million-settle-allegations-involving](http://www.justice.gov/opa/pr/nation-s-largest-nursing-home-pharmacy-company-pay-124-million-settle-allegations-involving)). What is striking about these examples is that, as in the case of Risperdal (a widely prescribed antipsychotic medication), patients who used the products in question and suffered side effects have sued the manufacturer. Johnson & Johnson, for example, has been sued for alleged Risperdal-induced gynecomastia, female breast development in boys

and men, many of whom were covered by Medicaid. Therefore, health care fraud cases and mass torts often overlap.

#### **When Mass Torts and False Claims Act Litigation Converge**

A conflict may arise if counsel who represents a relator in an FCA case knows there is a parallel mass tort litigation going on at the same time. Whether or not an attorney or firm represents clients in the mass tort, the relator's counsel needs to consider whether there is a duty to reveal the information about the whistleblower or his or her attendant information in the mass tort litigation. Even beyond these considerations, the plausibility of an FCA action is difficult to consider in parallel with mass tort cases because the relator's case may take some time to fully unfold while injured plaintiffs may face statutes of limitations that bar them from bringing their individual cases. This may ultimately lead, however, to a beneficial resolution for both the government and mass tort plaintiffs if the parties cooperate. Moreover, an announcement of the settlement of an FCA case during the pendency of a mass tort proceeding could affect that litigation. It is unlikely that the same attorney can represent both a whistleblower and injured plaintiffs in a related mass tort, but given the nature of pharmaceutical and medical device litigation, attorneys practicing medicine and law should consider all sides of the die. ❖

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