

# PHARMACEUTICAL FRAUD

The False Claims Act protects taxpayers from individuals and businesses that attempt to defraud the government by billing for false claims for payments. It began in 1863 and was previously known as the Lincoln Law after businesses defrauded the Union Army during the American Civil War.

## The Relationship Between Whistleblowers and the False Claims Act

Most False Claims Act cases arise when an individual — a “whistleblower” — alerts the government that fraudulent activity is taking place. To encourage people to come forward, the False Claim Act provides incentives in the form of compensation to whistleblowers under certain circumstances and when the government is successful in prosecuting its case. This compensation comes from the damages recovered in the case, which has totaled more than \$35 billion over the past 25 years. Of the \$35 billion, about 70 percent was recovered as a direct result of whistleblower activity.

Some of the largest health care False Claims Act recoveries have come from the pharmaceutical industry. Fraud in the marketing of prescription medications has become a special focus of government enforcement authorities. In particular, the government has stepped up the investigation of off-label drug sales, i.e., the marketing of drugs for non-FDA-approved uses. Since licensed physicians may prescribe a drug for any purpose, even one for which the drug is not approved, many pharmaceutical companies have unlawfully devised marketing campaigns to solicit off-label prescribing while, for example, a drug awaits FDA approval. Over the last year, there have been a number of False Claims Act settlements of off-label charges, including one in which a prominent pharmaceutical company paid more than \$1 billion dollars in penalties, including a False Claims Act recovery of more than \$700 million. Health care fraud lawyers were essential to winning these cases.

## WHISTLEBLOWER LEGAL REPRESENTATION FROM THE ATTORNEYS AT HODGSON RUSS

Whistleblower attorneys at Hodgson Russ have been part of a number of notable False Claims Act claims against pharmaceutical and life sciences companies. In 2013, a team of pharmaceutical fraud attorneys from Hodgson Russ represented two employees at Johnson & Johnson who filed a claim on behalf of the government under the provisions of the False Claims Act.

The case would see what was then the largest False Claims Act settlement ever awarded. The claim occurred when two whistleblowers approached lawyers at Hodgson Russ because they were concerned about drug marketing at Johnson & Johnson. Specifically, Johnson & Johnson was marketing its drug Risperdal – which had been approved for treatment of psychiatric disorders – for unapproved off-market uses. The company was promoting off-market use of the drug for dementia, mood and anxiety disorders, bipolar disorder and other conditions, even though the use of Risperdal was not approved for such uses.

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The claim resulted in a \$1.273 billion False Claims Act settlement and an \$800 million settlement stemming from a criminal investigation. Under the provisions of the False Claims Act, the whistleblowers represented by health care fraud attorneys at Hodgson Russ were entitled to 15 percent of these proceeds.

In another False Claims Act case, lawyers at Hodgson Russ represented a client in a claim involving ISTA Pharmaceuticals. In that case, ISTA Pharmaceuticals reached a \$15 million settlement after employee Keith Schenker, MD reported the company's promotion of the off-label use of Xibrom, a drug used to manage pain for cataract patients. The law makes it illegal for pharmaceutical companies to promote the use of prescription drugs for uses not approved by the FDA.

## Common Types of Pharmaceutical Fraud

Drug marketing cases typically arise from industry sales representatives and other insiders, but hospital and physician practices have also reported this type of illegal conduct and have shared in False Claims Act settlements.

In addition to fraud related to marketing prescription medications, other common types of pharmaceutical company false claims include:

- Average sales price fraud
- Clinical trial fraud
- Good manufacturing practices (GMP) fraud
- Kickbacks, including for illegitimate drug studies, grants, investigator and advisory board meetings, preceptorships, and speaking engagements
- Pricing fraud

Since 1817, Hodgson Russ has built strong relationships with clients through its talented representation of both businesses and individuals. Our pharmaceutical fraud attorneys offer sophisticated advisement and litigation services that respect your time and your resources. We have represented many prominent companies and individuals in complex cases as well as everyday compliance matters.

## Contact Hodgson Russ Attorneys for a Pharmaceutical Fraud Consultation

For more information about how a health care fraud attorney could help you please contact Dan Oliverio.

We also offer legal representation for Medicare & Medicaid fraud, procurement fraud, tax fraud and all other types of fraud covered under the False Claims Act.

Hodgson Russ has offices in New York City, Albany, Buffalo, and Saratoga Springs, New York. We also have offices in Hackensack, New Jersey, Toronto, Ontario, and Palm Beach, Florida.