

# The False Claims Act

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An Overview & Strategies to Minimize Exposure

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# What Is the False Claims Act?

## The False Claims Act, 31 U.S.C. §§ 3729-3733 (“FCA”)

- Civil statute
- Imposes liability on those who submit false claims or make false statements to obtain payment from the government.
- Treble damages & penalties
- Enacted in 1863 at the height of the U.S. Civil War.
  - Combat rampant fraud by vendors that sold broken guns, non-functioning gunpowder, sick horses, rancid food, and other worthless equipment to the Union Army.
  - Encourage private citizens to act as “whistleblowers” by permitting them to share in any recovery.

# What Role Does the Civil War Era Statute Play In Modern Litigation?

- **Historically:**

- FCA lay relatively dormant for 150 years until amended by Congress in 1986.
- 1986 Amendments significantly strengthened key provisions, including the whistleblower and damages provisions.

- **Expansion:**

- Since 1986, FCA litigation has increased dramatically.
- The FCA has become the U.S. government's primary "anti-fraud" weapon.
  - 11,359 new cases (including 7,202 *qui tam* actions; 573 filed in 2010 alone).
  - More than \$28 billion in recoveries since 1986.
  - As of January 2011, there were more than 1,300 new cases that are under seal and being investigated.

# When Does Liability Attach Under the False Claims Act?

- **Liability Provisions, 31 U.S.C. § 3729(a)(1)(A)–(G)**

- Seven liability provisions
- Most commonly used:
  - False claim provision, 31 U.S.C. § 3729(a)(1)(A)
    - Liability attaches if defendant “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.”
  - False statement provision, 31 U.S.C. § 3729(a)(1)(B)
    - Liability attaches if defendant “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.”

# Should Foreign Companies Be Concerned About The False Claims Act?

- Any industry that does business with the U.S. Government directly or indirectly is at risk.
- Risks include:
  - Exclusion from government contracts and government funded programs.
  - Mandatory treble damages.
  - Penalties of \$5,500 - \$11,000 per violation.
- Risks are heightened because of the FCA's whistleblower provisions.
- Popular targets under the False Claims Act:
  - Pharmaceutical, medical device, and health care industries.
  - Financial services, insurance, construction, and defense contracting industries.
  - Virtually every industry has been involved in False Claims Act litigation – including the automotive and food industries

# How May FCA Liability Attach For Foreign Companies That Do Not Submit Claims?

- A defendant is not required to directly submit the claim to be liable.
- A non-submitting entity may be liable under the FCA.
- Defendant is liable if it “causes” a third party to submit a false claim (or to make a false statement to get a false claim paid).
- In *United States ex rel. Hutcheson v. Blackstone Medical*, 2011 WL 2150191 (1<sup>st</sup> Cir. June 1, 2011), the court held that a defendant medical device manufacturer could be liable under the FCA for causing hospitals to submit Medicare claims which were tainted by the kickbacks allegedly offered by the defendant to doctors. The hospitals were unaware of the alleged kickbacks.
- The Deutsche Bank and GlaxoSmithKline cases are two other examples of entities alleged to have violated the FCA through the indirect submission of claims to the federal government.

# The Deutsche Bank Case

- In May 2011, the U.S. Attorney's Office in New York City filed a billion dollar False Claims Act lawsuit against Deutsche Bank and its U.S. subsidiary MortgageIT for alleged mortgage fraud during last decade's housing bubble.
- Deutsche Bank and MortgageIT participated in a federal residential mortgage program in which the federal government provides insurance for residential mortgages of qualifying low-income borrowers that would not otherwise qualify for mortgages.
- Under this program Deutsche Bank and MortgageIT had obligations to ensure potential borrowers met all of the qualifications.
- The United States alleges that Deutsche Bank and MortgageIT violated the False Claims Act by falsely certifying compliance with these obligations which led the federal government to insure residential mortgages where the borrowers ultimately defaulted.
- Most of the violations occurred prior to Deutsche Bank's acquisition of MortgageIT in 2007.
- Foreign companies that own subsidiaries that participate in federal borrowing programs are at risk.

# The GlaxoSmithKline Case

- GSK's subsidiary, SB Pharma, owned a plant in Puerto Rico which was alleged to have grossly violated current Good Manufacturing Practices (cGMP) set by the U.S. Food and Drug Administration ("FDA"). The plant was closed in 2009.
  - Between 2001 and 2005, the company allegedly knowingly manufactured, distributed, and sold:
    - **Paxil CR**, a controlled release antidepressant, that contained some split tablets causing some consumers to receive either product with no active ingredient or product with only the active ingredient layer and no controlled release mechanism;
    - **Avandamet**, a diabetes drug, that contained some tablets with higher or lower amounts of active ingredient than specified;
    - **Kytril**, an anti-nausea medication, that was labeled as sterile but was, in some vials, non-sterile; and
    - **Bactroban** anti-infection ointments and creams that, in some packages, contained microorganisms.

# The GlaxoSmithKline Case

- In October 2010, GSK paid \$750 million to settle the matter:
  - \$600 million in damages under the federal False Claims Act;
  - \$150 million criminal fine; and
  - felony plea by a GSK subsidiary.
- The GSK settlement marks the first time the DOJ has ever used the False Claims Act for violations of current Good Manufacturing Practices.
- The civil False Claims Act damages were four times the size of the criminal fine GSK paid to settle the matter.
- Any manufacturer that has received a Warning Letter for cGMP violations in the past several years is at risk.
- Other manufacturers have been reported to have received subpoenas investigating similar conduct (Gilead, J&J).

# Automotive Industry Case

- *United States ex rel. SNAPP v. Ford Motor Co., 2010 WL 3419433 (6th Cir. 2010)*
  - Ford, as a prime contractor of the United States, was required to establish a plan to provide the maximum practicable opportunity for small businesses and minority-owned businesses to subcontract with Ford.
  - The whistleblower, Ford's subcontractor, alleged that Ford exaggerated its dealings with small, minority-owned business.
  - For example, Ford claimed that the whistleblower was a small, minority-owned business when it was allegedly entirely owned and controlled by Ford.
  - Case was ultimately dismissed on procedural grounds.

# Food Services Industry Case

- Food Service Providers that contract with the government may be subject to False Claims Act liability.
- **Example - Sodexo**
  - Sodexo provided food services to New York public schools.
  - Former employees of Sodexo brought an action on behalf of the State against Sodexo under the New York False Claims Act, alleging that Sodexo overcharged the State by failing to disclose rebates.
  - Sodexo paid \$20M to settle the case.

# False Claims Act Cases: A Specialized Form of Litigation

## Not Quite Civil:

- Allegations in a civil FCA case are similar to accusations that would be made in a criminal case.
  - Include assertions that defendant submitted a false claim, made false statements to get a false claim paid, or conspired to submit a false claim.
  - Potential for exclusion from government funded programs.
- Shares many similar characteristics of a criminal action (and may involve an actual parallel criminal investigation).
  - Civil division may use government agents to assist in gathering evidence through informal interviews with witnesses.
  - Government may issue subpoenas (known as “civil investigative demands”) to obtain documents, oral testimony, or other information from the defendant or other witnesses.

# False Claims Act Cases: A Specialized Form of Litigation

## Not Quite Criminal:

- Even though a civil FCA case may have many of the same characteristics of a criminal action, there are important distinctions.
  - Easier burden of proof than criminal case.
    - Preponderance of evidence vs. beyond a reasonable doubt.
  - Lower level of intent required to sustain FCA claim.
    - “Knowledge” vs. specific intent.
  - If government chooses not to intervene, the whistleblower may continue the action on its own – even if government’s investigation revealed the whistleblower’s allegations had little or no merit.
  - Statutory False Claims Act damages permit larger recovery than a criminal fine for the same conduct.

# Whistleblowers

- Entitled to share up to 30% of any proceeds recovered in a judgment or settlement of the matter.
- Can be anyone with inside information about alleged violations of the FCA:
  - Former employees – most common
  - Current employees
  - Competitors
  - Customers and consumers
  - Others
- Whistleblower payouts can be staggering.
  - GSK whistleblower received \$96 million last year.
- Whistleblowers are entitled to special protections pursuant to the FCA's anti-retaliation provision.

# Whistleblowers

- Whistleblower must file his complaint “under seal” with the court.
  - Complaint is called a “*qui tam*” complaint.
  - Only government may review the *qui tam* complaint while it is under seal.
- Purpose of the seal is to give the government the chance to investigate the allegations in the complaint and decide whether government wants to intervene in the case.
- Defendant does not receive notice of the lawsuit until the court unseals the complaint.
- Average length of seal period is thirteen months, but can be several years in complex cases.

# The Government's Role

- Before the seal expires, the government must do one of the following:
  - Intervene and proceed with the action
  - Notify the court that it declines to take over the action
  - Move to dismiss the action
  - Attempt to settle the action
  - Pursue its claim through any alternate remedy available to the government

# Government Intervention

## If the Government Intervenes:

- Government is primarily responsible for prosecuting the action.
- Whistleblower has the right to assist the government and continue as a party to the action.
- Whistleblower's share ranges from 15% - 25% and is dependent on its contribution to the prosecution.

## If the Government Declines Intervention:

- Whistleblower retains the right to conduct the action on its own.
- Government is no longer an “active party” to the litigation.
- Whistleblower's share ranges from 25% - 30% to compensate it for its increased role in prosecuting the case.

# Consequences of the Government's Intervention Decision

## Intervened Cases:

- Government intervenes in less than 20% of cases.
- While 74% of *qui tam* cases are ultimately dismissed, only 5% are dismissed when the government intervenes.
- Largest judgments and settlements occur in cases where the government intervenes.
  - In 2010, total FCA recoveries were \$2.3 billion in intervened cases and \$97 million in declined cases.

## Declined Cases:

- 94% of declined cases are ultimately dismissed, typically at motion to dismiss stage.
- Prevailing defendant may recover attorney's fees and expenses if the court finds the *qui tam* claim was clearly frivolous, clearly vexatious, or brought primarily for harassment purposes.

# When Is A Claim “False” Under The False Claims Act?

- The FCA does not define what types of claims are “false.”
- Whistleblowers and the U.S. Department of Justice are constantly trying to stretch the bounds of what constitutes a false claim under the FCA.
  - Off-label marketing, cGMP violations.
  - Quality control deficiencies for products paid for by the government (e.g., federally guaranteed residential mortgages and student loans that default).

# Examples of “False” Claims

## Undisputed Examples

- Seeking payment for goods or services which were never provided.
- Double-charging for goods or services that were provided.
- Providing different goods or services than those agreed to.
- Providing worthless goods or services.

## Disputed Examples

- Certifying compliance with a governing statute or regulation and then failing to comply with those conditions.
  - Deutsche Bank and GSK cases are examples.

# State False Claims Acts

- 28 States have False Claims Acts.
- Most State False Claims Acts are modeled on the Federal False Claims Act, imposing liability for the same conduct, treble damages and civil penalties.
- The federal government provides a financial incentive to States that model their laws on the federal law and keep up with amendments that expand the scope of the Act and impose harsher penalties and damages.
- State courts frequently follow federal courts' interpretation of the Federal False Claims Act in adjudicating claims under the State False Claims Acts.

# Minimizing Exposure Under The False Claims Act

- **Perform an Audit to Determine:**
  - Whether the company provides goods or services to the U.S. government or otherwise contracts with the U.S. government.
  - Whether any products or services offered by the company are reimbursed by the U.S. government, either directly or indirectly.
- **If the Answer Is “Yes,” to Either of the Above:**
  - Determine which obligations are material conditions of payment.
  - Determine level of compliance with those obligations.

# Minimizing Exposure Under The False Claims Act

- **Implement a Robust Compliance Program (or make enhancements to an existing program)**
  - Program can dramatically reduce exposure.
  - Program is industry dependent.
  - Compliance standards are constantly evolving.
  - There is a need to examine current Corporate Integrity Agreements for similar industries.
  - Take corrective action as needed.
- **Perform an Outside Legal Audit of Company's Current Compliance Practices**
  - Determine whether company's practices meet current industry compliance standards.

# Minimizing Exposure Under The False Claims Act

- **Include FCA Exposure in Due Diligence Conducted for Potential Acquisition Targets.**
  - In the Deutsche Bank case:
    - Vast majority of violations were allegedly committed by Deutsche Bank's U.S. subsidiary MortgageIT.
    - Most violations occurred between 1999 -2006, prior to Deutsche Bank's acquisition of MortgageIT in 2007.
    - The DOJ claims that Deutsche Bank is liable for all violations.
- **Due Diligence Should Include Review Of:**
  - Government contracts executed by the target.
  - Applicable contractual and regulatory obligations.
  - Target's compliance with the above.

# Conclusion

- False Claims Act litigation and investigations continue to expand dramatically in new and diverse ways reaching virtually all industries.
- Foreign companies should be aware of the risks presented by the U.S. False Claims Act and the measures to minimize exposure under the Act.
- These measures include:
  - Legal audit of the company's current contracts and contacts with the U.S. government.
  - Implementation, or enhancement, of a robust compliance program.
  - Careful due diligence of potential FCA exposure when acquiring new companies, especially those whose products or services are heavily used or reimbursed by the U.S. government.