

The False Claims Act and Research Misconduct: Issues for Research Institutions

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

- Enacted in 1863 by a Congress concerned that suppliers of goods to the Union Army during the Civil War were defrauding the Army. (DOJ tutorial);
- Numerous amendments since; major amendments in 1986

Violations of the FCA occur when a person “knowingly:”

- Submits a false or fraudulent claim for payment;
- Causes such a claim to be submitted for payment;
- Makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;

Violations of the FCA occur when a person “knowingly:”

- Makes, uses, or causes to be made a false record or statement material to an obligation to pay money to the Government;
- Conceals or avoids an obligation to pay money to the government; or
- Conspires in such a way as to violate any of the above provisions.

Claims

- ‘At an operative level, the FCA posits that both “factually false” and “legally false” claims are actionable; “factually false” claims include goods or services either incorrectly described or not provided at all, and “legally false” claims are false based on statements, promises, or other certifications of compliance e.g. in PPAs.’ (Dellana, Pittsburg Law Review, 2016)
- Related terms: legally false, participation, certification

Claims

- “The Act defines a “claim” broadly. “In the context of a research institution, potential “claims” are everywhere. Not only are there invoices explicitly requesting money but there are also various financial reports, program eligibility requirements, grant applications, and progress reports, among others.” James, Morgenstern, Vernick, p. 2

Materiality

- ‘Although there is a materiality standard, it is relatively low. To establish that a false statement or record was material to the payment of a claim, the government must show only that the statement had “a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4). Similarly, under the improper retention of an overpayment provision an institution can violate the FCA simply by not taking action to return funds.’
James, Morgenstern, Vernick, p2

The Qui Tam Provision

- The FCA allows private persons to file suit for violations of the FCA on behalf of the government. A suit filed by an individual on behalf of the government is known as a “*qui tam*” action, and the person bringing the action is referred to as a “relator.” (DOJ tutorial)
- Definition: from the Latin, “*qui tam pro domino rege pro se ipso in hac parte sequitur*”– s/he who sues in this matter for the king as well as for him/herself (legaldictionary.net)

The Qui Tam Provision

- a *qui tam* complaint must be filed with the court under seal. The complaint and a written disclosure of all the relevant information known to the relator must be served on the U.S. Attorney for the judicial district where the *qui tam* was filed and on the Attorney General of the United States. (Section 3730(b)(2)) (DOJ tutorial)

The Qui Tam Provision

- The complaint is *sealed* for an initial 60 days while the government investigates and decides whether to join the suit. But this period maybe extended for months or even years during which time the potential respondent (university) has no knowledge of the suit. (There are a number of limitations to relator suits—see DOJ tutorial)

Limitations to Relator Suits

- Including: “The *qui tam* action is based upon information that has been disclosed to the public through any of several means: criminal, civil, or administrative hearings in which the government is a party, government hearings, audits, reports, or investigations, or through the news media (this is known as the “public disclosure bar.”) §3730(e)(4)(A). There is an exception to the public disclosure bar where the relator was the original source of the information. (DOJ FCA Tutorial)

Relator Incentives

- If the government intervenes in the *qui tam* action, the relator is entitled to receive between 15 and 25 percent of the amount recovered by the government through the *qui tam* action. If the government declines to intervene in the action, the relator's share is increased to 25 to 30 percent. (DOJ tutorial)

Damages and Penalties

- The current amounts are \$5,500 to \$11,000 (for each false claim) and treble the amount of the government's damages, plus the relator's share when applicable. "This can result in cases where the damages could total a staggering \$2 billion." (Dellana p. 220)

Unsettled Law and Trends

- The FCA is largely a judicial, not a statutory construct, (Dellana, 228); interpretation varies among the circuits; the law has been strengthened or weakened several times by Congress since the 1940s, with a current “leaked memo” from the Trump administration proposing to make it easier to dismiss claims.

Unsettled Law and Trends

- If the government has a range of administrative remedies by which to address the alleged violation, then the violation is likely to be considered a condition of participation. Conditions of payment were widely held to be the only conditions actionable under the FCA before Escobar. (Dellana, p. 230)

Unsettled Law and Trends

from Universal Health Services v. US ex rel. Escobar:

- “The unanimous Escobar (Supreme Court, June 2016) decision found that implied certification claims could succeed “at least” where the defendant has made “specific representations about the goods or services provided” and the “defendant’s failure to disclose its noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.” Jones Day website Jan 18 accessed 29 August 18

Unsettled Law and Trends

- ‘But in an eight to zero decision, the Court (2015) held that implied false certification was a valid theory of liability under the FCA. (Dellana 224) However, in Escobar, the high court stated the FCA is not “an all-purpose antifraud statute” and isn’t intended to punish “garden-variety breaches of contract or regulatory violations.’ ” (Tutuer and Young quoting the Escobar decision)

Unsettled Law and Trends

- Courts have traditionally held that when there are reliable administrative mechanisms to address certification violations (e.g. non-compliance with a PPA) those violations would be not subject to FCA. But because NIH/ORI has rarely exercised those mechanisms for cost recovery after misconduct findings, FCA suits, as an alternative, have arguably been stimulated.

Trends—much greater institutional risk:

- Explosive and continuing growth in qui tam litigation since the 1986 FCA amendment may be largely attributable to the enhanced role of whistleblowers, and particularly to the increased bounties promised to relators (Lockman)
- “Driven partly by a University of Iowa scandal that caught the attention of Sen. Charles Grassley, the DOJ has become more aggressive in pursuing False Claims Act (FCA) cases against research institutions where researchers have been accused of misconduct. (Tuteur and Young P 41)

Greater Institutional Risk

- Whereas previously FCA cases involving higher education tended to focus on issues such as effort reporting and false payments, the FCA is now also being applied to institutional misconduct cases
- (See James, Morgenstern and Vernick, Appendix A)

Greater Institutional Risk

- “. . . an emerging area of FCA activity is in the area of scientific compliance, specifically matters related to the integrity of scientific data and the intersection of scientific misconduct and the FCA. For example, fabricated data included in journal articles or grant applications can serve as the factual predicate for an FCA case alleging that the federal sponsor was induced to make one or more grant awards.”
James, Morgenstern and Vernick, p 5

Problems and Goals

- Institutions have generally handled misconduct cases without regard to possible FCA implications. The long period when universities and the government don't usually communicate while misconduct investigations proceed and qui tam suits are under seal likely represent missed opportunities for institutions to communicate and negotiate.

Problems and Goals

- The fact that NIH institutes have rarely sought cost recovery after misconduct findings used to be considered a blessing by institutions. It should rather be considered a liability because it may have discouraged institutions from pursuing effective administrative remedies for non-compliance (e.g. false certification), so that the FCA would generally not apply.

Mitigating the Potential for Qui Tam Suits related to Misconduct

- Identify triggers for urgent investigation for materiality in any major misconduct case involving significant federal funding
- Integrate Compliance programs and review Policy to assure proper communication/handling; (FCA misconduct cases often begin as something else, e.g. effort reporting, other financial fraud)

Mitigating the Potential for Qui Tam Suits related to Misconduct

- Handle whistleblowers/Potential Relators with care—duty to cooperate/avoiding retaliation;
- Protect the rights (including confidentiality) of Respondents during potential discussions with NIH, DOJ (some of the same issues as disclosing to journals)

Mitigating the Potential for Qui Tam Suits related to Misconduct

- Disclose Voluntarily as early as possible, invoking administrative remedies
- Repay voluntarily wherever appropriate (One of the bedrock principles of the FCA is restitution).

(James, Morgenstern, Vernick; Wright, Poynter Center 2011)

Selected References

- Dellana, “Higher Education: An Appropriate Realm to Impose False Claims Act Liability Under the Post-Formation Implied False Certification Theory,” *University of Pittsburg Law Review*,” 78, Winter 2016
- Department of Justice, “The False Claims Act: A Primer,” DOJ website
- James, Morgenstern and Vernick, “The False Claims Act and Other Enforcement Activity Related To Sponsored Research: What You Wish You’d Done Before the Feds Come Knocking and How to Manage When They Do,” NACUA Presentation, June 26-29, 2016

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- Lockman, Michael (2015) "In Defense of a Strict Pleading Standard for False Claims Act Whistleblowers," *University of Chicago Law Review*: Vol. 82 : Iss. 3 , Article 8.
- Michael J. Tuteur and Torrey K. Young "Scientific Research Misconduct vs. Fraud: How to Tell the Difference" *Health Care Law Today*, 07 May 2018