



Whistling While You Work: Dangers of a *Qui Tam* Lawsuit and How to Avoid Them

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The False Claims Act

- Primary government weapon in combating health care fraud
 - Huge penalties
 - Favorable burden of proof
 - “Intent” element is somewhat vague
 - Scope of activities covered: very broad
- Since 1986: \$13.5 billion recovered under FCA
- 12% of cases were HHS-driven in 1987; up to 66.5% in 2004.
- Whistleblower provisions are incorporated in FCA

Elements of the False Claims Act

- Submitting, causing to be submitted, or conspiring to submit:
 - A claim for payment to the government
 - When the claim is false or fraudulent and
 - When the defendant acted “knowingly”
- In addition, using a false record or statement in support of a claim is also actionable
- “Knowingly” means “deliberate ignorance” or “reckless disregard” of the truth or falsity of the submission
 - “Intent to defraud” need not be proven

Applying the FCA Beyond Mere Truth & Falsity of the Claim

- Anyone in the “chain of events” leading to an FCA violation is potentially liable
 - E.g., the senior citizen claiming PDP plan eligibility, the prescribing professional, the pharmacy providing the drug, the billing company, and/or the plan seeking reimbursement
- Implied Certification Theory
 - Failure to comply with any applicable law
- Subcontractor Risks

FCA Damages and Penalties: Enormous

- Treble the government's damages
- Additional penalties of \$5,500 - \$11,000 per claim
- Parallel consequences: loss of contract, debarment and/or program suspension
- Not to mention:
 - Time and effort
 - Attorneys' fees
 - Likely Corporate Integrity Agreement
 - Damage to reputation

Use of the FCA by Whistleblowers

- Statute provides that any person may bring an FCA action “for the person and for the government,” in the government’s name. It can be dismissed only if the court and the Attorney General consent.
- 1988: 60 cases; \$355,000 in recoveries
- 2003: 326 cases; \$1.6 billion in recoveries
- In 2004, 83% of all FCA recoveries via whistleblower cases

Recent Whistleblower Cases of Note

- AdvancePCS
 - Whistleblowers: clinical director, director of network management, and vice president of trade relations
 - Kickback case: drug manufacturers paid AdvancePCS for favorable FEHBP and M+C formulary treatment
 - Payment: \$137.5 million
- TAP Pharmaceuticals
 - Whistleblowers: Vice President of Sales; physician offered kickback
 - Improper billing by physicians for free TAP samples, kickbacks to physicians for prescribing Lupron over Zoladex
 - Payment: \$875 million
- HCA, Inc.
 - Multiple whistleblowers: hospital CFO; HCA reimbursement manager
 - Cost reporting fraud; payment of kickbacks to physicians
 - Payment: \$631 million

How a Whistleblower Case Works

- Whistleblower alleges FCA violation, needs to prove each element
- Additional hurdles for the whistleblower:
 - Relator must be the first to file and, if the federal government does not intervene, must be either:
 - An “original source” of the information; or
 - If not the “original source,” the information cannot have been previously, “publicly disclosed”

Government Intervention

- Relator files complaint in court and provides government with a copy of complaint and all material evidence & info
- Complaint is sealed for 60 days; government determines whether or not to join as plaintiff
 - Government often seeks extension of review period
 - Government may join later for good cause shown
- Since 1986, of the 3,600 cases in which government has made a decision, it intervened or pursued 22% of cases
- Relator receives smaller reward if government intervenes (15%-25% vs. 25%-30%), but likelihood of success is much higher (94% chance of settlement or judgment vs. 6% chance)

Practical Questions

- What are the risk areas that may generate FCA whistleblower actions?
- What are the indications that an FCA whistleblower suit has been filed?
- How should you handle a suspected whistleblower?

Practical Questions

- If possible FCA violations are discovered and reported to the government, will this eliminate the risk of a whistleblower suit?
- If you have reason to believe that a FCA whistleblower suit has been filed, what should you do?

Practical Questions

- Will the whistleblower's failure to disclose FCA allegations through compliance efforts or exit interview affect the case?
- Can the whistleblower interfere with your ability to settle alleged FCA violations with the government?
- How can you avoid whistleblower suits in the first place?