False Claims Act and State Investigations

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June 25, 2014

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Presentation Outline

- History of the False Claims Act
- Development of relator's bar
- Elements of a False Claims Act case
- Federal initiatives
- NY initiatives
- Defensive Strategies
- Questions

When did things change?

- In 1863 . . .
- “Lincoln Law” enacted to combat fraud by vendors of the Union Army
  - faulty guns and ammo., unhealthy mules and horses, rancid food
  - The FCA was little used until 1986 amendments
  - Historical focus on defense contractors

1986 Amendments

- Made the FCA for more friendly to whistleblowers or “relators”
  - Lower standard of proof – preponderance
  - Increased monetary awards
    - double to triple damages
    - higher transactional penalties
  - Increased relator’s share
  - Lowered the intent requirement
  - Lengthened the statute of limitations
  - Eliminated “government knowledge” bar; replaced it with “public disclosure” bar and “original source” exception
  - Whistleblower protections

If it's broke, fix it . . .

- 2009 FERA Amendments
  - No direct presentment to government, overriding *Allison Engine*
  - Easier to prove "reverse false claim"
  - For CIDs, eliminated AG approval requirement
- 2010 PPACA Amendments
  - Anti-kickback Act amended
  - "retention of overpayment"
  - Narrows the public disclosure bar – government's call
  - Expands the original source exception – "materially adds"
- Direct responses to new case law
- All relator and government friendly
  - Hmmm . . .

Leveraging the Relator's Bar

- From 1987 through 2013 . . .
  - 13,766 new cases
  - 9,244 of those were *qui tam* actions
  - $35.1 billion recovered
  - Expanded to other industries
    - general health care
    - pharmaceuticals
    - medical devices

Elements of a Violation

- Government must prove
  - A “claim”
  - that was “false or fraudulent”
  - “Materiality”
  - was “present[ed], or cause[d] to be presented, present[ed]”
  - “Knowingly”
  - for payment or approval by federal government
  - And payment was made
    - But, actual damages not required

Claim

- Claim means “any request or demand” for “money or property”
  - HCFA-1500
  - False compliance representation incorporated in contract
  - Cost report

Presentment

- Presentment means:
  - Direct submission to federal government – *e.g.*, CMS, other federal health care programs, federal grants
  - To fiscal intermediaries, government contractors or subcontractors, or a state or local government if the federal government will reimburse any portion of the requested money (2009 amendment)
  - "Cause to submit" – directing a billing company to submit a false bill to the government; recklessly failing to monitor billing company submissions
- "Reverse false claim" – e.g., retaining an overpayment

Knowingly

- Under the False Claims Act, “knowingly” means:
  - Actual knowledge of the information, or
  - Deliberate ignorance of the truth or falsity of the information, or
  - Reckless disregard of the truth or falsity of the information
- No proof of specific intent to defraud is required

“False or Fraudulent”

- Factual falsity
  - Something that did not happen
  - Or, did not happen as described – e.g., worthless services
    - Materiality not often an issue in factual falsity cases
- Legal falsity
  - false for an extrinsic, contractual or regulatory reason
  - False certification of compliance
  - Must be a condition of payment
  - General certifications of compliance with “all laws” may be too broad – *United States ex rel. Westmoreland v. Amgen, Inc.*, 707 F. Supp. 2d 123 (D. Mass. 2010)

Falsity in Health Care Cases

- Billing for services not rendered or substandard
- Failure to follow regulations or published guidance
- Billing a non-covered service as covered
  - Ineligible patients
- Use of unlicensed providers
- No medical necessity
- Embellishing diagnosis and upcoding
- Unbundling of comprehensive codes
- Double-billing
- Duplicate billing by two providers – x-rays
- Paying or receiving kickbacks

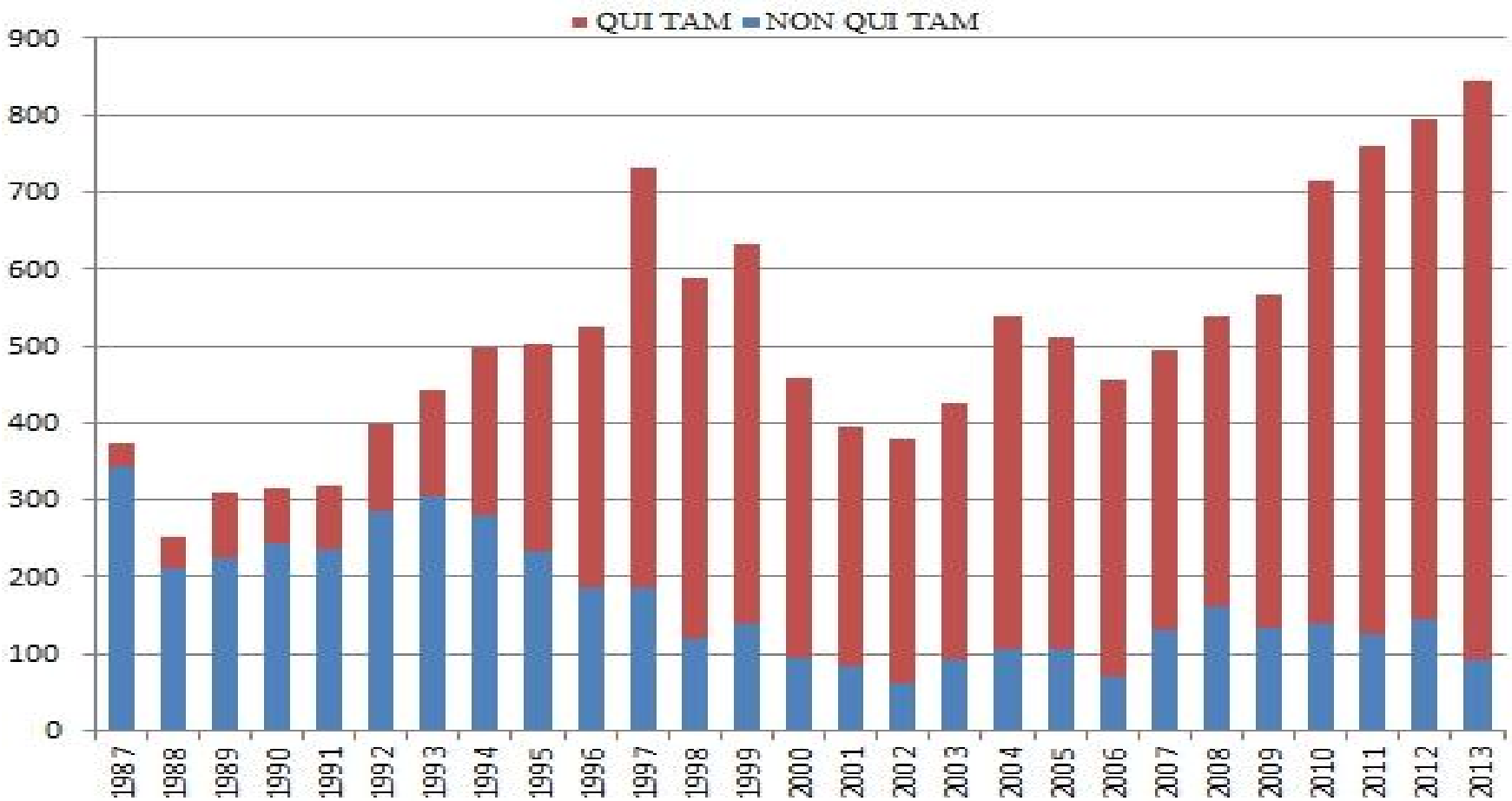
Proving a False Claim in the Health Care Context

- Peer analysis
  - New York Times database
- Expert medical reviews of patient files
  - Probe samples
  - Random samples
- Review of date, time and location of services billed for
  - Open MRI case
- Impossible days
- Defendant's billing pattern while working for another provider
- Comparison of billing patterns among government insurers and private insurers
- Eyewitnesses – nurses, technicians, aids, office personnel

DOJ's Continued Focus on Health Care Fraud

- Medicare Fraud Strike Forces
  - Miami, Los Angeles, Detroit, Houston, Brooklyn, South Louisiana and NOLA, Tampa, Chicago and Dallas
- HEAT – Health Care Fraud Prevention & Enforcement Action Team (2009)
  - Greater collaboration between DOJ and HHS
- More indictments, interventions, settlements and exclusions

Qui Tam Vitals



Source: DOJ "Fraud Statistics – Overview" (December 23, 2013)

Hard Choices, Getting Harder

- Parallel investigations
- Expanded use of CIDs
- Industry-wide sweeps
- Bad news on statute of limitations
- More resources devoted to FCA cases
- Different settlement expectations
  - Dollars
  - Admissions
- Insurance companies getting involved

New York State False Claims Act

- Effective April 1, 2007
- Similar to federal Act
- Notable differences:
  - 10-year statute of limitations
  - Includes tax fraud
- Amended to track the federal FCA – effective April 2013
- Financial incentive under federal law for New York FCA to follow federal law

A New Approach in NY

- Collaboration between DOJ and MFCU
- Expanded reliance on NY FCA
- Parallel federal and state filings
- Conversion of overpayment cases to FCA cases

Collateral Consequences

- Exclusion
- De-credentialing
- Licensure issues
- Negative publicity
- Additional compliance costs

Defensive Strategies

- DOJ intervenes in 20% of qui tam cases
- Intervention cases account for 95% of recoveries
- Only 5% of intervention cases are dismissed
- Settlement is more difficult
- Price of poker goes up

Avoiding Intervention is Key

- Immediately contact government after receipt of CID or subpoena
  - Consider contacting insurance carrier as well
- Determine scope of request and investigation
- Request complaint and disclosure statement in relator cases
- Conduct mirror investigation, with experts, if necessary
- Make persuasive case for government not to intervene
- Don’t worry about who whistleblower is; worry about the facts and legal arguments

Compelling Arguments

- Prove services were rendered
  - even if not according to best practice
- Make the issue one of medical necessity
  - Rely on experts
- Ambiguous laws, regulations, advisory opinions
- Did HHS or other agency know about conduct; review audits
- Was conduct isolated
- Demonstrate that compliance was robust
  - Show prior discipline of offenders
- What is the worst-case damages estimate
- Show that you are taking the matter seriously

Post-Intervention Strategy

- Do not panic
  - Most cases still settle
  - And most cases are difficult to prove
  - Even if not conceptually difficult to prove, the cases are hard to marshal
  - Ability-to-pay
- Consider dispositive motions
- Attack government's case through discovery
  - More trials in 2013 than in previous years

Questions

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