



The False Claims Act

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Agenda

Background on the False Claims Act

Legal Issues

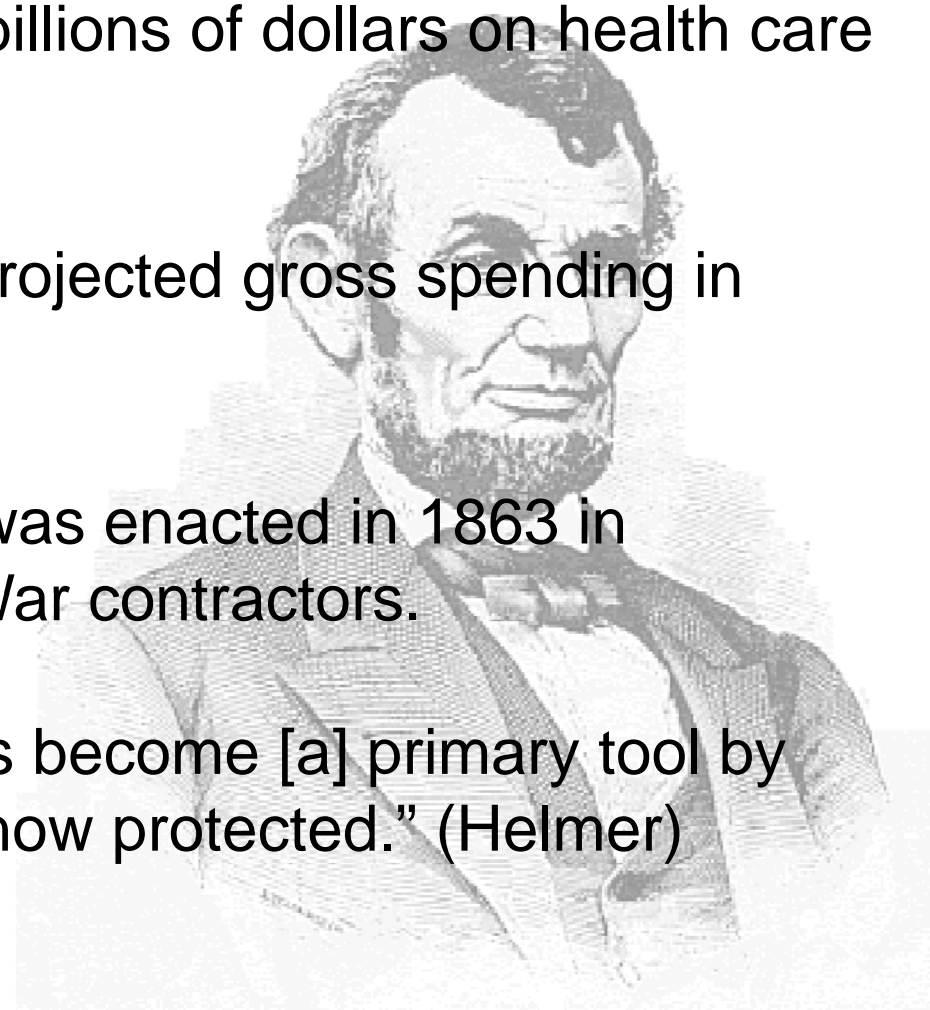
Application in the Health Care Context

Major Settlements and Future Outlook

Takeaways

Background

- Federal government spends billions of dollars on health care expenditures each year.
 - For example, \$85.2 billion projected gross spending in 2015 for Medicare Part D
- The False Claims Act (FCA) was enacted in 1863 in response to fraudulent Civil War contractors.
- “The False Claims Act . . . has become [a] primary tool by which the federal treasury is now protected.” (Helmer)



False Claims Act

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

- Imposes liability on individuals and entities for defrauding federal government programs
- Includes *qui tam* provisions allowing individuals (“relators”) to file actions on behalf of the government
- Prohibits false claims and false statements

- It is unlawful to knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval.
(31 U.S.C. § 3729(a)(1)(A))
- It is unlawful to knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim. (31 U.S.C. § 3729(a)(1)(B))

Enforcement

- Department of Justice (DOJ)
- Health and Human Services Office of Inspector General (HHS-OIG)
- Whistleblowers (*qui tam* relators)
- Medicaid Fraud Control Units (MFCUs)



Whistleblowers

- Relators must disclose allegations to the government.
- Government has the option of intervening.
- Relator can proceed without government intervention.
- Successful relators receive 15-30% of money recovered for the government.



Who Are Whistleblowers?

Current and former employees

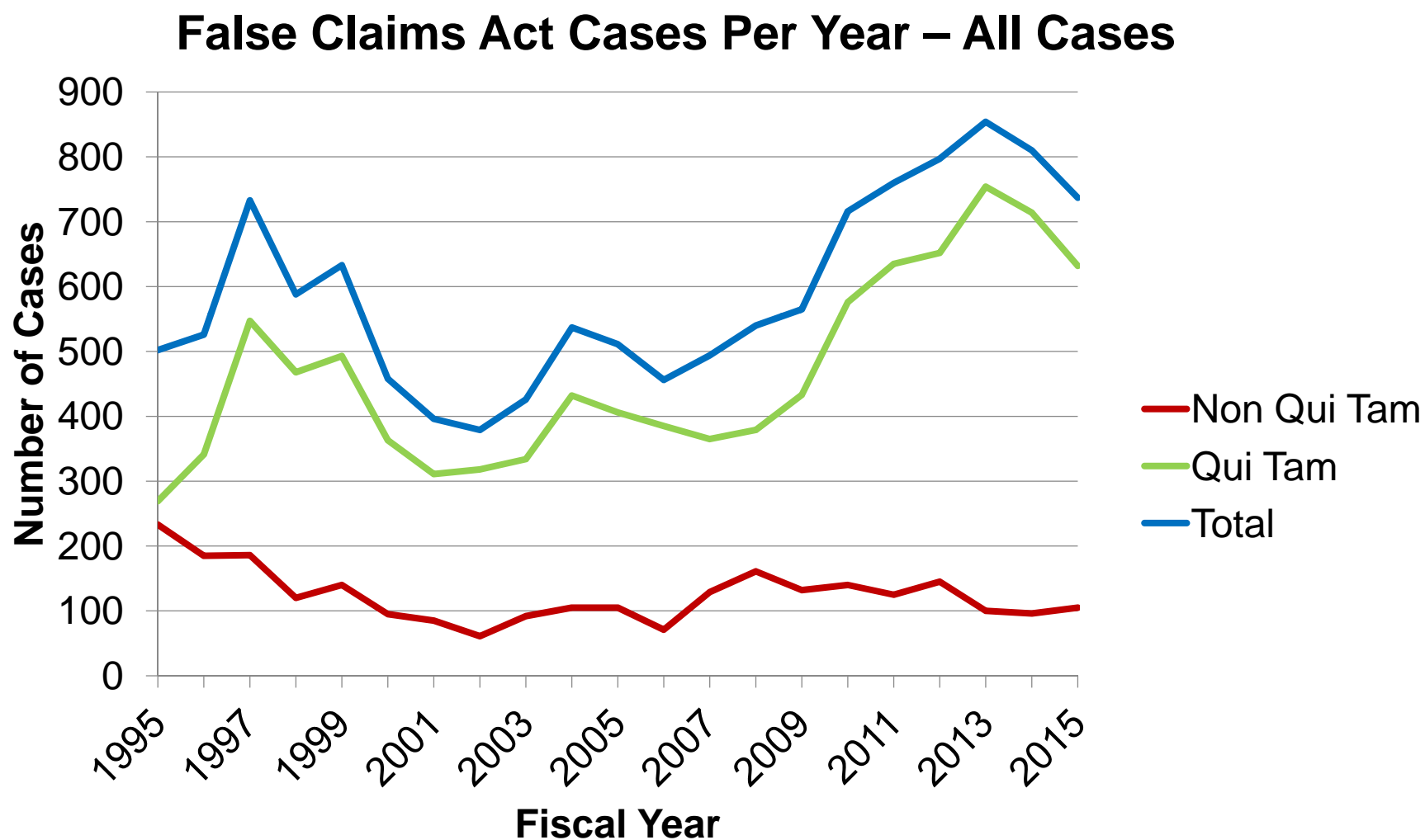
Physicians

Compliance officers

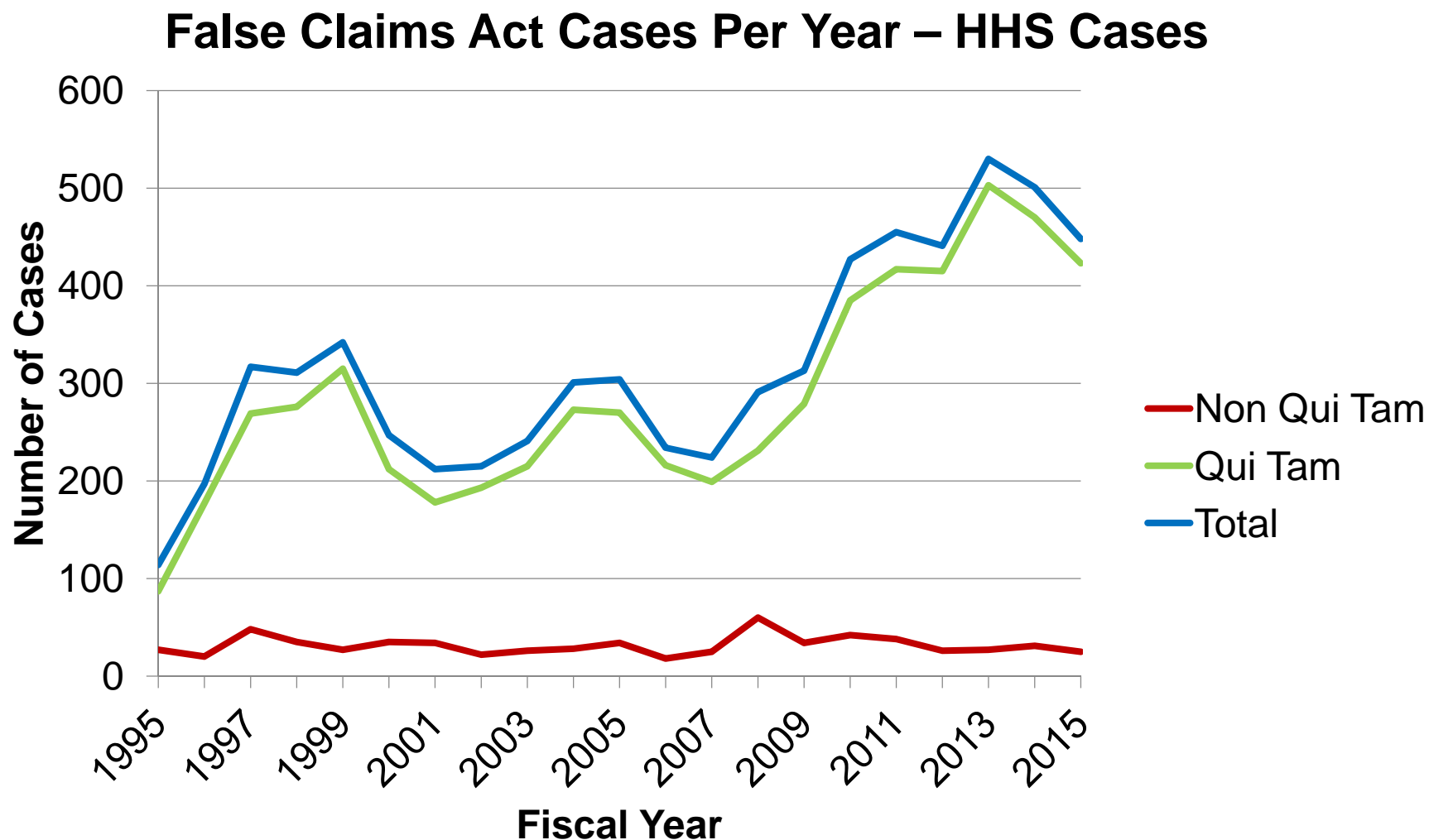
Competitors



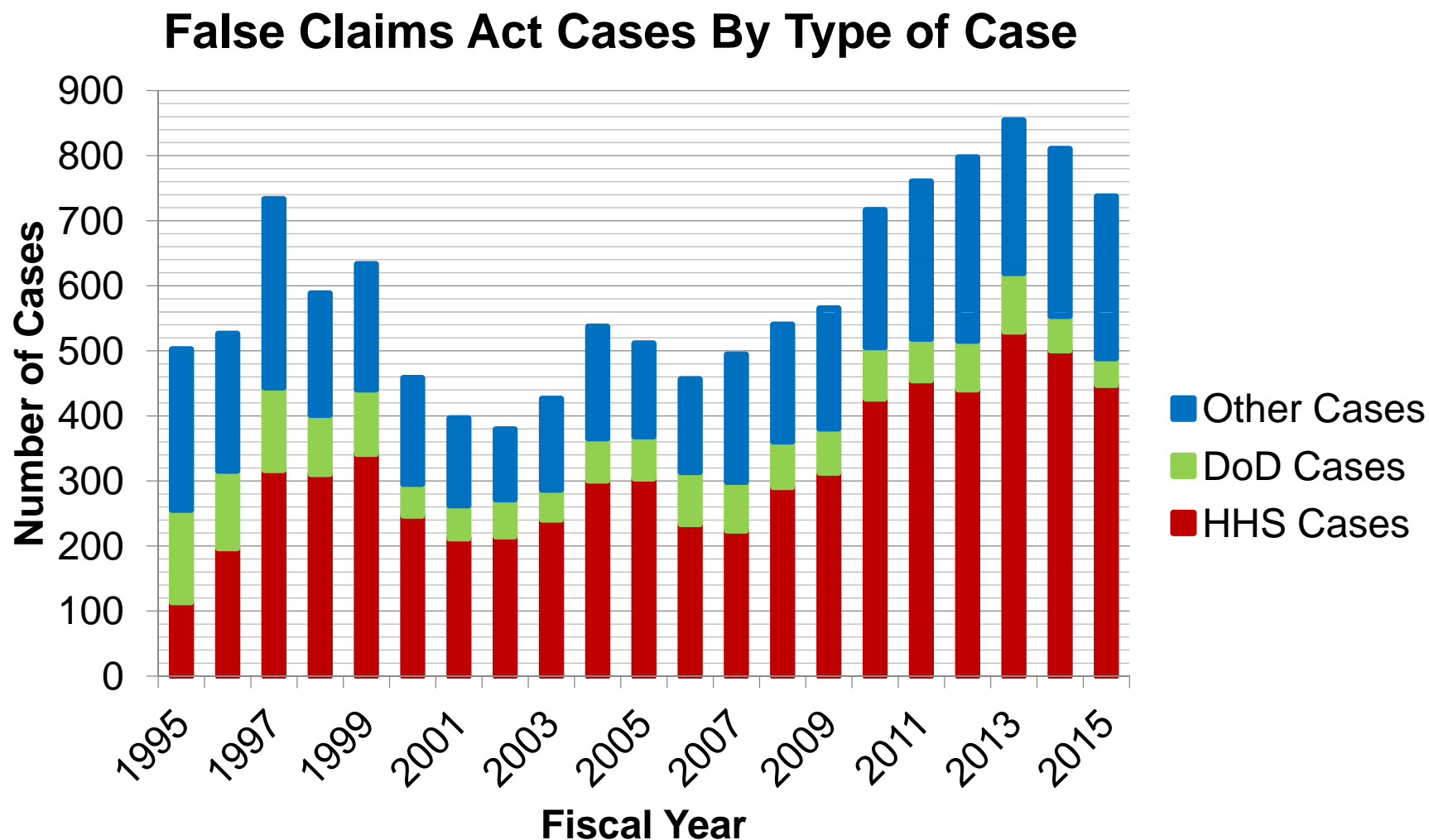
Historical Perspective



Historical Perspective (Cont.)

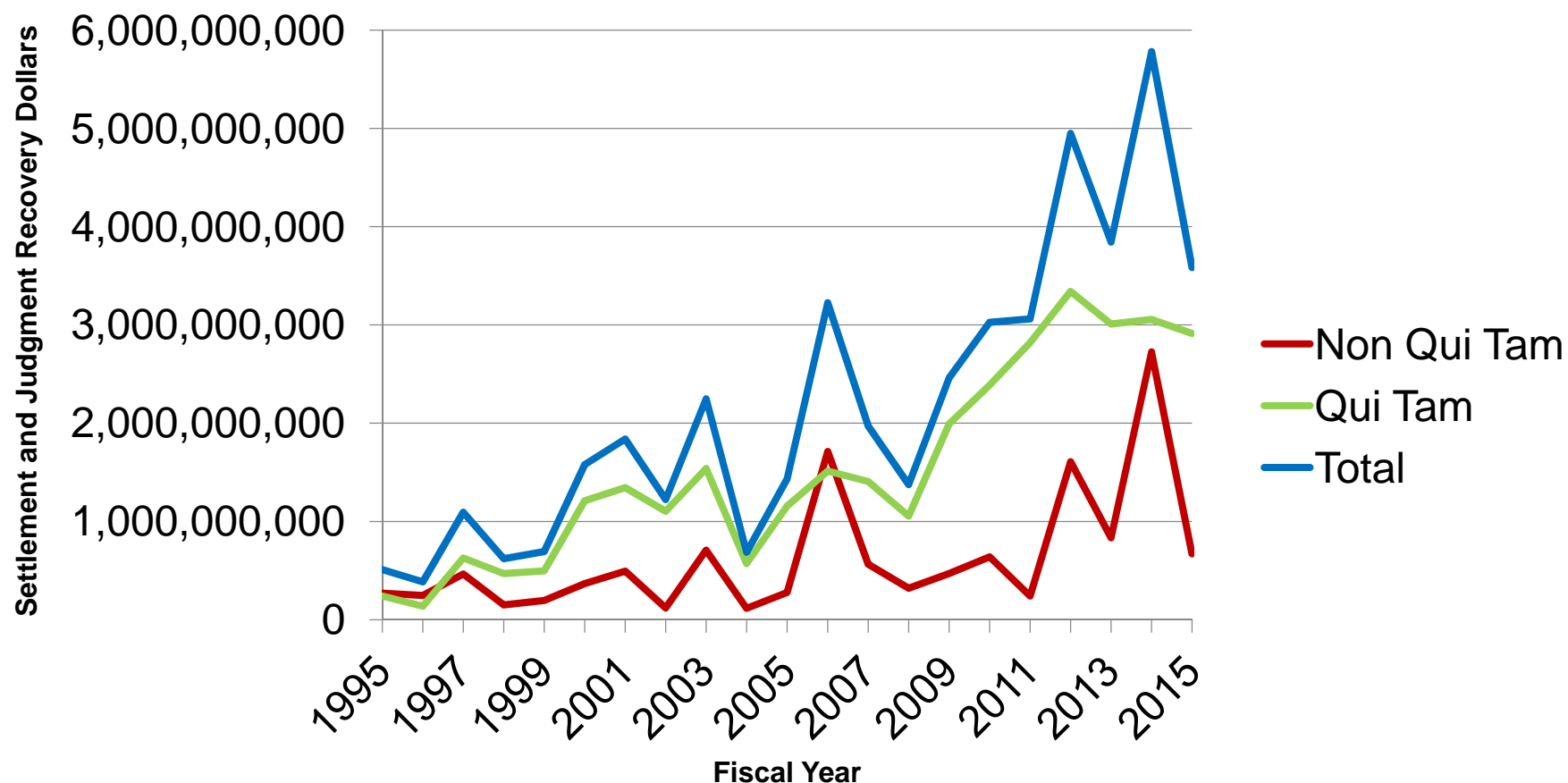


Historical Perspective (Cont.)



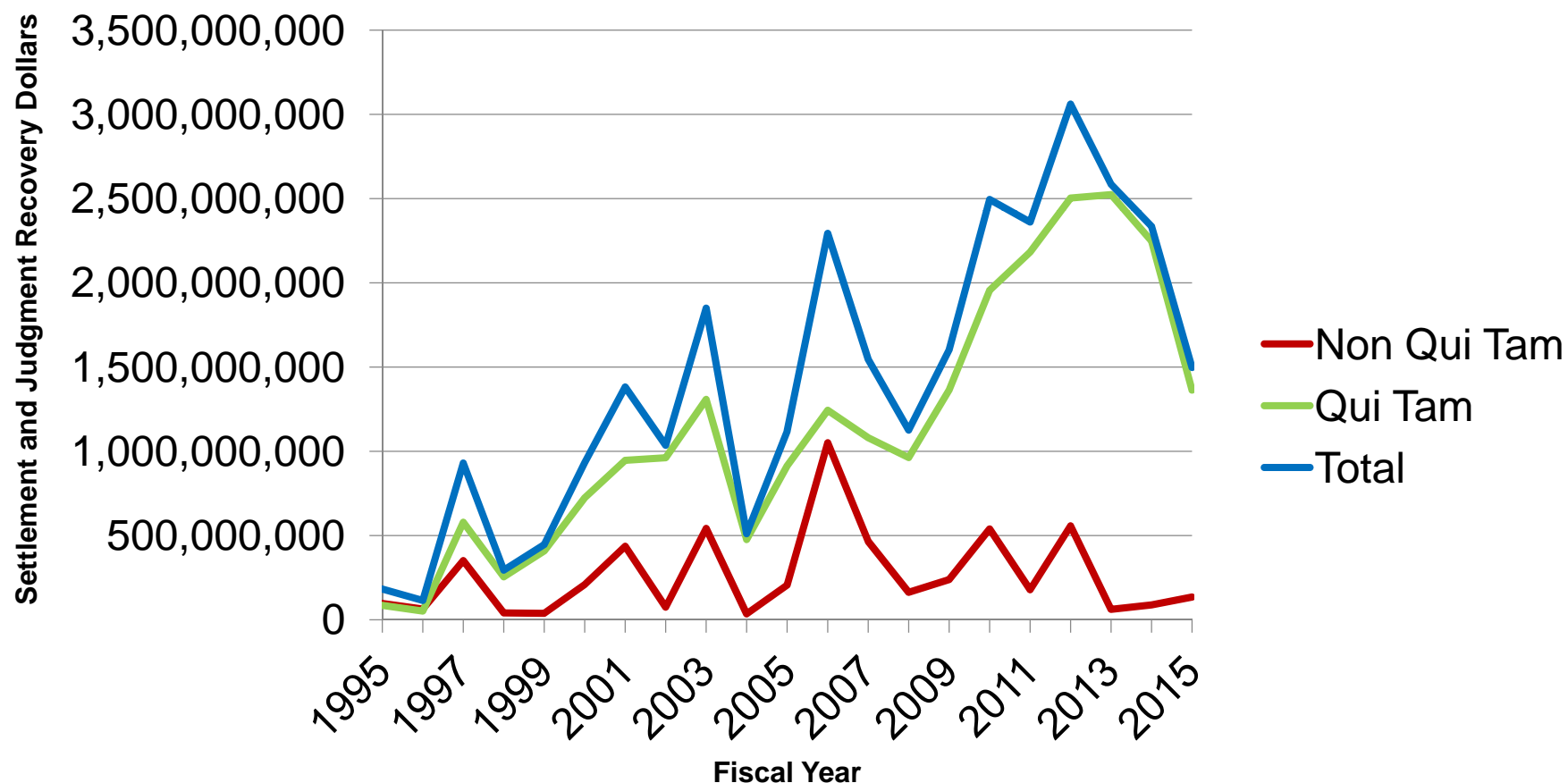
Historical Perspective (Cont.)

Settlement and Judgment Recovery Dollars by FY – All Cases



Historical Perspective (Cont.)

Settlement and Judgment Recovery Dollars by FY – HHS Cases



Penalties

- Treble damages
- \$5,500-\$11,000 *per claim*
- Up to \$50,000 for each violation
- Attorney's fees and costs
- Permissive exclusion
- Corporate Integrity Agreements



Elements of the Offense

1. Knowledge
 - Actual knowledge
 - Deliberate ignorance
 - Reckless disregard
2. Claim submitted to the government for payment
 - Directly or indirectly
3. False or fraudulent
 - Factually False
 - False Express Certification
 - False Implied Certification
4. Materiality
 - “Having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.”

Knowledge Requirement

- Knowledge-based defenses are gaining force in district courts.
 - *United States ex rel. Johnson v. Kaner Medical Grp.* (5th Cir. 2016) affirming summary judgment for KMG based on finding that alleged false claims were the result of KMG's misunderstanding of legal requirements.
 - *United States ex rel. Saldivar v. Fresenius Medical Care Holdings, Inc.* (N.D. Ga. 2015) finding defendant reasonably interpreted ambiguous Medicare rules and conformed with industry practice.
 - *United States ex rel. Budike v. PECO Energy* (E.D. Pa. 2015) finding mistakes, problems, and negligence did not establish knowledge requirement.

FCA and the Anti-Kickback Statute

Federal Anti-Kickback Statute (AKS):

- Makes it a crime to “knowingly” offer, pay, solicit, or receive any remuneration to induce referrals of services or items paid for by a federal health care program.
- Remuneration can take many forms, including lease agreements, consulting agreements, speaker fees, no show jobs, and services paid in excess of fair market value.
- *A violation of the AKS constitutes a false or fraudulent claim under the FCA.*

Express and Implied Certification

- Express Certification:
 - Payment of a claim may require an express certification of compliance with a contract term, statute, or regulation, or satisfaction of eligibility requirements.
 - A finding of non-compliance may make the claim “false” under the FCA.
- Implied Certification:
 - Some courts hold that submitting a claim for payment can by itself *imply* material compliance with contract terms, statutes, regulations, or eligibility requirements.

Developments: Implied Certification

Universal Health Services v. United States ex rel. Escobar

- Supreme Court will decide whether implied certification is a viable theory of FCA liability.
- Implied certification theory considers a claim “false” if it implies compliance with federal rules that are prerequisites to payment but not identified in the claim itself.
 - 7th Circuit largely rejects the implied certification theory.
 - Most other circuits accept the theory but apply a variety of standards.



Common Defenses

Federal Rule of Criminal Procedure 9(b)

- Circumstances constituting fraud must be pled with particularity
- “Who, what, when, where, how” must be pled with specific facts

Public Disclosure Bar

- Prohibits relators from bringing an action if the fraud allegations have already been publicly disclosed
- Prohibits complaint that is “substantially the same” as (rather than “based upon”) allegations or transactions contained in public disclosures, unless the plaintiff is the original source of the information

First to File Rule

- Bars a later allegation of fraud if it states all the essential facts of a previously-filed whistleblower claim or the same elements of a fraud described in an earlier *qui tam* suit

Application in the Health Care Context

- Examples include:
 - Services Not Rendered
 - Kickbacks
 - Up-Coding
 - False Certification
 - Off-Label Promotion
 - Reverse False Claims
 - Overpayments



Case Study: Kickbacks and PODS

- *United States of America v. Reliance Medical Systems, LLC* (C.D. Cal., November 5, 2014)
 - DOJ charged device manufacturer, two related distributors and several of their physician owners, based on the theory that investment returns from these physician-owned distributors (PODs) were unlawful kickbacks.
 - PODs offered investment to physicians who are expected to order devices.
 - Volume or value of a physician's own referrals correlated to investment returns.
 - POD alleged to have funneled improper payments to doctors and encouraged medically unnecessary procedures.

Off-Label Promotion

- Historically, off-label promotion has resulted in some of the largest FCA recoveries.
- Typically pursued under implied certification theories
- Examples include (mix of criminal and civil penalties):
 - GlaxoSmithKline (\$3 Billion)
 - Allergan (\$600 Million)
 - AstraZeneca (\$520 Million)
 - Wyeth Pharmaceuticals (\$490.9 Million)

Off-Label Promotion

- Government's off-label promotion theories are under assault.
 - *Caronia v. United States*, 703 F.3d 149 (2nd Cir. 2012) vacated the conviction of a pharmaceutical representative, holding that the government violated his First Amendment rights by prosecuting him for truthful and non-misleading speech about a lawful but unapproved use of a drug.
 - *Amarin v. United States*, 2015 U.S. Dist. LEXIS 103944 (S.D.N.Y. Aug. 7, 2015) rejected FDA's narrow interpretation of *Caronia* and reiterated First Amendment protection for "truthful and non-misleading" off-label speech.
- Future off-label enforcement will likely involve cases where the government believes it can prove "false and misleading" off-label promotion.

Developments: *Amarin* Settlement

- March 8, 2016 Settlement Agreement
 - FDA agreed that Amarin may engage in truthful off-label marketing.
 - FDA agreed that the combination of statements and disclosures Amarin proposed were truthful and non-misleading.
 - “Amarin bears the responsibility, going forward, of assuring that its communications to doctors regarding off-label use of [its product] remain truthful and non-misleading.”

“Reverse” False Claims

- Using a false record material to an obligation to pay the government
- Improperly avoiding an obligation to pay the government

Reverse false claim liability extends to one who “knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” 31 U.S.C.3729 (a)(1)(G)

- An “obligation” is “an established duty” that may arise from:
 - an express or implied contractual, grantor-grantee, or licensor-licensee relationship
 - a fee-based or similar relationship
 - statute or regulation, or
 - the retention of any overpayment

Overpayments

- FCA imposes an affirmative obligation to return overpayments:

‘A person that has received an overpayment shall:
(A) report and return the overpayment to the
Secretary, the State, an intermediary, a carrier,
or a contractor, as appropriate, at the correct
address; and
(B) explain in writing the reason for the overpayment.

- may include funds received under Medicare or Medicaid to which an individual or entity is not entitled
- an overpayment not timely reported and returned is an “obligation” under the FCA
- overpayments must be reported and returned within 60 days of when the overpayment was actually identified or should have been identified with reasonable diligence

60-Day Rule

- Centers for Medicare and Medicaid Services issued a final rule on the reporting and refunding of overpayments.
- Overpayments must be repaid within 60 days after the overpayment is “identified.”
- An overpayment will be considered “identified” when a provider “has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount to the overpayment.”
- Actual knowledge is not required.

Case Study: Overpayment

- *United States ex rel. Kane v. Healthfirst, Inc., et al.* (S.D.N.Y. Aug. 3, 2015)
 - Relator alleged that software glitch caused improper billing of NY Medicaid program.
 - Defendant repaid in full over two years, but relator alleged that defendant fraudulently delayed repayment.
 - SNDY denied motion to dismiss based on the 60-day rule, because the defendant had 60 days to repay from the time it was “put on notice of a potential overpayment.”

Fiscal Year 2015 FCA Recap

- 638 *qui tam* suits filed in 2015
- More than \$3.5 billion in settlements or judgments
 - \$597 million to whistleblowers
 - \$1.9 billion recovered from health care industry
- Federal Civil Penalties Inflation Adjustment Improvement Act
 - Requires DOJ to increase FCA penalties
 - Could raise per claim penalty to \$18,600 in 2016



Major Settlements

- Novartis (November 2015): \$370 million to settle allegations that it gave kickbacks to specialty pharmacies in return for recommending its drugs; \$20 million forfeiture of proceeds.
- Pfizer (February 2016): \$784.6 million to settle allegations that its Wyeth unit overcharged government Medicaid health programs for heartburn drug.
- Olympus Corporation of America (March 2016): \$623 million to settle FCA/AKS allegations including “permanent loans” of equipment, payments for “consulting services” and “grants.”
- NuVasive, Inc. (July 2015): \$13.5 million to resolve allegations related to kickbacks and marketing device for unapproved surgical uses.
- AstraZeneca LP and Cephalon, Inc. (July 2015): \$54 million to settle alleged underpayment of Medicaid drug rebates.

Developments: Individual Responsibility

- In Fiscal Year 2015, the government intervened and named individuals as defendants, reaching settlements of \$1 million or more with more individuals.
- “Yates Memo” (September 9, 2015) announced DOJ’s initiatives to hold individuals responsible for corporate misconduct.
 - Identifies six “key steps” to encourage effective pursuit of individuals
- Potential sea change in civil cases.



Yates Memo

1. “To be eligible for any cooperation credit, corporations must provide to the [DOJ] all relevant facts about the individuals involved in the corporate misconduct.”
2. “Both criminal and civil corporate investigations should focus on individuals from the inception of the investigation.”
3. “Criminal and civil attorneys handling corporate investigations should be in routine communication with one another.”
4. “Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals.”
5. “Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires and declinations as to individuals in such cases must be memorialized.”
6. “Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond that individual’s ability to pay.”

Considerations and Challenges

- If DOJ begins to routinely pursue FCA actions against individuals, FCA cases may change drastically.
- FCA actions could become more like criminal cases, with companies focused not only on their liability but the liability of their executives.
 - More counsel may be necessary for individual representation.
 - More counsel could make it increasingly difficult to coordinate on everything from factual investigation priorities to communications with the government.
- It could take longer to resolve allegations and reach a settlement.
 - Yates memo directive provides that corporate settlements cannot resolve individual liability except in extraordinary circumstances.
 - Drawn-out internal investigations will require additional company resources.
 - Settlement negotiations will become increasingly complicated as the parties negotiate to allocate damages between the company and responsible individuals.

Enforcement Trends

- Physician-Owned Distributors
 - 2013 OIG Special Fraud Alert
 - *United States of America v. Reliance Medical Systems*
- Overpayments
 - Recent developments clarify repayment obligations
- Mid-Size and Small Companies
 - OtisMed CEO sentenced to 2-year prison term in June, 2015
 - Jacob Elberg, Chief of Health Care and Government Fraud Unit in New Jersey suggests more cases like OtisMed are on the horizon
- Device Manufacturers
 - US Attorney Wagner in E.D. Cal: “If we find examples where we can show that people are going under the knife for reasons that are not medically justified, we are going to track that back as far as we can.”

Enforcement Trends

- DOJ will seek more admissions of fact.
 - “We’re looking at having more admissions in our settlement agreements,” Marie Spencer, Medicaid fraud specialist in the New York attorney general’s office.
 - “This topic of admissions — I think you’re going to see it increasingly on the federal side as well,” Zachary Cunha, AUSA in Rhode Island.



Internal Investigations

DO:

- ✓ Investigate promptly
- ✓ Communicate responsibly
- ✓ Preserve documents
- ✓ Collect and review documents
- ✓ Consider separate representation for individuals
- ✓ Conduct interviews
- ✓ Maintain privilege
- ✓ Develop plan to address stakeholders and media

DO NOT:

- Ignore employee concerns
- Assume communications will be privileged
- Underestimate litigation potential

Takeaways

- The FCA is one of the government's most powerful enforcement tools in the health care and life science sectors.
- Understanding and minimizing your FCA risk is essential in the current enforcement environment.
- Acknowledging potential whistleblowers and addressing allegations appropriately is a necessary component of doing business in this industry.
- Stay abreast of enforcement developments to spot and address issues before they become litigation risks.

Original Source: The Sidley Austin False Claims Act Blog

fcablog.sidley.com

10/17/2015

Sidley False Claims Act Blog

ORIGINAL SOURCE
False Claims Act Enforcement and Litigation

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Welcome to Original Source: The Sidley Austin False Claims Act Blog

The False Claims Act (FCA) has long been a key enforcement tool for the federal government in matters involving government contracts or other expenditures of government funds. FCA enforcement has traditionally focused primarily on two industries receiving a substantial amount of government funds: healthcare and defense and other government contractors. Recently, however, FCA enforcement has expanded to other industries, including financial services. Through the False Claims Act Blog, lawyers in Sidley's [White Collar](#), [Healthcare](#), [FDA](#), [Government Contracting](#), [Financial Services](#), [Appellate](#), and other practices will provide timely updates on new and interesting developments relating to FCA enforcement and litigation.

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California District Court Denies Government's Request to Maintain Documents Under Seal

 OCT 06 2015  JAIMELM.JONES AND CATHERINE KIM  0

On September 25, 2015, a Central District of California Judge denied the government's request to maintain documents under seal in a declined *qui tam* suit, on the basis that the documents describe only routine investigative methods of the government. See *United States ex rel. Hong v. Newport Sensors, Inc. et al.*, No. 13-cv-01164-JLS-JPR (C.D. Cal. Sept. 25, 2015). This order followed the court's prior denial of an attempt by the government to maintain the seal for a failure to show good cause to limit the unsealing to only specific documents.

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