

# HCCA Research Compliance Conference: June 4, 2018



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## **Whistleblowers in the Research Setting:** *FCA Risks and Proactive Compliance*

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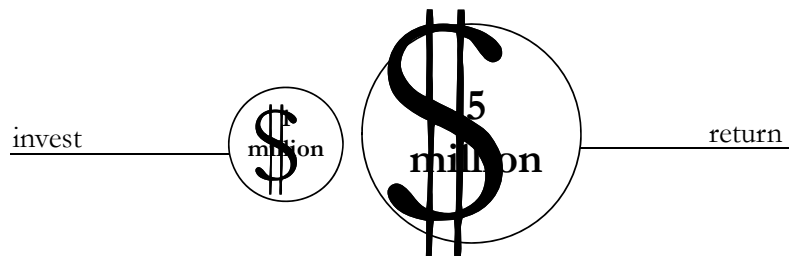
# Agenda

- **Introduction to the FCA**
  - What is it?
  - Why is it important?
  - How does it relate to research compliance?
- **Research Compliance**
- **Practical Takeaways**

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# Government Emphasis on Fraud

Prosecuting "fraud" is good business



In January 2017, an HHS report stated that for every \$1 invested in OIG, DOJ and FBI investigations related to health care fraud in the past three years, \$5.00 was returned

# History of the FCA

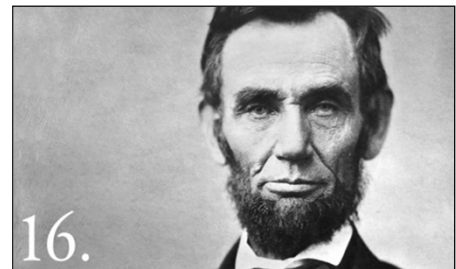
- **The False Claims Act (31 U.S.C. § 3729)**

- The Lincoln Law passed in 1863:

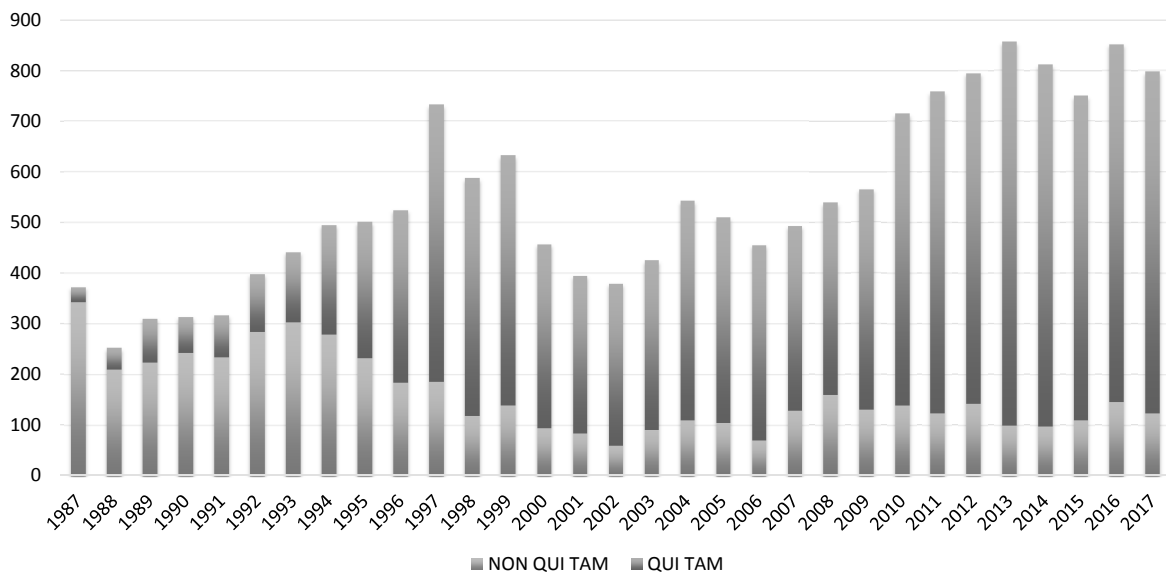
*"You can sell anything to the government if you just have the guts to ask."* – Civil War Profiteer, Jim Fisk

- **Revisions**

- 1943: *Public Disclosure Bar*
    - 1986: *Birth of Modern FCA*
    - 2009: *Fraud Enforcement and Recovery Act*
    - 2010: *Affordable Care Act*



## Number of New FCA Actions



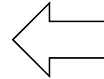
Source: DOJ "Fraud Statistics – Overview" (Dec. 19, 2017)

# Anatomy of a Violation

**submitting** or causing  
**submission** of a false  
claim

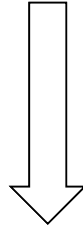


WITH



actual knowledge

**making, using,** or causing  
making or use of a **false**  
**record or statement**  
material to a false claim



deliberate ignorance

**retaining** an overpayment

reckless disregard

VIOLATION

## What is a *false claim*?

- **Factual Falsity:** Material factual misrepresentations
  - *Service billed for but never provided*
  - *False statements used to secure grant funding*
- **Legal Falsity:** Good or service provided but in violation of a statutory, regulatory, or contractual requirement
  - *Grant violations*
  - *Up-coding / Overbilling*
  - *Anti-Kickback or Stark violations*

## What is the cost of a false claim?

- **Penalties**

- Three times Government's actual damages
- Penalties of \$10,957 – \$21,916 per violation
- Attorneys' fees and costs (if Government declines intervention)
- Exclusion from Government pay programs
  
- Government actions under Criminal FCA statute can include imprisonment

## Who brings an FCA lawsuit?

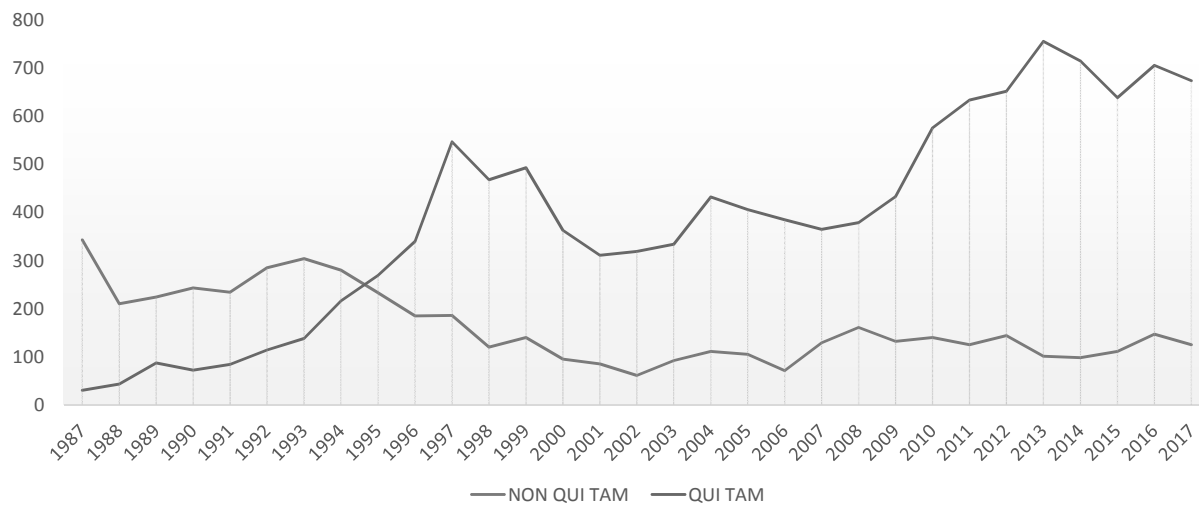
- **The Government (Federal & State)**

- The United States Attorneys' Office can initiate claims
- Begin with Civil Investigatory Demands (CIDS); subpoenas

- **Whistleblowers**

- Special enforcement mechanism
- Allows private individuals to notify governments under seal
- Individual may pursue action even if government chooses not to

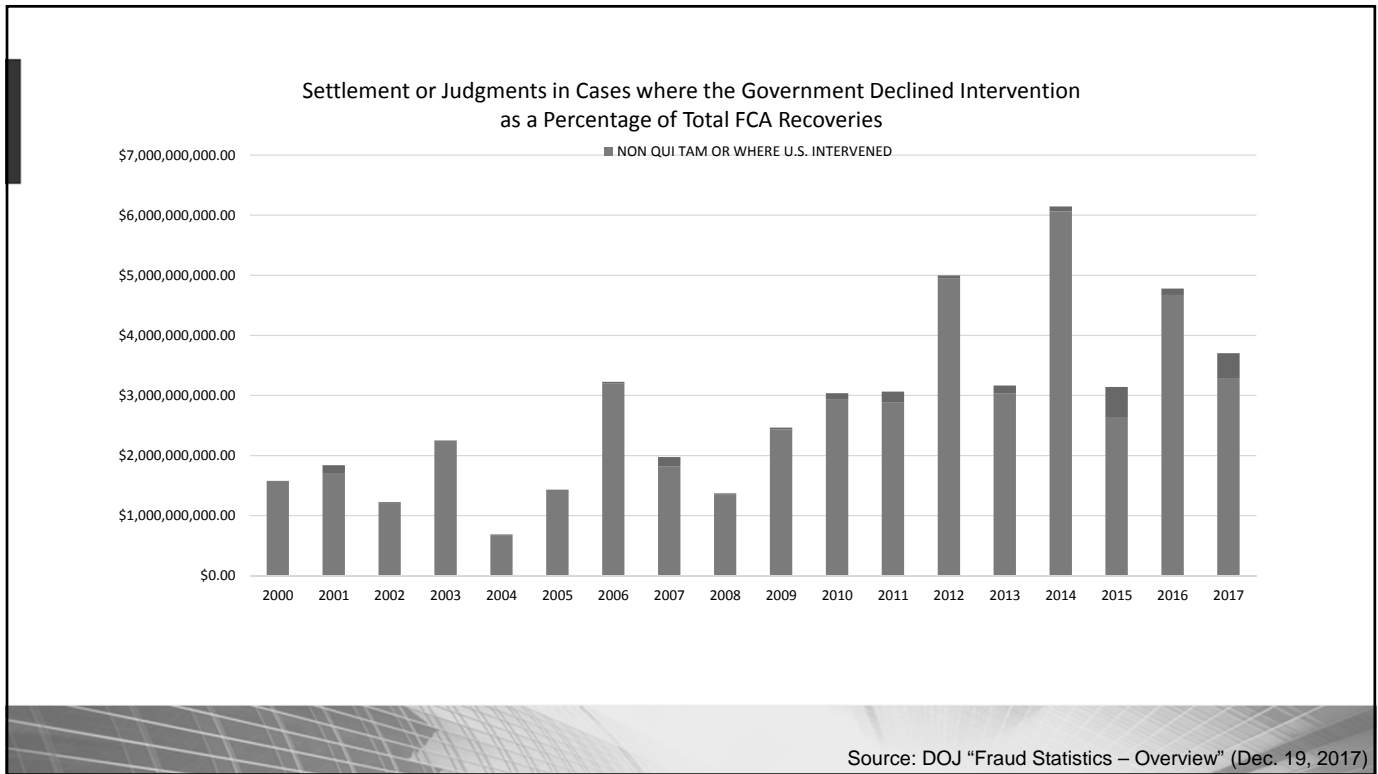
## Who Really Brings Claims?



Source: DOJ "Fraud Statistics – Overview" (Dec. 19, 2017)

## Why Whistleblowers?

- **Mechanism of encouragement: Financial Incentives**
  - Government intervenes: up to 25% of Recovery
  - Government declines: up to 30% of Recovery
  - Attorneys' fees and costs
- **FCA prohibits retaliation**
  - Reinstatement
  - Double back pay & interest



## Why Research Organizations?

- **Key Supreme Court Case – *Escobar***
  - Answered conflict among courts of appeals
  - Exposes entities and individuals for liability re: material misrepresentations
- **September 2017 OIG Report**
  - Fear of retaliation stifling whistleblowing at OHRP
  - Recommended education re: whistleblower protections
  - Encouraged HHS to consider improvement of whistleblower protections
- **Increased Litigation**
  - Government and whistleblowers pursuing research FCA actions
  - Significant settlements

## Research Compliance

- FAR 52.203-7 requires Federal contractors to implement procedures designed to prevent and identify possible violations of the anti-kickback law (41 U.S.C. Ch. 87)
  - Must promptly report if have “reasonable grounds” to believe there is a violation in Contractor’s operations
  - Must “cooperate fully” with any Federal agency investigation
  - Amount of kickback may be offset by Contracting Officer against any amount owed under the prime contract, or direct Contractor withhold that amount from subcontractor payments

## Research Compliance

- Whistleblower Protections under ARRA
  - Applies to employees and contractors
  - Must be posted and included in subcontracts/grants
- 3909-1: Government can’t fund contracts with entities that require employees and subcontractors to sign confidentiality agreements that would prohibit reporting of waste, fraud or abuse to government. Does not apply to standard US Government Forms related to Nondisclosure of Classified Information and Sensitive Compartmented Information



## Research Compliance

- FAR 52.203-13: Requires Contractor of >\$5 M, 120 days to:
  - Establish a Code of business ethics and conduct
  - Make Code available to each employee performing the contract
  - Exercise due diligence to prevent and detect criminal conduct
  - Otherwise promote a culture of ethical conduct and compliance with law
  - Timely disclose to the OIG any time there is credible evidence that a principal, employee, agent or subcontractor has committed:
    - A violation of Federal law involving fraud, COI, bribery, or gratuity
    - A violation of the False Claims Act

## Research Compliance

- Columbia University and International Center for AIDS Care and Treatment Programs - \$9 Million settlement
  - Allocated time across a number of grants
  - PI verified T & E reports; no actual knowledge of time spent on grant activities
  - Charged non-chargeable activities such as grant-writing



## Trouble in the Summer



- Yale paid \$7.6 Million to settle False Claims Act allegations:
  - Of inappropriate charges against grants that were close to expiration to “spend down” funds
  - That researchers charged summer salaries against grants, although the work was not research-related, because otherwise no salary would have been paid

## Scientists Behaving Badly

- *Qui-tam* lawsuit can be brought based on research misconduct
- Fabrication, falsification, or plagiarism of research record
- Not clear whether *qui-tam* relator is required to identify any specific payment affected by the bad data
- Consider impact of *Escobar*



## Scientists Behaving Badly

- What do you call an individual that brings possible research misconduct to your attention?
- How do you handle the allegations?
- How do you balance the need to not submit further federal claims with the obligation of fairness to Respondent?



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## Anyone Can Be a Whistleblower

- University of California filed a complaint against clinical trial company and a number of healthcare providers alleging a fraudulent health care scheme targeting students.
- Students were provided “marketing” jobs if they signed up for “clinical trials” of certain medications and provided health information.
- Medications were packaged in convenience kits and billed as more expensive patented drugs; prescribed without medical examination or diagnosis that required treatment with the drug.

## Recent Research Settlements

- ***University of Florida - \$19.875 Million***
  - Settled allegations of overstated admin costs under hundreds of federal grants.
- ***University of North Texas - \$13 Million***
  - Settled claims re: failure to adequately pay, track, and measure efforts by researchers.
- ***Columbia University - \$6 Million***
  - Settled allegations of overstated reimbursement for over 420 NIH grants.
- ***University of Pittsburgh Professor - \$132,000***
  - Settled allegations of submitting false documents to National Science Foundation to obtain grant funding.

## Takeaways

- **Research FCA Actions**
  - Here to stay.
  - Focus on individual liability growing.
  - Anticipate increased whistleblower activity.
- **Research Compliance**
  - Attention to the little details is critical
  - Research compliance requires special training
  - Embrace good-faith reports of concerns and listen to the grapevine





Visit the Hall Render Blog at <http://blogs.hallrender.com> for more on health care law.

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