

**The Three I's  
Conference 2020**

**The False Claims Act's  
Application to Research Integrity**

September 14, 2020, 1:30 EST

**Potomac  
LAW GROUP**

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**Legal Disclaimer**

- This presentation has been prepared by the attorneys of Potomac Law Group, PLLC. The opinions expressed during the presentation, or in these materials, are solely their views and not necessarily the views of any other individual, entity, or organization. The information provided during today's presentation, or in these materials, do not constitute legal advice or professional services. If legal advice is needed, you should reach out to an attorney directly for that advice.

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**Agenda**



Part 1

Introduction and Overview of the False Claims Act



Part 2

Case Studies



Part 3

Compliance and Self-Disclosure



Part 4

Whistleblowers

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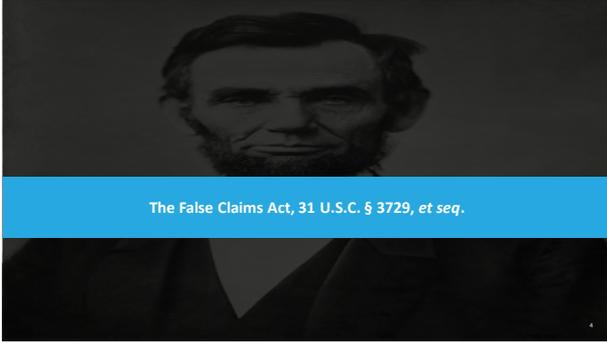
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**POLLING QUESTION 1**

How familiar are you with the False Claims Act?

- A. Not at all
- B. Somewhat
- C. Familiar
- D. Very familiar

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**History**

- Passed in 1863 (during the Civil War)
- Enacted to protect Union Army from rampant fraud
- Contractors selling sick mules, lame horses, sawdust instead of gunpowder, and rotten ships disguised with fresh paint



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### Elements of FCA

1. False or fraudulent claim
  - Omissions count
  - False statements material to a claim
  - Claim can be made through intermediary
  - Beware of reverse false claims
2. Knowledge/intent
  - Actual knowledge;
  - Deliberate ignorance; or
  - Reckless disregard
3. Material
  - See *Universal Health Services, Inc. v. U.S.*, 136 S.Ct. 1989 (2016)
4. Causation

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### Powerful Civil Enforcement Tool

- Since 1986, \$62 billion recovered under the FCA
- \$44 billion recovered through whistleblowers
- 94 percent when DOJ intervenes
- More than \$7 billion paid to whistleblowers
- 633 new qui tam lawsuits filed last year



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### Powerful Civil Enforcement Tool

- Treble damages (actual losses x 3)
- Penalty per claim (\$11,665 to 23,331)
- Whistleblower's expenses, costs, attorney fees



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### Long memory and civil burden

- Up to 10-year statute of limitations
- Pre-litigation subpoena power
- Preponderance of the evidence standard



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### Who is at risk?

- Individuals
- Companies
- Non-profits
- Private universities, schools, and colleges
- Local governments (counties, towns, cities and municipalities)
- States, and state agencies, are exempt
- Public universities? It depends.

Chick County, 81 F. 3d, 1139 (11th Cir. 2000)  
Vermont Agency of Natural Resources v. U.S. ex rel. Stevens, 529 U.S. 765 (2000)  
See e.g., United States ex rel. Chicago, N. & W. Ry. v. Chicago, 497 U.S. 678 (2000)

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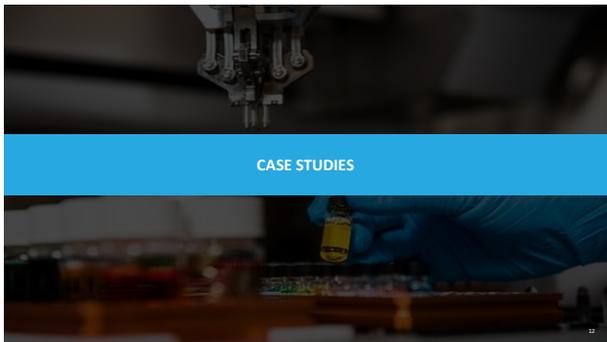
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**Case Studies**

- 1) Research Administration
- 2) Research Misconduct
- 3) Research Compliance

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**POLLING QUESTION 2**

What are you most interested in learning about?

- A. Research Administration cases
- B. Research Misconduct cases
- C. Research Compliance cases
- D. I think I'm in the wrong Zoom room

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**Case Studies: Research Administration**

- F&A rates
- Rebates and discounts
- Cost allocation
- Time & Effort

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### Case Studies: Research Administration

#### Columbie University \$9.5 million (July 14, 2016)

- Improperly applied its "on-campus" indirect cost rate (61%), instead of its much lower modified "off-campus" indirect cost rate (29.4%), when seeking federal reimbursement for 423 NIH grants where research was primarily performed at off-campus facilities owned by NY and NYC

#### University of Wisconsin-Madison \$1.5 million (March 21, 2019)

- Allegedly failed to comply with Office of Management and Budget (OMB) cost principles that require rebates and discounts to be credited to the federal grants and awards
- Specifically, the DOJ alleged that the university participated in rebate and discount programs that were applied to certain supplies and equipment purchased by the university, however, the university failed to credit the rebates and discounts associated with these purchases to the federal grants and awards

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### Case Studies: Research Administration

#### Texas A&M Research Foundation (TAMRF)

\$750,000 (September 20, 2018)

- DOJ alleged that TAMRF improperly charged additional compensation to federal grants for academic employees of an institution of higher education ineligible to receive such pay
- Also alleged that TAMRF improperly charged federal grants for expenses not properly allocable to them, including salaries and wages for individuals not working on the grants and supplies and equipment unrelated to the grants. As well as travel expenses unrelated to the objectives of the grants or for unaffiliated parties not working on the grants.

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### Case Studies: Research Administration

#### University of Florida \$19.875 million (November 20, 2015)

- Alleged to have improperly charged HHS for salary and administrative costs on hundreds of federal grants - didn't have documentation to support level of effort claimed
- DOJ also alleged that the university charged grants for administrative costs for equipment and supplies when those items should not have been directly charged to the grants

#### University of North Texas Health Science Center \$13 million (February 16, 2018)

- University of North Texas Health Science Center inaccurately measured, tracked and paid researches for efforts spent on certain NIH-sponsored research grants
- Failed to maintain accurate records reflecting the work performed on specific grants, and did not have an appropriate system of internal controls. As a result, it received payments for inaccurately and untimely time and effort certifications and received salary payments when the correlating payments did not match the accompanying time and effort reports.

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### Case Studies: Research Administration

#### Scripps Research Institute \$10 million (September 11, 2020)

- The Scripps Research Institute (TSRI) is a non-profit biomedical research institute with campuses in Florida and California.
- Settlement alleged that, between 2008 and 2016, TSRI failed to have a system in place for its faculty to properly account for time spent on activities that cannot be charged directly to NIH-funded projects or are unrelated to the research activities of the NIH-funded project.
- As a result, TSRI improperly charged NIH-funded projects for time spent by faculty on other activities unrelated to the funded projects, such as teaching, TSRI committee work, and other administrative tasks.
- Former TSRI employee brought qui tam lawsuit - will receive \$1.75 million of the resolution.

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### Case Studies: Research Misconduct

#### Research Misconduct

- Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. *See* 42 C.F.R. § 93.103.

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### Case Studies: Research Misconduct

#### Duke University \$112.5 million (March 25, 2019)

- Whistleblower alleged that a clinical research coordinator working in the pulmonary division, Erin Potts-Kant, falsified and fabricated research data that her and her supervisor then utilized in dozens of publications in scientific journals
- Further alleged that Duke, Potts-Kant, and supervisor submitted applications and progress reports that contained falsified research on federal grants to the National Institutes of Health (NIH) and to the Environmental Protection Agency (EPA)

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Case Studies: Research Misconduct

- **Harvard University Affiliate \$10 million (April 27, 2017)**
  - Harvard self-disclosed concerns of research misconduct to the government
  - Believed that one of its prominent heart researchers, Dr. Piero Anversa, who pioneered the field of cardiac stem cell therapy, had issued 31 publications that included falsified and/or fraudulent data
  - He and his colleagues had claimed that they had identified stem cells (known as c-kit cells) in the heart that could regenerate cardiac muscle. But various research teams were unable to reproduce his results.
  - A former research fellow had described an atmosphere of fear and information control in Anversa's lab

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Case Studies: Research Misconduct

- ***U.S. ex rel. Hill v. University of Medicine & Dentistry of New Jersey*, 448 Fed. Apprx. 314 (3rd Cir. 2011)**
  - Doctor alleged that a colleague in the radiology department failed to follow the proper scientific protocol, dismissed her concerns, and utilized fabricated data in NIH grant applications
  - District court found for defendants on summary judgment and the Third Circuit confirmed ("Because plaintiff presented evidence only demonstrating a scientific disagreement over the reliability of the data, and not evidence as to defendants' knowledge of the falsity, liability does not attach")
  - University's RIO fielded the complaints and conducted a thorough investigation of the allegations, concluding that insufficient evidence of misconduct existed
  - Office of Research Integrity at HHS also pursued the complaints, conducted an independent analysis of the data and concluded there was insufficient evidence to warrant a further review

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Case Studies: Research Compliance

- ***Singletary v. Howard University*, 939 F.3d 287 (D.C. Cir. 2019)**
  - Retaliation case under 31 U.S.C. 3730(h)
  - Whistleblower was Attending Veterinarian and member of University's Animal Care and Use Committee
  - Alleged that University violated the Animal Welfare Act of 1966, 7 U.S.C. §§ 2131-2159, and the Health Research Extension Act of 1985, 42 U.S.C. § 289d
  - Allegedly failed to maintain acceptable air temperature in the laboratory animals' living quarters, and failed to report deviations of standards to NIH
  - Alleged false claims were certifications of compliance with federal requirements
  - In 2 v. 1 split, the D.C. Circuit overruled district court and found the complaint sufficient to survive a motion to dismiss by defendant

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### Cooperation Credit

- HHS Grant Self-Disclosure Program
- DOJ Civil Cooperation Credit
- DOJ Criminal Cooperation

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### Cooperation Credit

#### June 2019: HHS OIG Grant Self-Disclosure Program

- Details mandatory and voluntary disclosures
- OIG's general practice is to require a multiplier of 1.5 times the damages in cases of self-disclosure, rather than 2 or 3 times
- Coordinates with DOJ civil and criminal

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### Cooperation Credit

#### May 8, 2019: CIVIL Guidance Issued by the DOJ

- Timely and voluntary self-disclosure is most important
- Other forms of cooperation during investigation are rewarded
- Remedial actions are important
- Maximum cooperation can result in a reduction to single damages, lost interest, cost of the investigation, and a relator's share

See Justice Manual, Section 4-4.112

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### Cooperation Credit

#### June 2020: Criminal Guidance Issued by the DOJ

- Well-designed and effective corporate compliance programs
- Adequate resources and access to data
- Third-party risk management

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**Whistleblower protections**

- Employees, contractors, or agents are protected from:
  - Discharge, demotion, suspension, threat, harassment, or in any other manner discriminated against in terms or conditions of employment
  - Because of lawful acts done in furtherance of an FCA action or done to stop FCA violations

*See*31 U.S.C. § 3730(h)(1)

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**Retaliation remedies**

- Reinstatement
- Two times amount of back pay
- Interest on back pay
- Special damages sustained as a result of discrimination, including litigation costs and attorney fees

*See*31 U.S.C. § 3730(h)(2)

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**Who are whistleblowers?**

- Internal employees
- Consultants and external vendors
- Competitors
- Companies created to blow the whistle

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**How to address whistleblowers**

- Complaint hotlines
- Thoroughly investigate complaints
- Keep whistleblower informed (as much as possible) of investigation

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**Questions**

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