Lessons from the Duke University Case: Warning Signs of Research Misconduct

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Overview of Legal Practice

 Represent whistleblowers in a variety of cases, primarily False Claims Act cases.

 Founder and national Chair of the Federal Bar Association Qui Tam Section

Prior experience as US Marine attorney.

False Claims Act

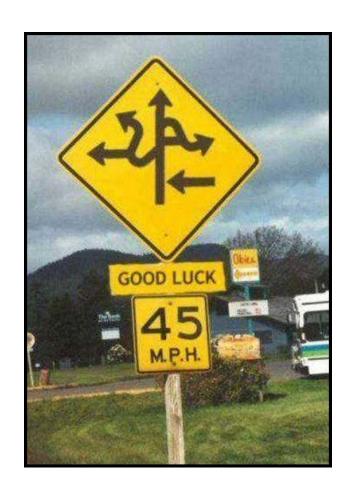
"Lincoln Law"

 Qui Tam provisions allow private whistleblowers to bring suit on behalf of the United States Government.

- Elements: (1) Falsity; (2) Scienter (Knowledge); (3) Materiality; and (4) Damages
- Treble Damages
- Whistleblowers ("Relator") may receive up to 30% of the recovered amount.

Whistleblower Goals

- Scientific Integrity
- Protection from Retaliation
- Transparency
- Saving Resources
- Consequences for Wrongdoers





Duke University is at the center of a whistleblower lawsuit concerning potential research misconduct. USCHOOLS UNIVERSITY IMAGES/ISTOCKPHOTO

Whistleblower sues Duke, claims doctored data helped win \$200 million in grants

Disclaimer

 Some information related to my cases remain non-public, and we will not share any such information in this presentation.

 The settlement in the Duke case did not involve an admission on the part of Duke as to liability or any of the factual particulars of the case.

Any factual analysis are our impressions and opinions.

US *ex rel.* Thomas v. Duke University, *et al.*

Core Laboratory

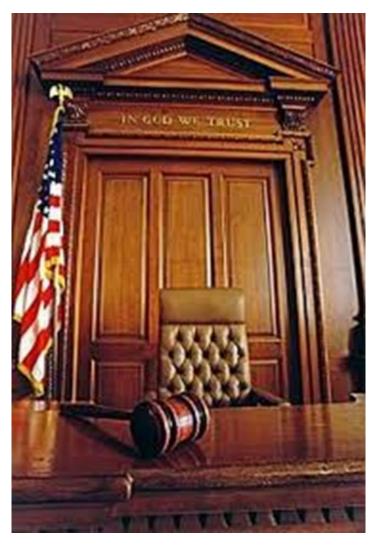
8 years of pulmonary research

~50 publications

•~35 grants

Procedural History of Case

- Filed May 2013
- DOJ investigated for 4 years, Litigated for 2 years
- 52 depositions, 15+ experts
- Settled in November 2018
- \$112.5M USD



Challenges

• FCA is an anti-fraud statute – usually used for Medicare fraud and procurement fraud, not scientific fraud.

Objective vs. Subjective

Materiality

Red Flags



Scientific Red Flags

Suspicious Lab Practices

Small Lies

Personal Behavior and Toxic Work Environment

Lack of Transparency

"Revolutionary" Findings

Practical Red Flags

Toxic Work Environment

Inappropriate Gifts and Financial Arrangements

Sexual Harassment

Absentee Leadership

Takeaways

Legal system can have a role in addressing research misconduct

 Institutions need to better understand whistleblower motivations and respond

 Increased legal (and financial) exposure may lead many universities to increase efforts to address research misconduct

Questions?

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