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

By Alison McCook, Retraction Watch | Sep. 1, 2016, 2:00 PM

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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