Truth, Lies, and Materiality
Facts, Intent, and the Intersection between the False Claims Act and Research Misconduct

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Disclosure

- Pfizer (through my husband)* helps pay Gretchen’s mortgage

  *P.S. Thanks honey!
Agenda

• False Claims Act
  ◦ History
  ◦ Definition
  ◦ Application to Biomedical Research

• Assessment
  • Our responsibility
  • A potential plan of action
False Claims Act - the Lincoln Law

• 31 U.S.C. §§ 3729 - 3733 – enacted in 1863
  • Concerned that suppliers of goods to the Union Army during the Civil War were defrauding the Army.
  • Any person who knowingly submitted false claims to the government was liable for double the government’s damages plus a penalty of $2,000 for each false claim.
REJECTED MEDICAL CLAIM
What’s the Big Deal?

- Investigations & Settlements
  - BIDMC – 1999 ($920K) & 2004 (with Harvard) ($3.3M)
  - Northwestern – 2003 ($5.5M)
  - Johns Hopkins/Bayview Med. Ctr – 2004 ($2.6M)
  - U. of Alabama Birmingham – 2005 ($3.4M)
  - Mayo Foundation – 2005 ($6.5M)
  - Weill Med. College of Cornell – 2006 ($4.4M)
  - U. of Connecticut – 2006 ($2.5M)
  - Yale – 2006 (ongoing)
False Claims Act – Liability

- Liability for any person who
  - knowingly submits a false claim to the government, or
  - causes another to submit a false claim to the government, or
  - Knowingly makes a false record or statement to get a false claim paid by the government. Section 3827(a)(1)(A) and (B).

- Reverse False Claim – Section 3729(a)(1)(G)
  - Liability for any person who acts improperly to avoid having to avoid paying money to the government

- Conspiracy – Section 3729(a)(1)(C)
  - Liability for those who conspire to violate the FCA.
False Claims Act

- Knowledge required for liability
  - Actual knowledge
  - Deliberate ignorance of the truth or falsity of the information
  - Reckless disregard of the truth or falsity of the information

- Damages
  - $5,500 - $11,000 for each false claim
  - Treble damages
  - Not less than double damages in some circumstances
False Claims Act

- What is a claim?
  - Demand for money or property made directly to the government, contractor, grantee, or other recipient if money is spent on the government’s behalf and the government provides the government money demanded.
Whistleblower – Qui Tam Provision

• An individual (the original source) can file a lawsuit under seal on behalf of the government = Relator
  ◦ Complaint and written disclosure must be served on U.S. Attorney in judicial district.

• Claim sealed for 60 days while government investigates. Extensions possible.

• Government decides whether to intercede
  ◦ If decline, the relator may pursue on his/her own.
Principal Investigator Assurance:

I certify that the STATEMENTS HEREIN ARE TRUE, COMPLETE and ACCURATE to the best of my knowledge. I am aware that any FALSE, FICTITIOUS, OR FRAUDULENT statements or claims may subject me to CRIMINAL, CIVIL OR ADMINISTRATIVE PENALTIES. I agree to accept responsibility for the SCIENTIFIC CONDUCT of the project and to provide the required PROGRESS REPORTS if a grant is awarded as a result of this application.
Institutional compliance certification

Certification must include statement: “(1) that the information submitted within the application is true, complete and accurate to the best of the PI's knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject the PI to criminal, civil, or administrative penalties; and (3) that the PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application.”

Many Responsibilities of Academic Scientist

- Data Integrity & Reproducibility
- Publication & Promotion
- Grant Application and Management
- Material Management
- Subject Protection
- Personnel management
Yates Memo – 09/15
Corporate Cooperation Credit

• Individual Accountability for Corporate Wrongdoing - Does an individual possess the knowledge and criminal intent necessary to establish their guilt beyond a reasonable doubt?
  • 1. Corporations must provide all relevant facts
  • 2. Focus in individuals at outset of investigation
  • 3. Civil and criminal investigations should be in routine communication
  • 4. Do not release individuals from liability when resolving a matter with a corporation
Yates memo, cont.

• 5. Should have clear plan about how to resolve individual cases

• 6. When deciding whether to pursue civil charges, must evaluate whether to bring charges not just on individual’s ability to pay.

• https://www.justice.gov/archives/dag/file/769036/download
So, what can we do? One institution’s approach

• Preliminary Assessment –
  ◦ Did the alleged misconduct occur in the publication of data? If so, look to see if federal grant funding cited as the sponsor/support for the data.
    • Call your Office of General Counsel!
  ◦ Did the alleged misconduct occur in the performance of research? If yes, Call your Office of General Counsel! and
    • Were federal funds used to support respondent salaries?
    • Were research resources (supplies, animals, etc.) supported by federal funds?
The analysis, cont.

- Preliminary Assessment –
  - Did the alleged misconduct occur in the proposing of research? If so, call your Office of General Counsel!
    - Review grant applications and progress reports for active federal grant funding to determine if data are included
    - Review IRB, IACUC protocols to determine if data in question were included
  - Did the alleged misconduct occur in the review of research? If so, call your Office of General Counsel!
    - Determine when this occurred:
      - Grant review process
      - Protocol or manuscript review process
Misconduct vs. Material Data?

- Determine whether the data inauthentic.
  - If yes, we conduct a materiality analysis with your Office of General Counsel – was the inclusion of the inauthentic data *material* to the decision to fund the project. In other words, did the government rely on the inauthentic data when making its decision to fund a proposal.
Misconduct vs. Material Data?

- If the data was material to the decision to fund the project, we:
  - Conduct a financial review with the Office of General Counsel to identify expenses associated with the materially inauthentic information.
  - Determine whether necessary to suspend active spending
  - Determine what needs to be reported to whom, and when
An example

Luk Van Parijs

• In 2009, PHS found engaged in scientific misconduct
  ◦ False data in 7 published papers, 3 submitted papers 1 submitted book chapter and multiple grant applications & presentations

• Fall out
  ◦ Pleaded guilty to making a false statement in 1 federal research grant application
  ◦ Sentenced June 14, 2011 – 6 mos house arrest, fine, banishment from receipt of NIH funding
In summary

• Understand your obligation as an individual and as an institution
• Ask Questions
• Do the Right Thing
• Document, Document Document

• And don’t do this….
Ostriches may feel safe
but, they don't live longer!