

**Cause and Effect**

False Science =? False Claim

HCCA Annual Research Compliance Conference

Margaret L. Hutchinson  
Assistant United States Attorney  
Chief, Civil Division  
Eastern District of Pennsylvania

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**DISCLAIMER**

- Opinions expressed are those of the speaker and do not necessarily reflect the views of the U.S. Department of Justice or the U.S. Attorney's Office for the Eastern District of Pennsylvania.

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**History Lesson I**

- Charter for National Academy of Sciences signed by President Lincoln, 1863
  - Academy's definition of scientific misconduct: "fabrication, falsification, or plagiarism in proposing, performing, or reporting research."

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## History Lesson II

- False Claims Act Signed by President Lincoln, 1863
- Definition of False Claim: “any person...who shall make or cause to be made, or present or cause to be presented for payment...any claim against the Government of the United States...knowing such claim to be false, fictitious or fraudulent...shall be punished by fine and imprisonment...”

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## The False Claims Act Today

- The False Claims Act imposes liability on one who:
  - Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval
    - 3729(a)(1)(A)
  - Knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim
    - 3729(a)(1)(B)
  - Improperly avoids or decreases an obligation to pay or transmit money or property to the U.S.
    - 3729(a)(1)(G)

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## What Is A “Claim”?

- Definition:
  - Any request or demand, whether under a contract or otherwise, for money or property whether or not the U.S. has title to it if it is presented to the U.S. or is presented to a contractor, etc., if it is to be spent on the Government’s behalf.
    - 31 U.S.C. 3729(b)(2)
  - “This remedial statute reaches beyond ‘claims’ which might legally be enforced, to all fraudulent attempts to cause the Government to pay out sums of money.”
    - Neifert-White Co., 390 U.S. 228 (1968)

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### What Is An "Obligation"?

- Definition
  - An established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee or licensor-licensee relationship...or from the retention of any overpayment.
    - 31 U.S.C. § 3729(b)(3)
  - Leads to liability for improper retention of overpayments.

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### What Makes a Claim False?

- Knowingly:
  - Has actual knowledge of the information; OR
  - Acts in deliberate ignorance of the truth or falsity; OR
  - Acts in reckless disregard of the truth or falsity
  - No specific proof of intent to defraud is required
    - 3729(b)(1)

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### Examples of Claims

- Loan Applications
- Grant documents




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### Grant Vulnerabilities

- Application Misrepresentations:
  - Capability, Personnel Responsible, Qualifications of Personnel, Prior Research
- Claiming Costs That Are Not Allowed
- Misrepresenting Direct/Indirect Costs
- Misrepresenting Percentage of Effort Relating to Researchers
- Falsely Certifying Costs that are Funded or Provided In-Kind by a Third Party (Such as a Sponsor)
  - Not Following Federal Rules with Respect to Valuing in-kind Contributions
  - Falsely Claiming Costs Actually Paid by the Federal Government Through Another Grant or Otherwise by the Federal Government

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### And Yet More Grant Issues

- Failure to Obtain Pre-Approval (Where Required) of:
  - Budget Changes
  - Changes in Principal Investigator
  - Changes in Scope and Objectives
- Periodic Reporting Misrepresentations
  - Misstating Accomplishments
  - Not Correctly and Accurately Stating Goals
  - Misrepresentations Regarding Findings and Relevant Data
- Misrepresenting Compliance with Remedial Action Demands

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### Problems at the Very End of the Process

- Close Out Vulnerabilities
  - Failure to Return or Account for Property or Funds
  - Transferring Acquired Property Without Approval
  - Supplies Acquired with Federal Funds
  - Equipment Acquired With Federal Funds
    - Used Inappropriately to Support Non-Grant Activities
    - Failing to Pay Government Pro Rata FMV Where Equipment No Longer Needed for Federal Project and Placed into Non-Federal Project

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### Compromised Scientific Integrity and Misconduct

- Investigator Bias Run Amok
- Misrepresentation
  - Compliance with Protocols
  - Compliance with Controls
  - Misstating Data
  - Manipulating Data Inappropriately
  - Taking Inappropriate Credit or Denying Appropriate Credit
    - Can Become an Anti-Kickback Issue
    - Primary Authorship as an Auctioned Good

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### Allegations of Compromised Scientific Integrity and Misconduct From False Claims Act Complaints

- “False and misleading statements to the FDA caused the FDA to approve the drug”
- “False reporting of research outcomes to support off-label use”
- “Failure to capture good and bad outcomes of study in articles for medical journals”

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### More Allegations of Misconduct From False Claims Act Complaints

- “Defendant paid physicians to write and submit articles to the New England Journal of Medicine advocating the use of \_\_\_\_\_ when the Defendant knew the research study showed bad outcomes.”
- “Defendant paid physicians to be ‘authors’ of studies written by Defendant.”
- “Defendant paid the institution for bogus research used to support a false and misleading New Drug Application.”
- “Doctor X took kickbacks and then misled the medical community by misreporting his research results.”

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- Were these false records or statements material to a false or fraudulent claim?
- Did these false representations of research findings influence the FDA approval?
- Did these false representations of research findings appear in compendia publications?
- Did these false representations of research influence the Medicare or Medicaid programs' decisions to pay the claims?

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- ### How Will We Find Out?
- Whistleblower Protection
    - Federal False Claims Act
    - State False Claims Acts
    - Other state laws i.e. Conscientious Employee Protection Act (New Jersey)
  - Tort and Class Action Claims
    - Inspection Reports, Self-Reporting

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- ### Research and the Human Element
- University of Pennsylvania – 2/05 Settlement/CIA
    - Jesse Gelsinger – gene therapy research participant – died from research role
    - Researchers ignored bad results, failed to halt study
    - Research team failed to halt study on learning of serious toxicities, and failed to disclose risks to participants
    - It is not just about money

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An Artless Tale

- *An Artless Tale: Challenges Faced in Clinical Research*  
by: Steven Raper, Associate Professor of Surgery, Vice-Chairman for Quality and Risk Management,  
Department of Surgery, University of Pennsylvania  
Health System

71 Food & Drug Law Journal, Volume 77 (2016).

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ANY QUESTIONS?

Contact:  
Margaret L. Hutchinson  
Civil Chief  
U.S. Attorney's Office, EDPA  
615 Chestnut Street, Suite 1250  
Philadelphia, PA 19106  
Phone: 215-861-8282  
Email: [Margaret.Hutchinson@usdoj.gov](mailto:Margaret.Hutchinson@usdoj.gov)

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