Harvard Yale Symposium 2016
May 3rd

The False Claims Act and the IBC

Workplace Fairness
December 30, 2015 ·

Lawsuit claims University of Louisville biosafety violations
http://buff.ly/1MH3qMw

Lawsuit claims U of L biosafety violations

Former employees accuse U of L of making false claims, violating laboratory safety procedures, and wrongful termination

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Qui Tam Suit
False Claims Act

- Suit "unsealed" 12/28/15
- Two former biosafety officers filed lawsuit alleging multiple violations of lab safety procedures and improper disposal of biologically hazardous materials.
- Examples: researchers not wearing PPE, improper air pressure in lab, unreported spills, exposures, accidents.

Qui Tam Procedure: The whistleblower must file his/her lawsuit on behalf of the government in a federal district court, and kept "under seal" (confidential) during governmental review and investigation of the allegations

- **Rights of Parties:** If the government determines that the lawsuit has merit and decides to intervene, the prosecution of the lawsuit will be directed by the Department of Justice. If the government decides not to intervene, the whistleblower may continue with the lawsuit on his or her own.

- **Awards to Qui Tam Whistleblowers:** If the lawsuit is successful, and certain legal requirements are met, the whistleblower may receive an award ranging from 15 to 30 percent of the amount recovered, and may be entitled to reasonable expenses for bringing the lawsuit.

WANTED!

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Any person having horses and mules to sell will find a market by calling at

on the day of 1862.

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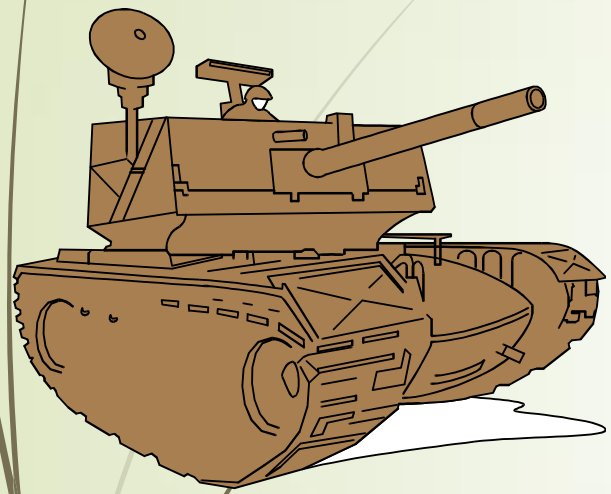
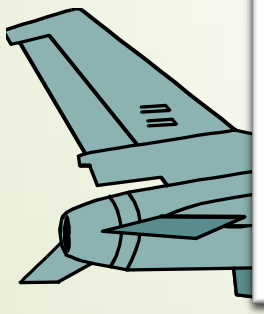
1980s

1986 Amendments



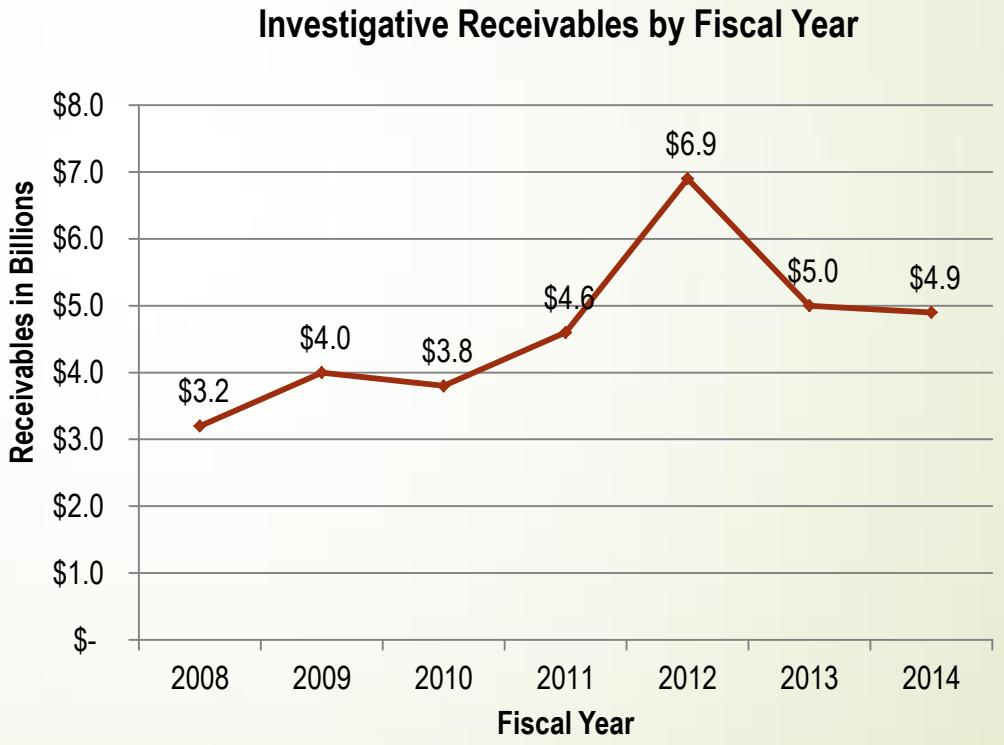


Regulatory Environment

A decrease in federal and non-federal funding for sponsored projects has required award recipient institutions to proactively address internal and external concerns and challenges in recent years.

Regulatory Trends:

- Recoveries from federal investigations/audits are significant and receivables resulting from penalties increased in recent years.
- In FY 2014, OIG reported $4.9 billion in financial penalties resulting from federal audits and investigations consisting of:
  - $834.7 million in audit receivables
  - $4.1 billion in investigative receivables
- Additionally, in the first half of FY 2014, the number of annual criminal actions against individuals or entities totaled 971 and 533 civil actions.
- Civil actions include false claims and unjust-enrichment lawsuits filed in Federal district court, CMP settlements, and administrative recoveries related to provider self-disclosure matters.



Source: Department of Health and Human Services Office of the Inspector General Work Plan FY 2015 https://oig.hhs.gov/reports-and-publications/archives/workplan/2015/FY15-Work-Plan.pdf

FCA Applied to Sponsored Research

1998
University of Minnesota
Misuse federal funds
$32 million

2004
George Washington Univ.
$1.8 million

1991
Stanford
Inflated research grant costs
$1.2 million

2005
Univ Alabama/Birmingham
Effort Certification & Clinical Research Billing
$3.4 million

2005
Florida International Univ
Effort Certification & Direct Costs
$11.5 million

2005
U. Conn.
service centers billing rates
$2.5 million

2004
Harvard/BIDMC
Costing Issues
Self-Reported
$3.25 million

2008
Yale Univ.
Effort Reporting
Cost Transfers
Subrecipient Monitoring
$7.6 milliion

2004
Johns Hopkins Univ
Effort Certification
$2.7 million

1997
New York University Medical Center
Inflated research grant costs
$15.5 million

2005
Mayo Foundation
Mischarging federal grants
$6.5 million

2005
2009
Cornell Medical (2)
Clinical Research Issues
Other Support/Commitments
$4.4 million / $2.6 million

2003
Northwestern University
Committed Time/Effort
$5 million

Parties Named

- Plaintiffs:
  - Carol Whetston, former U. of L Institutional Biological Safety Officer, CDC Responsible Official
  - Karen Brinkley, former U. of L Biological Safety Specialist

- Defendants:
  - University
  - Research Foundation
  - 7 Principle Investigators
  - EHS Director, Cheri Hildreth

Allegations in Complaint

"Each year researchers affiliated with and/or employed by Louisville Defendants apply for and receive millions of dollars in grants from the Government, specifically and from the United States, generally."

"In order to receive its extensive and ongoing grant funding, Defendants submitted numerous grant applications to the Government…."

"Prior to the receipt of any funds from the Government and/or beginning any research, Defendants submitted, or were supposed to submit, completed applications to the UL Institutional Biosafety Committee to ensure that research would be conducted in accordance with the Government's stated terms and conditions. In their capacity as Biological Safety Specialist and Biological Safety Officer, Plaintiffs-relators served in a support role with respect to the IBC and assisted with application review.

"As part of the Government approval and award process, the Government requires that grantees and their respective grantee institutions accept specific terms and conditions prior to the receipt of grant funds. Those terms and conditions include compliance with applicable federal and state laws and regulations as well as compliance with the NIH Grant Policy Statement and NIH Guidelines…."

65. On or about August 2011, the researchers for the Cardiology group, including Defendant Bhatnagar were performing research under grant 2P20GM103492-06 as well as other federal grants in the cardiology lab.

66. On or about August, 2011, Defendants became aware of …and continue to allow…researchers…to collect small pipette tips in small plastic beakers and then dump the beakers in a large biohazard bag lined boxes for disposal. These items may cause leaks and the Cardiology group uses human derived material.

67. …on or about March 2013, Defendant Bhatnagar's viral vector lab *failed to have appropriately set up biosafety cabinets, improperly placed standing vertical pipette decontamination containers outside of biosafety cabinets, improperly disposed seropipettes in biohazard bag-lined burn boxes that could be punctured, improperly taped biohazard bags on the front of the biosafety cabinet, failed to place kill pans….inside the biosafety cabinet, improperly used 70% ethanol as a disinfectant, and/or improperly permitted blockage of the grills that recirculate air in the cabinets.*

68. In addition the failure to comply with NIH Guidelines, this method of disposal does not comport with the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030, UL's model Exposure Control Plan and. Or the NIH's Waste Disposal Procedures, which the Cardiology group was required to complete due to the use of human deprived material. Failure to comply with the model Exposure Control Plan was reported to UL administrative and management personnel including, but no limited t o, the assistant director of Environmental Health and Safety….

Protocol Amendments

75. Beginning on or about August 2011, UL responsible officials…did not require IBC committee review of modifications to IBC protocols that added genes, plasmids and/or viral vectors and UL researchers were not properly submitting modifications to IBC protocols to the IBC for approval

76. During this time period, Defendant Geoff Clark began adding oncogenes with viral vectors to protocols for his research….

77. These protocols generally fall under sections III-A to III-E of NIH Guidelines and must be fully reviewed by the IBC according to NIH guidelines. In addition, Defendant Clark failed to obtain a proper risk assessment as required by NIH Guidelines II-A-3.

Expired IBC Protocols

106. Beginning on or about December 2013, Defendant Charles Scoggins's IBC Protocol, a human gene protocol involving application of killed pancreatic cells genetically modified to express surface receptors in order to induce an immune response in cancer patients expired and was not renewed until March 2014.

107. Despite the expiration of Dr. Scoggin's IBC Protocol, patients were still treated with redombinant material.

108. UL Administrators and/or managers. Including but not limited to the IBC Chair, Vice-President for Research and Innovation and/or the Director of the Department of Health and Safety were aware of these actions and specifically decided not to report this violation within the 30 day time period required by NIH Guideline IV-B-2-b-(7).

IACUC – Related Allegations

82. Beginning on or about 2008 and continuing until at least mid-2013, pursuant to an improper agreement by and or between Cheri Hildreth, the UL Department of Environmental Health and Safety; Erin Foley, the UL Lab Safety Coordinator; and/or Dr. William King, the UL Director of Research Resource Facilities, only the cover sheet of IACUC animal research proposals had been reviewed in order to expedite animal research approvals. This was a violation of UL chemical safety procedures as well as OSHA Guidelines.

83. Due to the ongoing failure to fully review animal research proposals, numerous chemicals were not declared on the cover sheets and animal research protocols were not appropriately handled or reviewed for years. This specifically resulted in the improper approval of numerous projects including, but not limited to, the research conducted by Defendants Clark and Kaplan….

84. Beginning on or about November 2012, researchers began adding biological hazards to animal protocols that had already received Biosafety office approval. Louisville Defendants, including but not limited to the IACUC, were aware of the improper protocol changes and permitted them to occur.

85. As a result of the IACUC's ongoing failure to properly review research proposals, NIH funded research was performed by Defendant Henry Kaplan without proper approval and in violation of NIH Guidelines….

Retaliatory Conduct

136. On numerous occasions, Plaintiffs-relators informed their supervisors and other management of Defendants that their conduct constituted noncompliance with NIH Guidelines, could affect future funding and/or grant approvals, and encouraged Defendants to alter their behavior.

137. Moreover, Plaintiffs-relators informed their supervisors that other management of Defendants that their conduct constituted noncompliance with NIH Guidelines should be reported but Defendants chose not to do so. At this meeting numerous incidents of noncompliance were discussed and Plaintiff-relator Brinkley was specifically told she would not be retaliated against….

138. In addition to reporting the Defendants' noncompliance internally, Plaintiff –relator Brinkley sought to remedy Defendant's noncompliance by bringing it to the attention of numerous government agencies and officials including the NIH, the FBI, and multiple elected representatives….

Repercussions

- IBC Community Member resigned
- NIH conducted own investigation "lack of investigator awareness was a common root cause for research being conducted without IBC approval."
- Following termination, consultants brought in – outsourced IBC to commercial IBC
- Overhaul of IBC membership and policies
- US Government declines to intervene in lawsuit

Thank you

The opinions expressed in this presentation are those of the presenter personally.