

Whistleblower Actions and Healthcare

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Speaker Biography: **Shauna Itri**

Shauna is a partner at Seeger Weiss LLP and represents whistleblowers in False Claims Act lawsuits in state and federal courts throughout the United States, and tax and securities whistleblowers with claims under the IRS and SEC whistleblower programs. She received a B.A. and an M.A. from Stanford University, where she captained the University's Women's soccer team and received her J.D. from Villanova University. She is presently an adjunct professor at Widener Law School, teaching a white-collar crime and corporate deviance course.



Overview of Whistleblower Laws

Federal and
State False
Claims Acts

IRS
Whistleblower
Act

SEC
Whistleblower
Act

California
Insurance Fraud
Prevention Act

Introducing the False Claims Act

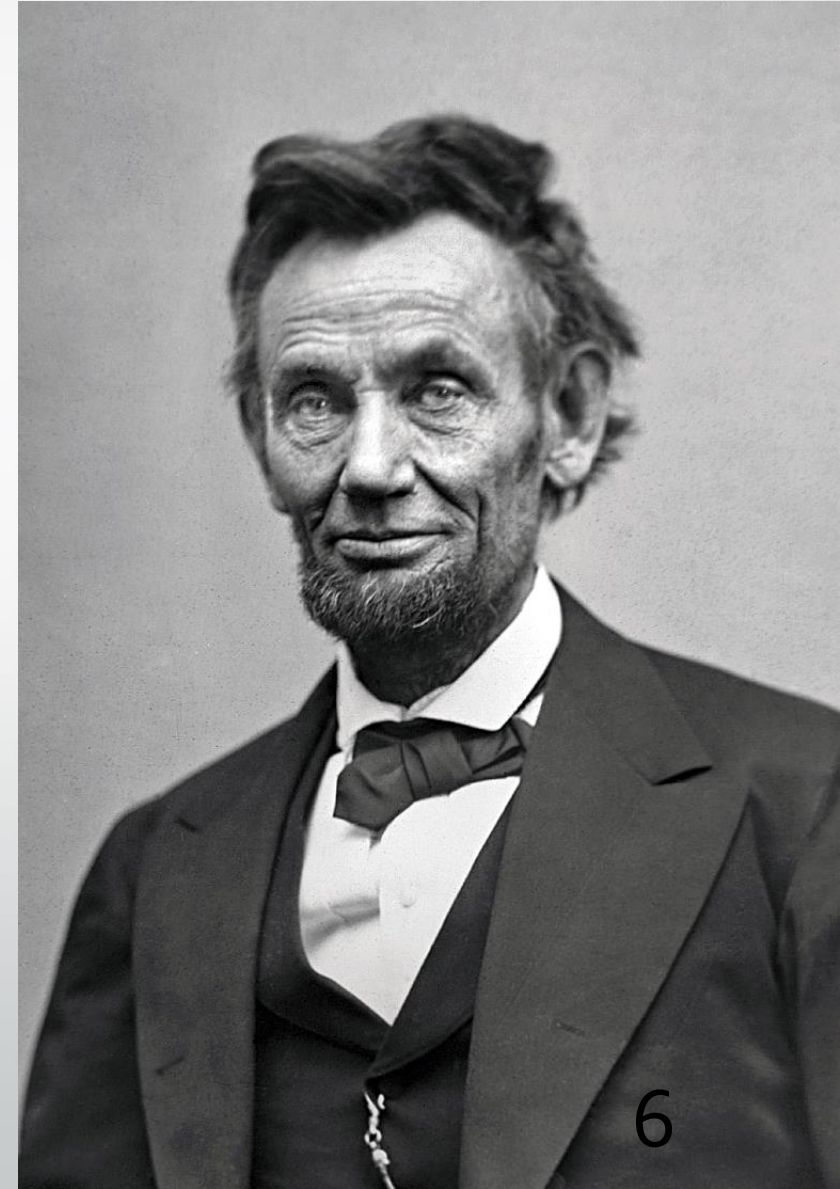
The False Claims Act



- Allows citizens with evidence of fraud against government programs to sue.....on behalf of the government
- Whistleblower may be awarded a portion of the funds recovered

History and Amendments

- “Lincoln’s Law ”
 - Solution for Defective Military Supplies
 - Not Enough Federal Investigators to Properly Investigate Contracting Crimes



False Claims Act

March 1863

696	THIRTY-SEVENTH CONGRESS. Sess. III. Ch. 59-61, 67. 1868.
Construction of 1862, ch. 182, § 2. <i>Id.</i> , p. 562.	eighteen hundred and sixty-three, and for the fiscal year ending June thirty, eighteen hundred and sixty-four, is hereby appropriated therefor. SEC. 3. <i>And be it further enacted</i> , That nothing contained in the third section of an act entitled "An act making supplemental appropriations for the year ending June thirty, eighteen hundred and sixty-three, and for the year ending June thirty, eighteen hundred and sixty-two, and for other purposes," approved July sixteen, eighteen hundred and sixty-two, shall be construed to increase the salaries of the Superintendent of the Census or the Assistant Postmasters-General. APPROVED, February 25, 1868.
Feb. 25, 1863.	CHAP. LX. — <i>An Act to prevent Correspondence with Rebels.</i> <i>Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled</i> , That if any person, being a resident of the United States, or being a citizen thereof, and residing in any foreign country, shall, without the permission or authority of the Government of the United States, and with the intent to defeat the measures of the said Government, or to weaken in any way their efficacy, hold or commence, directly or indirectly, any correspondence or intercourse, written or verbal, with the present pretended rebel Government, or with any officer or agent thereof, or with any other individual acting or sympathizing therewith; or if any such person above mentioned, not duly authorized, shall counsel or assist in any such correspondence or intercourse, with intent as aforesaid, he shall be deemed guilty of a high misdemeanor, and, on conviction before any court of the United States having jurisdiction thereof, shall be punished by a fine not exceeding ten thousand dollars, and by imprisonment not less than six months nor exceeding five years. SEC. 2. <i>And be it further enacted</i> , That where the offence is committed in any foreign country, the district court of the United States for the district where the offender shall be first arrested shall have jurisdiction thereof. APPROVED, February 25, 1868.
Correspondence written or verbal, with rebel government or agents or persons therein, how punished.	
In what court offence to be tried.	
Feb. 25, 1863. 1863, ch. 180. <i>Id.</i> , p. 577.	CHAP. LXL. — <i>An Act to amend an Act entitled "An Act to prevent Members of Congress and Officers of the Government of the United States from taking Considerations for procuring Contracts, Office, or Place from the United States, and for other Purposes."</i> <i>Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled</i> , That the provisions of said act shall be so construed as to embrace any agent of the Government of the United States. APPROVED, February 25, 1868.
Contracts with government.	
March 2, 1863.	CHAP. LXVII. — <i>An Act to prevent and punish Frauds upon the Government of the United States.</i> <i>Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled</i> , That any person in the land or naval forces of the United States, or in the militia in actual service of the United States, in time of war, who shall make or cause to be made, or present or cause to be presented for payment or approval to or by any person or officer in the civil or military service of the United States, any claim upon or against the Government of the United States, or any department or officer thereof, knowing such claim to be false, fictitious, or fraudulent; any person in such forces or service who shall, for the purpose of obtaining, or aiding in obtaining, the approval or payment of such claim, make, use, or cause to be made or used, any false bill, receipt,
Persons in military or naval service making or presenting fictitious claim, &c., against the government, how punished.	

1943 Amendments

FCA Weakened by Congress in 1943 during WW2 Due to Numerous Suits Filed Against Defense Contractors in an Improper Manner

1986 Amendments

- 1986 - greatly strengthened the false claims act in response to over charging by defense contractors
- treble damages
- \$5000-10,000 per false claim
- increased the % of the recovery to the relator to 15-30%



\$600

Toilet Seat



\$7000
Coffee Pot



2010 Affordable Care act

Provisions of the
ACA significantly
strengthen once
more the False
Claims Act



State False Claims Acts

- Generally, Modeled After the Federal FCA
- * Medicaid Only
- Includes Tax – New York

State False Claims Acts

California

Louisiana *

North Carolina

Colorado *

Maryland *

Oklahoma

Connecticut *

Massachusetts

Rhode Island

Delaware

Michigan *

Tennessee

District of Columbia

Minnesota

Texas *

Florida

Montana

Vermont

Georgia

Nevada

Virginia

Hawaii

New Hampshire *

Washington *

Illinois

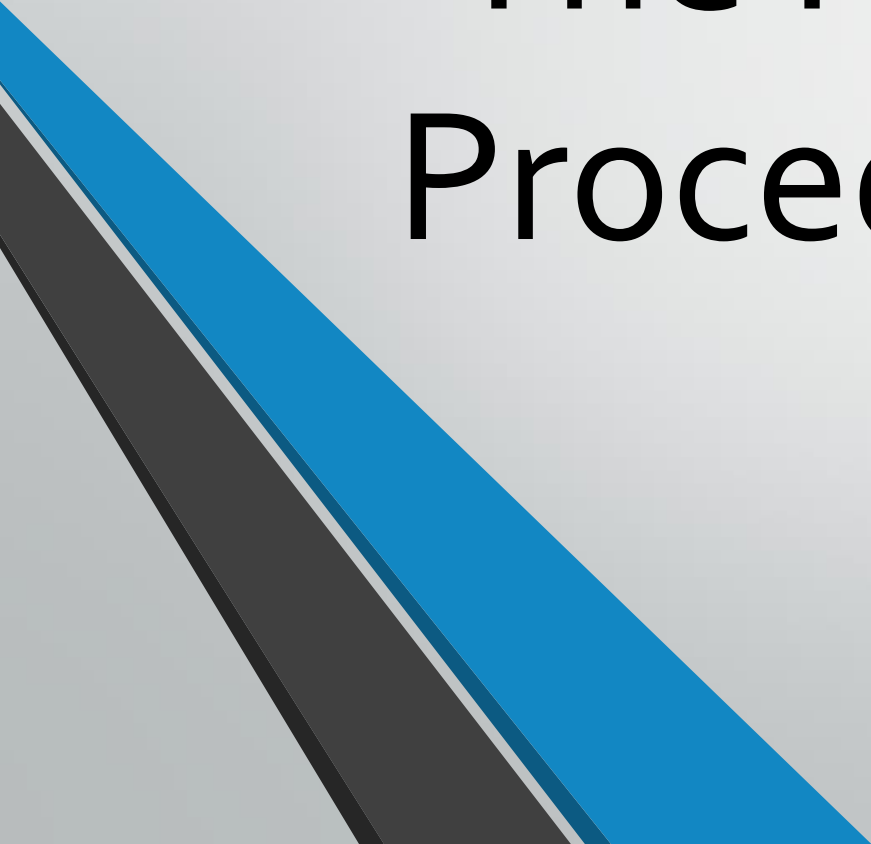
New Jersey

Indiana

New Mexico

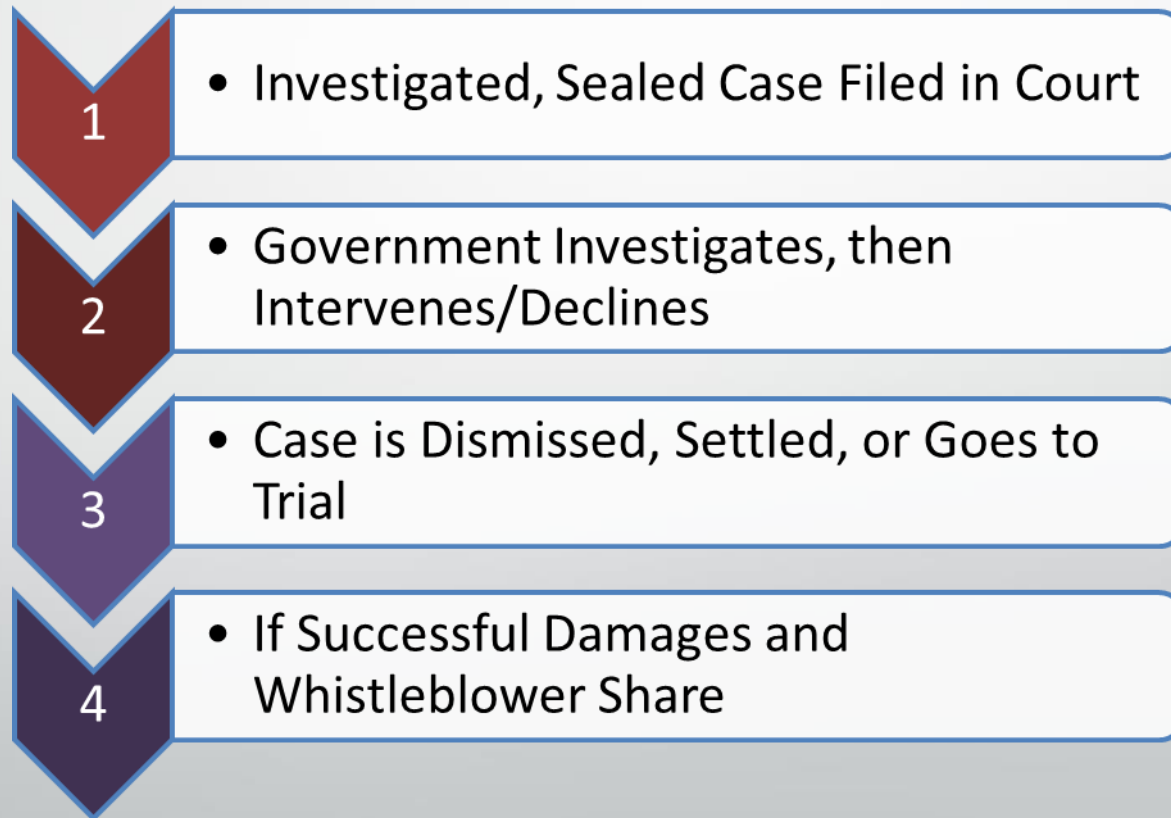
Iowa

New York



The False Claims Act, Procedurally Speaking

False Claims Act: Procedural Steps

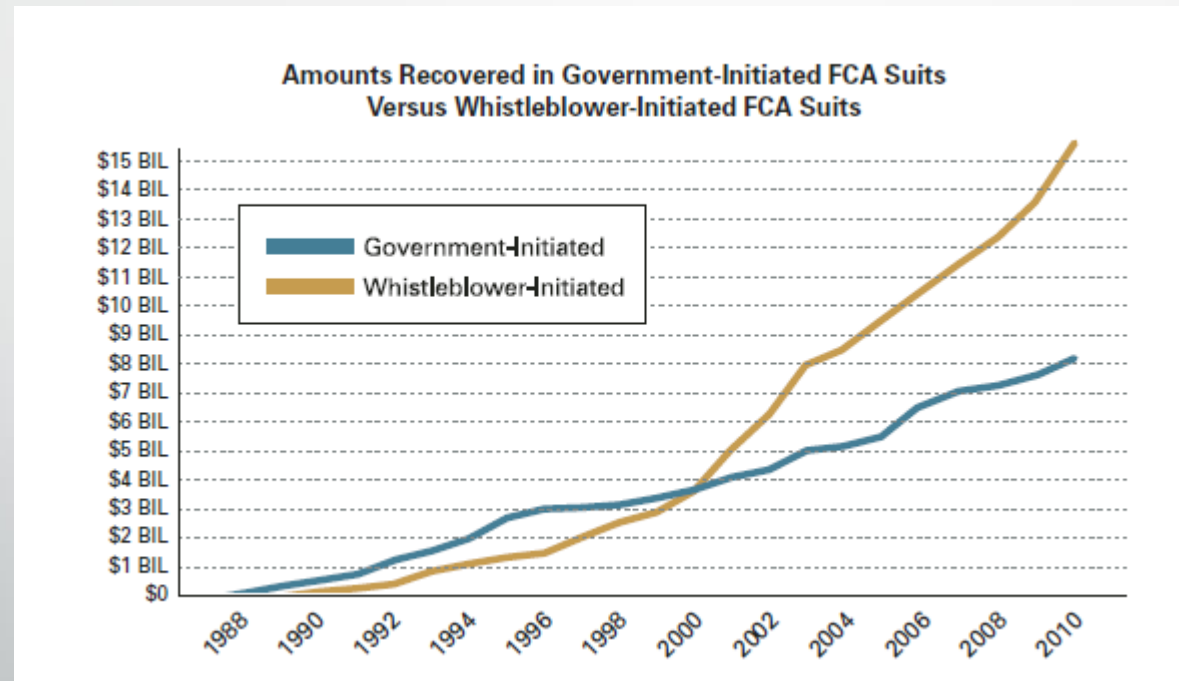




The False Claims Act, Generally Speaking

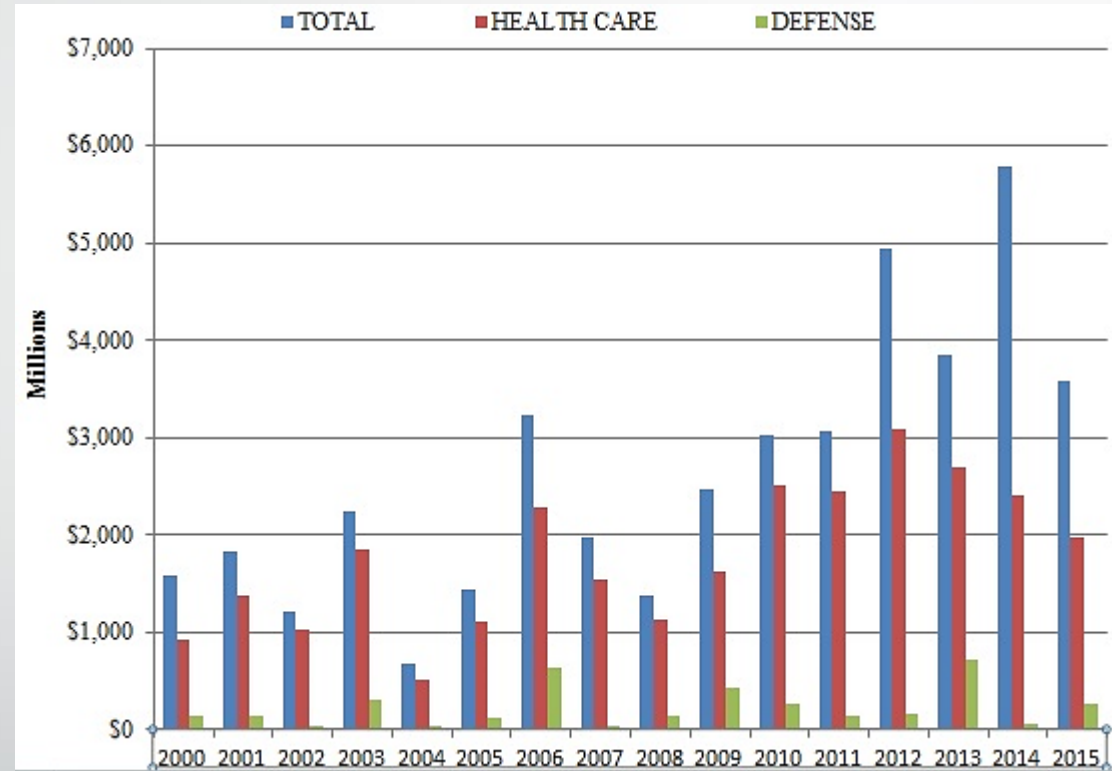
False Claims Act: Generally

- Important Tool In Fighting Government Waste, Fraud & Abuse
- Over \$40 billion recovered in 29 years



False Claims Act: Types of Cases

Source: Gibson Dunn "2015 Year-End False Claims Act Update" (January 6, 2016)



Who Can Be a Whistleblower?

Insider

Competitor

Former
Insider

Any one with
"Knowledge"

Who to Sue?



Companies



Parent Companies
(maybe)



Individuals
(maybe)



Solvent/Ability to
Collect



Co-Conspirators

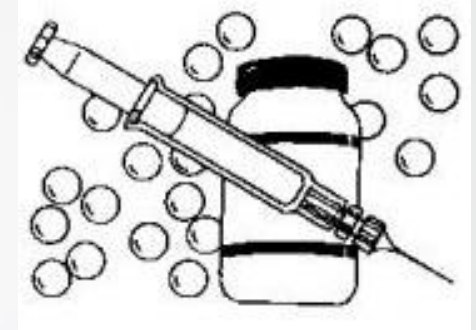


Examples of Fraud Under The False Claims Act, Specifically Speaking



Examples of Fraud Under The False Claims Act

Examples of Fraud Under the False Claims Act



- Inpatient v. Outpatient: Performing and billing procedures as inpatient procedures when the government believe they should have been performed as outpatient procedures.
- Unlicensed Billing: Billing for the services of improperly licensed personnel or for professionals excluded from participation in Medicare and Medicaid.
- Upcoding: Falsely representing that patients received a more complex or expensive service than what was actually provided.

Examples of Fraud Under the False Claims Act: Continued

- Charging For Services Or Supplies Not Provided : submitting claims to the Medicare or Medicaid for services or supplies that the provider did not deliver to a patient or beneficiary.
- Falsifying or Failing to Maintain Records : Medicare and Medicaid will only reimburse a provider for services or supplies if those services or supplies are medically necessary. Providers are required to maintain various forms of documentation demonstrating medical necessity. If a provider or supplier either falsifies those records, or fails to maintain them, then the provider may be committing fraud when it submits claims for payment to the Medicare or Medicaid.




Grant Fraud and the False Claims Act

Grant Fraud

“Northwestern University To Pay Nearly \$3 Million To The United States To Settle Cancer Research Grant Fraud Claims” – *Department of Justice.*





Kickbacks:
Payment (Kind) of Something of
“Value” In Exchange for Referrals Any

NOT KICKBACKS: *US ex rel. Shapiro v. Medtronic*

- General allegations; amounted to little more than claiming Medtronic sponsored conferences, reimbursed attendees for some expenses, provided food and promoted the devices.

KICKBACKS:

- Sham Studies
 - Biovail \$24 M Settlement in May 2008
 - Cardizem Sham Study
 - \$1000 per enrollee
 - 1 month: prescribe drug, three visits, small questionnaire
 - Stated objective accelerating uptake Rx's among doctors
- Exorbitant payments (>FMV!!) in exchange for referrals
- Employment Arrangements above FMV: *Tuomey Hospital* (verdict \$45million) and *Covenant Medical Center* (settlement \$4.5million)
- Sham Directorships: *McAllen Hospitals* (\$25 million settlement)
- Bogus Lease Arrangements: see above

Kickback Examples



Clinical Trial Billing

Clinical Trial Billing Fraud Examples

- Billing for services that are part of a non-qualifying clinical trial
- Double Billing
- Using Research Funds for Routine Care



Off-Label Marketing of Drugs



Off-Label Marketing Examples

Off-label use is the use of drugs/devices for an unapproved indication or in an unapproved age group, unapproved dosage, or unapproved form

- Drugs: *U.S. ex rel. Franklin v. Parke-Davis*: Pfizer promoted Neurotonin (indicated for seizures associated with epilepsy) for pain/psychiatric disorders
- Devices: *U.S. ex rel. Colquitt v. Abbott Laboratories*: scheme to thwart the FDA approval process for vascular stents by fraudulently obtaining FDA clearance for devices

Medical Necessity

- Billing for services that are not medically necessary
- “Objective falsity” test
- Battle of Medical Experts
- Case-by-Case File Review
- Examples:
 - Americare Ambulance: Ambulance Transports
 - Skin Cancer Center: MOHS Procedures

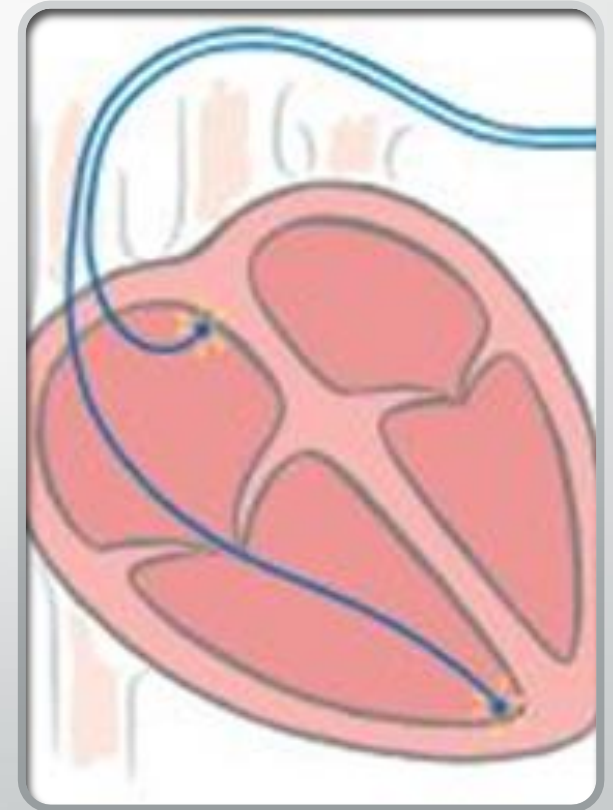
Pricing Fraud

- AWP Wholesale Litigation: Defendant Pharmaceutical Companies Inflated benchmark AWP.
- Rebate Fraud: Drug manufacturer classify drugs as generic to avoid obligation to pay higher rebates under the Medicaid Drug Rebate Program

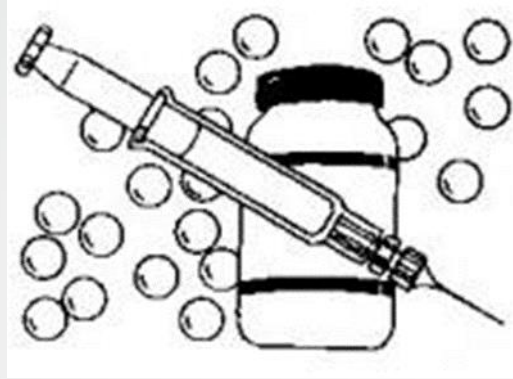


Adverse Events Reporting

- Guidant withheld information about a life-threatening defect in its implantable cardiac devices
- In June 2005, the company finally went public about the problem with information it had known for 10 months
- Settled \$30 million; \$2.25 million relator share



Fraud/Misconduct in Device Approval Process



Agilent Tech., paid \$7 million to settle allegations that it sold faulty medical monitoring devices to the government and failed to properly investigate product failures even though the company was aware of them

Commercial Good Manufacturing Practices

- If not inline with cGMP then adulterated and misbranded and not in “approved” form and ineligible for government coverage
- cGMP Violations = basis for FCA case
 - Ranbaxy – settle for \$500M in 2013
 - GSK- settle for \$750M in 2010
- UNTIL *US ex rel. Rostholder v. Omnicare* (4th Cir) February 2014
 - Repackaging in violation of cGMPs
 - Drugs were covered even if adulterated
 - FCA not a “sweeping mechanism to promote regulatory compliance”

Decision Making “Take-Aways”



Whistleblower Options

- Not Report the Fraud at All (move on or potentially commit fraud)
- Report the Fraud Internally - Company fixes the problem or explains why not fraud, Continue Fraud, Retaliation
- Report the Fraud to Government – Deal With the Consequences
- Explore Option of Filing a Whistleblower Case – Consult With Qualified Attorney Free of Charge


Pros and Cons of Filing and NOT Filing a Whistleblower Case

Pros of Filing a Whistleblower Case	Cons of Filing a Whistleblower Case
Bounty/Reward If Successful	Counterclaims (i.e., documents, trade secrets, confidentiality agreements, HIPPA)
Reputation in Field (ethical, “play by the rules,” trust)	Reputation in Field (“snitch,” no loyalty, blackballed) – but, “Jane/John Doe”
	Retaliated Against By Employer (i.e., Harassment or Termination)
Action is Taken (if fail to file and only report internally or to government – potentially no action)	Government’s Case – takes a long time, lose some control (employee liability)
Eliminates Stress (knowing fraud and not doing anything)	Time (minimal), Stress (litigation), NO COST

Traps for the Unwary

- Bankruptcy
- Divorce
- Parallel Litigation
- Lawfully Obtain Evidence
- Counter Claims
- Seal
- Severance Agreements and Release of Claims





California Insurance Fraud Prevention Act

California Insurance Fraud Prevention Act

- ~ California Private Insurance Qui Tam Statute
- allows individuals to *sue on behalf of private insurance companies*
- Similar procedurally but California Insurance Department and District Attorney
- Little Case Law Available
- See <https://nationalwhistleblowerlawyer.org/whistleblower-areas/california-insurance-fraud-prevention-act-california-qui-tam/>

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