

False Claim & *Qui Tam* Litigation Update

Representing The Whistleblower

Mass Torts Made Perfect

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FCA Liability in a Nutshell

§ 3729(a)(1)(A)&(B): 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.

§ 3729(a)(1)(G): Gives rise to liability where one acts improperly – not to get money from the government, but to avoid having to pay money to the government.

§ 3729(a)(1)(C): Creates liability for those who conspire to violate the FCA.

(§ 3729(a)(1)(D), (E), and (F) are rarely invoked)



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The False Claims Act (1863)

(FCA) 31 U.S.C. § § 3729 – 3733

Healthcare

- Drugs
- Devices
- Pricing
- Billing



Reverse False Claims

- Purposeful Avoidance of Payment

Procurement/Contracting

- Defense
- Stimulus
- Grants
- Services
- Goods



Don't forget!

State Analogue False
Claim Statutes

New Whistleblower laws on the horizon



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SEC Whistleblower?



- Dodd-Frank Act:
 - Securities
 - Commodities
 - \$1 Million+
 - Disgorge
 - Anonymity
 - Anti-Retaliation
 - Filed with SEC and CFTC
 - Appealed to US Ct. of App.
 - Backlog



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IRS Whistleblower?



- I.R.S. Whistleblower Claims:
 - \$200K income
 - \$2 Million fraud
 - No judicial oversight, unless appealed
 - Discretionary if less \$2Mill
 - Backlog



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Recent Gov't Action

Record level of revenue and enforcement 2011 & 2012

2011:

- DOJ opened 1,110 Criminal healthcare fraud investigations
- 911 new civil investigations
- 1430 Convictions
- Government's prevention efforts recovered nearly \$3.2 billion



DOJ currently has 1,873 Criminal healthcare fraud investigations pending against 3,118 potential defendants.



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2013 Enforcement & Recovery

\$3.8 Billion

- Healthcare Fraud - \$2.6 Billion
- Defense Contract Fraud = \$889 Million
- 752 Qui Tam Suits Filed
- Whistleblowers paid \$345 Million
- Since 2009 total recovery is \$17+ Billion

2012 Recovery Year was Largest in US History = **\$4.9 Billion**

- 647 Qui Tam suits resolved
- 1/3 of the Government's total recovery since 1986
- \$3.3 Billion recovered as a result of whistleblowing
- \$1.4 Billion in Housing & Mortgage Fraud



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2013 Healthcare Recovery Stats

\$2.6 Billion

- **\$12.1 Billion** federal healthcare dollars recovered since 2009
 - Does not include \$1.5 Billion settlement w/ Abbott Labs (FY 2013)
- **\$1.8 Billion** Drugs and Devices under federal healthcare programs
- Abbott agreed to **\$1.5 Billion** FCA settlement
- Ranbaxy USA paid **\$505 Million** (extra-territorial reach of FCA)
- **\$237 Million** judgment against Toumey Healthcare System Inc. (app pending)
- Tampa Pathology/Dr. Steven Wassermen paid **\$26.1 Million**



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2012 Housing Fraud Recovery Stats

Financial Fraud Enforcement Task Force:

- **\$25 Billion** Settlement between 5 banks and 49 States and the Federal Government

JPMorgan 

citigroup 

WELLS
FARGO

Bank of America 

ally

MT
MP

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2012 Housing Fraud Recovery Stats

False claims in connection with federally insured mortgages:

- **\$203.3 Million** Deutsche Bank AG
- **\$158.3 Million** CitiMortgage, Inc.
- **\$132.8 Million** Flagstar Bank



2012-2013 Procurement Recovery Stats

2012 = \$427 Million & 2013 = \$887 Million

Recovered in false claims involving goods or services purchased by the federal government.

- **\$73 Million** related to Iraq and Afghanistan:
 - \$37 Million against ATK Launch Systems, faulty flares
 - \$31.9 Million against Mearsk, overcharging of troop transport
- 2013: Record Year! Largest FCA judgment in history against United Technologies Corp. \$664 Million.
- General Services Admin. & Multiple Award Schedule Frauds (See WW. Grainger , et al)



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2012 Procurement Recovery Stats

\$200 Million against Oracle

failure to provide best price for software licenses

The largest General Services Contract recovery in history!



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Why the uptick?

Health Care Fraud Prevention & Enforcement Action Task Force

H.E.A.T

- New state-of-the-art technology to fight fraud (Pattern Analysis)
- Expanded data sharing procedures between HHS and DOJ.
- Outreach meetings with top anti-fraud leaders in congress, law enforcement, health care providers and the private sector
- New funding to monitor Medicare Parts C & D compliance and enforcement.
- Expansion of the CMS Medicaid provider audit program
- Use of Web-based reporting systems (StopMedicareFraud.Org)



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Expanding Scope of Enforcement

- Ink S.C. Holdings Co. Ltd. (\$45 Million):
 - *“Country of Origin Fraud”*
- Education Holdings Inc. (\$10 Million):
 - *“Princeton Review” Dept. of Educ. Grant Fraud*
- Fraud Enforcement & Recovery Act (FERA 2009)
 - *“Settling In” to the scope an applicability FERA*
- Affordable Care Act (ObamaCare, 2010)
 - *Contains significant fraud counter measures*



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Healthcare Cases

Medical Services Fraud

- Illegal Kickbacks
- Self Referral Violations
- Up-coding
 - Services
 - Durable Medical Equip. (DME)
- Over Treatment
- Unqualified Personnel
- Simple Billing Fraud
 - Services Not Performed
 - Double Billing



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Healthcare Cases

Pharma/Device Fraud

- Off-label Marketing
 - False Claims
 - Drugs & Devices
- Overpricing
 - Drugs & Devices
- Prescription Fraud
 - Counterfeit Drugs
 - Fraudulent Rx Filling/Billing



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Where Healthcare Fraud Occurs

(AKA Potential Defendants)

- Hospitals
- Surgical Centers
- Laboratories
- Doctor's Offices/Clinics
- Rehabilitation Centers
- Chiropractic Practices
- Hospice Facilities
- Nursing homes (OIG Report 11-9-12, 25% of all claims false!)
- Inside Patient's Homes

Often, the scheme will involve multiple entities = conspiracies



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The Victims

1. Tax Payers

- a) Via Government Insurance Programs
 - i. Medicaid
 - ii. Medicare
 - iii. TRICARE
 - iv. Federal Employees Health Benefits Programs (FEHBP)
 - v. Veteran's Affairs Health Benefits
 - vi. Worker's Compensation
 - vii. Bureau of Prisons



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The Victims

2. The Whistleblower

- a) Retaliation and Blacklist
- b) Force to choose between career and principles
- c) Required silence to preserve the seal
- d) Anti-Retaliation provisions allow double back pay, costs, interest and attorneys' fees



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Recent Device Kickback Recoveries

(2009-2011)

- Medtronic (2011) Pacemakers.....\$23.5 Million
- St. Jude Medical, Inc. (2011) Inducement.....\$16 Million
- Exactech, Inc. (2010) Sham Consulting.....\$3 Million
- Kos Pharma (2010) pay to play.....\$41 Million
- Amentox, Ltd, (2010) referral buying.....\$16.5 Million
- ELA Medical (2010) referral buying.....\$9.2 Million
- Wright Medical (2010) Sham Consulting.....\$7.9 Million
- General Electric (2010) Iraqi HC Bribes.....\$23.4 Million
- United Shockwave/Urology (2010) referral buying.... \$7.4 Million
- St. Jude Medical, Inc. (2010) rebate scam.....\$3 Million
- AtriCure, Inc. (2010) Sham Consulting.....\$3.76 Million
- Cardia Monitoring Services (2010).....\$2.23 Million
- St. Jude Medical, Inc. (2010) Faked Studies.....\$16 Million
- Boston Scientific, Inc. (2009) pay to play.....\$22 Million



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Recent Pharma False Claim Recoveries (2009-2013)

- GSK (Avandia/Welbutrin/Paxil).....\$3 Billion
- AstraZeneca (Seroquel).....\$520 Million
- McKesson (Inflated AWP).....\$190 Million
- Johnson & Johnson (Risperdal).....\$2.2 Billion
- Abbott Labs (Depakote).....\$1.5 Billion
- Eli Lilly (Zyprexa).....\$1.4 Billion
- Kos Pharma (Advicor).....\$41 Million
- DAVA Pharma (Rebate Fraud).....\$11 Million
- KV Pharma (False Inclusion).....\$17 Million
- DFB Pharmaceuticals (Xenaderm).....\$48 Million
- Abbott Labs (Depakote).....\$1.5 Billion
- Amgen, Inc.....\$762 Million
- Ranbaxy, USA.....\$505 Million
- J&J (Risperdal, et al).....\$2.2 Billion



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Tip of the Iceberg

The past years' gross recoveries represent less than 5% of the **\$120 Billion** in Healthcare fraud that occurs annually.

Even with the increased federal effort, state and federal entities lack sufficient resources to pursue the most egregious and sophisticated fraudsters.

The only fraud that the government seeks to address without the assistance of Private Counsel are the cases of "Naked Fraud".

Billing for Services Not Rendered

Simply billing for clients never treated. Therefore, the majority of complex fraud remains unaddressed by the government; the need for whistleblowers and their private counsel is greater than ever!



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It's all about Placement and Partnership

Know your venues and establish a strong partnership with the Government

1. Broad venue rule: Wherever a defendant can be found, resides, transacts business, or where false claims were submitted.

2. Know the venue and the AUSA!

- Local Counsel
- Will the AUSA push the case?
- Is there a public health or safety risk?
- Is there a national security threat?
- File the "righteous" case.

3. Present the case in advance, if possible.

4. Routinely communicate, update and participate.



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Protecting Your Clients

Whistleblower v. Defendant v. Government

1. Don't go public, if necessary weigh your client's culpability
2. Choose the proper partner/venue
3. Qualify your client as an "original Source"
4. Disclose the case to the Government
5. Prepare & serve a thorough, accurate and encompassing declaration.



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Protecting Your Clients

Whistleblower v. Defendant v. Government

6. File first, earn standing
7. File under seal and protect the confidentiality of the case
8. Plead all analogous state-based claims too!
9. Plead with specificity: FRCP 9b applies!
10. Keep investigating & cooperate



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Protecting Your Clients

Whistleblower v. Defendant v. Government

11. Work to develop the damages theories
12. Prepare for retaliation
13. Prepare for trial, earn & protect the Relator's share



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Risks & Pitfalls

Whistleblower suits are not a slam-dunk!

1. Ever-changing Political Environment:
 - A. Concerted effort to thwart federal/state retention of private counsel.
 1. Transparency in Private Attorney Contracting (TIPAC)
 2. Private Attorney Retention Sunshine Act (PARSA a.k.a. ALEC)
2. Government declines to intervene = 75%
3. Pending Actions RE: Constitutionality of Contingency Fees in Quasi-Criminal Actions: South Carolina, Kentucky & Louisiana.



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Risks & Pitfalls

Whistleblower suits are not a slam-dunk!

4. Requires a long-term investment by a firm (2-5 years for results)
5. Defense costs can be assessed to the Relator. “Clearly Vexatious” Standard
6. Malpractice Pitfalls: Presentment, Protection, Performance, Payment.



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Recent Cases and Decisions

Takeda Pharmaceuticals North America, Inc. x 2

1. *U.S. ex rel. Nathan v. Takeda Pharmaceuticals N.A.* (No. 11-2077, 4th Cir. 2013): Off-Label Marketing Case (Kapidex) Sales Rep Relator
 - Fourth Circuit rejected suit because no specific reimbursement claims submitted to Medicare. Rule 9b & Causation.
 - Court required specific allegations, cannot rely on statistics for information.
2. *U.S. ex rel. Helen Ge v. Takeda Pharmaceuticals N.A.* (1:11-cv-10343-FDS Document 43, Dismissal granted 11/01/12). Failure to Report Accurate Risk Data.
 - Whistleblower Dr. Helen Ge was a reviewer in the pharmacovigilance division.



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Recent Cases and Decisions

- *U.S. ex rel. Benjamin Carter v. Halliburton et al.* (1:11-cv-00602-JCC-JFA) March 18, 2013. tolling of FCA SOL
- Wartime Enforcement Fraud Act of 2008, S. Rep. No. 110-431. Tolls SOL of FCA (6 years from act, 3 years from disco.) The WSLA was enacted in 1942 to extend the time for prosecution to bring charges relating to criminal fraud offenses against the United States during times of war.

“Courts are in disagreement as to which version of the WSLA applies to offenses that occurred before the amendments of 2008. Additionally, courts are in conflict as to whether the pre-amendment WSLA requires a formal declaration of war or whether the authorized use of military force shall suffice.”

“The WSLA tolls the applicable period for a specified and bounded time while the country is at war”



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Recent Cases and Decisions

- *U.S. ex rel. Karen Hobbs v. MedQuest Assoc., Inc. et al.* (6th Cir. April 1, 2013).
 1. Conditions of participation in Medicare are different than conditions of payment by Medicare.
 2. “Medically necessary care provided by a qualified physician.”
 3. No FCA violation in the absence of a regulation conditioning payment on accurate, updated enrollment information reflecting current practice ownership.
 4. 8th Amendment Appeal: Excessive Fines, Cruel & Unusual Punishment.



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Recent Cases and Decisions Cont.

- **U.S. Ex Rel. Lesinski v. South Florida Water Mngmt Dist.**
 - (2014 U.S. App LEXIS 14):
 - 11TH Cir. Ct. of App. Affirmed the dismissal of qui tam suit filed against SFWM because the entity was not a “person” as defined by the FCA and that in determining whether an entity is a “person” the “arm of the state test should be applied.
 - “Arm of the State” Tests Factors:
 - How state defines the entity;
 - Degree of state control;
 - Source of funding for entity;
 - Who bears responsibility for judgment against the entity.



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How can I get involved?

Always Consider the False Claim Potential:

*Drugs, Devices, Products, Services, Grants, Loans,
Reimbursements, Taxes, Accounting Measures.*

Add Two Questions to Your Client Questionnaires:

1. Do you work for a company or business that contracts with or sells anything to any governmental office or agency?
2. If so, are you aware of any suspicious, fraudulent or wrongful activities or billings involving the government??

www.sheller.com

www.pathtojustice.com

www.lwanttoreportfraud.com



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