Hot Topics in the False Claims Act

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The views of the government attorneys as expressed in this presentation are their own personal views and do not necessarily express the views of the Department of Justice or US Attorney's Offices.

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The Role of Counsel
Whistleblower, United States, Defendant

- **Matthew Organ**
  - Principal, Goldberg Kohn Ltd.
  - Represents whistleblowers reporting alleged FCA violations
- **Sarah Bogni**
  - Assistant U.S. Attorney, Department of Justice
  - Investigates and prosecutes alleged FCA violations
- **J.D. Thomas**
  - Partner, Waller
  - Defends businesses and individuals accused of FCA violations

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False Claims Act Statistics

- Qui Tam Filings:
  - 1987: 30
  - 1997: 547
  - 2007: 365
  - 2017: 674
- Qui Tam Settlements and Judgments:
  - 1987: 0
  - 1997: $627,940,474
  - 2007: $1,411,973,849
  - 2017: $3,702,620,187
- Notes:
  - Relator share awards were $392,959,388 in 2017
  - Only 11% of recoveries in 2017 came through cases the United States declined
  - Recoveries and filings have steadied over the past five years:
    - Filing "high mark" of 756 in 2013
    - Recovery "high mark" of $6,144,268,085 in 2014

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False Claims Act Statistics - Healthcare

- Qui Tam Filings:
  - 1987: 3 (10%)
  - 1997: 269 (49%)
  - 2007: 199 (54%)
  - 2017: 491 (73%)
- Qui Tam Settlements and Judgments:
  - 1987: 0
  - 1997: $579,079,581 (92%)
  - 2007: $1,082,072,486 (77%)
  - 2017: $2,444,491,192 (66%)
- Notes:
  - Relator share awards were $282,835,584 in 2017 (72%)
  - Only 16% of recoveries in 2017 came through cases the United States declined
  - Recoveries and filings have steadied over the past five years:
    - Filing "high mark" of 504 in 2013
    - Recovery "high mark" of $3,099,971,931 in 2012

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Hot Topics

- Legal Issues:
  - Does the alleged violation matter to the government? Materiality
  - Does the Complaint have enough detail? Fed. R. Civ. P. 9(b)
  - Medical Necessity and Objective Falsity
  - Scienter - Did the Defendant have the requisite intent?
  - Do recent Department of Justice memos change the landscape?
- Recent Settlements
- Practical Issues

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Universal Health Services v. Escobar

"Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material"

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Escobar and Aftermath

- *Escobar* holding erased $348M FCA verdict in *US ex rel. Ruckh v. CMC II LLC et al.* (M.D. FL 2018)
  - *Ruckh* involved appropriate billing levels for therapy services and declined *qui tam* action arising from inflated Resource Utilization Group scores (among other claims)
  - District Court set aside $350 million judgment because relator failed to offer evidence of materiality, in that the evidence "shows not a single threat of nonpayment, not a single complaint or demand, and not a single resort to an administrative remedy or other sanction for the same practices that result in the enormous verdict at issue."
  - On appeal to the Eleventh Circuit, motion to dismiss filed by Consulate nursing home chain, because whistleblower sold some of her interest in the case's outcome to finance it
  - Government (which had not intervened in the *qui tam*) supports relator's effort to revive it, claiming district court "fundamentally misunderstood FCA standards," and the decision "threatens important government interests in remedying and deterring fraud"
- But see *US ex rel. Campie v. Gilead Scis.* (continued payment not dispositive) (cert pending)

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Materiality

- *US ex rel. Escobar v. Univ. Health Servs.* (1st Cir. 2016) (on remand, affirming prior holding of materiality found where a reasonable person would expect healthcare workers to have required qualifications)
- *US ex rel. Prather v. Brookdale* (6th Cir. 2018) (reversing district court based on sufficient pleading of materiality regarding timing of need certifications)
- *United States v. Luce* (7th Cir. 2017) (materiality found where owner of mortgage originator falsely certified that he had no criminal record; he could not have done business with the government without the certification and, when the government learned the true facts, it terminated his eligibility to participate in the program)

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Materiality

- *United States v. Triple Canopy, Inc.* (7th Cir. 2017) (on remand, affirming prior holding that misrepresentation that guards could "shoot straight" was material, based on "common sense" and defendant's efforts to cover up noncompliance)
- *US ex rel. Miller v. Weston Educ., Inc.* (8th Cir. 2016) (on remand, reversing prior result by finding that failure to keep accurate records was material in fraudulent inducement case, where a reasonable person would attach importance to promise to keep accurate records and where agency had history of policing violations)
- *US ex rel. Campie v. Gilead Scis.* (9th Cir. 2017) (materiality found for GMP violations, despite FDA approval and continued payment; court warned that "read[ing] too much into the FDA's continued approval…would be a mistake") (cert pending)

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No Materiality

- *US ex rel. Petratos v. Genentech Inc.* (3d Cir. 2017) (no materiality where relator "essentially concedes that CMS would consistently reimburse these claims with full knowledge of the purported noncompliance")
- *US ex rel. Spay v. CVS Caremark* (3d Cir. 2017) (no materiality for dummy identifiers in Part D claims because agency regularly paid claims with actual knowledge of use of dummy identifiers as a work-around)
- *Abbott v. BP Exploration & Prod.* (5th Cir. 2017) (no materiality where allegations led to Congressional hearings, a DOI investigation, and report that found the allegations "without merit" and "unfounded")
- *US ex rel. Harman v. Trinity Indus.* (5th Cir. 2017) (no materiality where agency was aware of noncompliance and in an official memorandum states that the product is nevertheless eligible for payment) (cert pending)

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No Materiality

- *United States v. Sanford-Brown, Ltd.* (7th Cir. 2016) (on remand, affirming prior holding on lack of materiality and finding violation of incentive compensation ban was immaterial where agency examined defendant "multiple times over" and continued to pay)
- *US ex rel. Kelly v. Serco, Inc.* (9th Cir. 2017) (no materiality where government knew of and agreed to defendant's use of noncompliant reporting process, accepted the reports, and paid defendant for its work)
- *US ex rel. McBride v. Halliburton Co.* (D.C. Cir. 2017) (no materiality where false data did not affect costs billed; government investigated relator's allegations and did not disallow costs, and thereafter awarded fee for exceptional performance)

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Rule 9(b): What does it mean to plead fraud with particularity?

- Fourth, Sixth, Eighth, Eleventh Circuit
  - Whistleblowers must identify specific billing claims they allege to be fraudulent
  - First Circuit applied exception to strict standard, if there exists "statistical certainty" of false claims
  - *US ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29 (1st Cir. 2017) (cert denied) (finding that the relators fit into the "more flexible" approach used when evaluating the sufficiency of fraud pleadings in connection with indirect false claims for government payment where the complaint essentially alleged facts showing that it was statistically certain that defendant caused third parties to submit false claims to the government)
  - *US ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905 (6th Cir. 2017) (cert denied) (affirming the dismissal of a *qui tam* action under the FCA that alleged Bristol-Myers Squibb engaged in a nationwide scheme to promote off-label uses of an anti-psychotic drug, because relator failed to allege an entire causal chain including (1) improper promotion to a specific doctor, who (2) prescribed the drug to a particular patient, who (3) had the prescription filled at a pharmacy, that (4) submitted a claim for reimbursement)

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Rule 9(b): What does it mean to plead fraud with particularity?

- Second, Fifth Circuit
  - Relator need not plead details of specific alleged false billings, only allege facts leading to a strong inference that specific claims were submitted and that information about them are peculiarly within the defendant's knowledge
  - *Chorches v. American Medical Response, Inc.*, 865 F.3d 71 (2d Cir. 2017) (where complaint set forth specific instances in which defendant's supervisors required that records be falsified so that reimbursable claims could be submitted to Medicare, the court found that, "in alleging that supervisors specifically referenced Medicare as the provider to whose requirements the allegedly falsified revisions were intended to conform, the [complaint] supports a strong inference that false claims were submitted to the government")

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Rule 9(b): What does it mean to plead fraud with particularity?

- Tenth Circuit
  - Seemingly an exception to 9(b) standard: can "excuse deficiencies" if relator does not have enough access to crucial information
- *Polukoff v. St. Marks Hosp.* (10th Cir. 2018)
  - Declined *qui tam* action alleging unnecessary patent foramen ovale closure procedures
  - Defendant argued he believed the procedures were necessary to treat migraines and prevent strokes
  - District Court concluded that absent a specific regulation addressing the necessity of the treatment, a physician's medical judgment concerning the necessity of a treatment could not be "false or fraudulent" under the FCA
  - Tenth Circuit reversed, holding that "a doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase [in the Medicare Program Integrity Manual]."

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United States v. Paulus (6th Cir. 2018)

- Cardiologist convicted of criminal healthcare fraud for exaggerating the extent of blockages he saw on angiograms to justify stents
- Defendant argued that his angiogram interpretations were reasonable
- Also claimed that since angiogram interpretation is subjective and can be interpreted differently by different physicians, it cannot be shown his interpretation was false
- Sixth Circuit rejected the argument, holding that weighing the views of competing experts was the providence of the jury

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False Claims Act – Scienter

- Deliberate ignorance and the duty of reasonable inquiry
  - *US ex rel. Swoben v. Secure Horizons* (C.D. Cal. 2017) (defendant paid $270M to settle FCA liability for providing inaccurate information that cause Medicare Advantage Plans to receive inflated Medicare payments)
  - *US v. Scan Health Plan et al.* (C.D. Cal. 2017) (granting defendant's motion to dismiss because the suit was too vague, did not show intentional wrongdoing, and did not show that the government would have withheld payment if it had been aware of the alleged violations – specifically, it "fail[ed] to allege that [Medicare] would have refused to make risk adjustment payments to [UnitedHealth] if it had known the facts about [UnitedHealth's] alleged involvement with the Healthcare Partners' chart review process")
- Reverse false claims and knowledge of the underlying obligation
  - *US ex rel. Harper v. Muskingum Watershed Conservancy District* (6th Cir. 2016) (relators failed to allege requisite knowledge where defendant did not act "knowingly," which requires "both the existence of a relevant obligation and the defendant's own avoidance of that obligation.")

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False Claims Act – Scienter

- Reasonable interpretation of ambiguous rule
  - *US ex rel. Purcell v. MWI Corp.* (D.C. Cir. 2015) (reversing multimillion dollar jury verdict for government and holding there can be no violation of the FCA where (1) the law or regulation at issue is ambiguous, (2) the defendant's interpretation of that language is reasonable, and (3) the agency issued no formal or official guidance indicating that the defendant's interpretation is wrong)
- Advice of counsel
  - *US ex rel. Kieff v. Wyeth* (D. Mass. 2016) (finding courts may compel attendance from witnesses from anywhere in the United States for civil FCA cases if good cause is shown)
- Government knowledge
  - *US ex rel. Harman v. Trinity Industries* (5th Cir. 2017) (reversing $663M judgment for allegedly misleading the government by selling unsafe highway guardrails, and finding no liability for defendant because the government continued paying for the guardrails after it learned of the alleged fraud)

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US ex rel. Streck v. Allergan (3d Cir. 2018)

- Declined *qui tam* action arising from exclusion of certain credits in the calculation of "Average Manufacture Price"
- "Basing a defense on a reasonable, but erroneous, interpretation of a statute includes three distinct inquiries:
  1) whether the relevant statute was ambiguous
  2) whether a defendant's interpretation of that ambiguity was objectively unreasonable; and
  3) whether a defendant was 'warned away' from that interpretation by available administrative and judicial guidance."

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Limiting FCA Liability

- *US ex rel. Ribik et al. v. HCR ManorCare* (E.D. VA 2017)
- In 2015, DOJ brought massive FCA action against skilled nursing facility giant HCR ManorCare, alleging six-year scheme to provide unnecessary therapy services
- Case sought to extrapolate sample of 180 claims to universe of 250,000 claims; ultimately found to be entirely dependent on testimony of one nurse from Advancemed
- Discovery took 2.5 years, dozens of experts, and nurse found to have "utter lack of credibility" having lied about existence of notes
- "I don't think this case should have ever been brought. I have looked at this stuff, and I'm appalled, I'm embarrassed, I'm ashamed that [DOJ] would rely on this kind of nonsense…" US Magistrate Judge Theresa Carroll Buchanan, E.D. VA

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DOJ Motion to Dismiss *Qui Tam*

- 21 U.S.C. § 3730(c)(2)(A)
  - "The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion."
- Courts are split on what standard to apply
  - *US ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.* (9th Cir. 1998) (government must show a "valid government purpose" the accomplishment of which is rationally related to dismissal)
  - *Swift v. United States* (D.C. Cir. 2003) (government has an "unfettered right" to dismiss an FCA action under § 3730(c)(2)(A))

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Granston Memo

- January 10, 2018 memo by Michael Granston, Director of DOJ's Commercial Litigation Branch, outlines factors DOJ should consider in deciding whether to seek dismissal (notwithstanding view of relator) including:
  - Curbing meritless *qui tam* actions
  - Preventing parasitic or opportunistic *qui tam* actions and controlling litigation
  - Preventing interference with agency policies and programs
  - Certain procedural and policy concerns

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Brand Memo

- January 25, 2018 memo by Rachel Brand, then the Associate Attorney General:
  - Reminds DOJ litigators that agency guidance documents (as opposed to regulations) "cannot create binding requirements that do not already exist by statute or regulation."
  - Declares that DOJ "may not use its enforcement authority to effectively convert agency guidance documents into binding rules."
  - Instructs DOJ litigators that they "may not use noncompliance with guidance documents as a basis for proving violations of applicable law"
  - Explains that guidance may still be used to "simply explain" existing legal mandates, and as evidence that a party had the requisite knowledge of those mandates

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Noteworthy FCA Settlements (>$20M)

- June 2018: SNF operator Signature HealthCARE LLC agrees to $30M FCA settlement
- March 2018: Alere to pay $33M to resolve FCA allegations involving faulty testing device
- January 2018: Dental management company Benevis and affiliate Kool Smiles pay $23.9M to settle FCA allegations relating to medically unnecessary pediatric dental services
- October 2017: Hospice provider Vitas Hospice Services LLC agrees to $75M FCA settlement

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More FCA Settlements (<$20M)

- July 2018: NY medical device maker AngioDynamics resolves FCA allegations for $12.5M
- June 2018: Hospice chain Caris to pay $8.5M to resolve FCA allegation
- May 2018: NY urgent care practice pays $6.6M in Medicare fraud case
- April 2018: RoTech pays $9.68M to resolve whistleblower allegations
- January 2018: NY home care service to pay $6.4M in fraud settlement
- November 2017: NY Catholic system to pay $6M in fraud case
- October 2017: SC hospital to pay $7M to resolve Medicare billings case

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US ex rel. Silver v. Omnicare, Inc. (3d Cir. 2018)

- Public disclosure bar is not triggered when a relator "relies upon non-public information to make sense of publicly available information, where the public information—standing alone—could not have reasonably or plausibly supported an inference that the fraud was in fact occurring."
  - Revived March 2011 *qui tam* filed against PharMerica by whistleblower Marc Silver
  - Swapping allegation: company reportedly agreed to provide drugs to nursing home Part A patients at low per-diem rates (as little as $8 per day) in exchange for opportunity to provide drugs at a higher cost to the nursing home's Medicaid and Medicare Part D patients

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Practical Issues

- Settlement
  - United States approval is required in declined cases
  - Relators attorneys' fees
  - Multiple relator issues
    - Attorneys fees for multiple relators
    - *United States ex rel. Doghramji v. Community Health Sys. Inc.*, 2018 WL 4148840 (M.D. Tenn. Aug. 30, 2018)
- Relationships
  - United States and Relator
  - United States and Defendant
  - Defendant and Relator

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Questions?

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Thank You

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