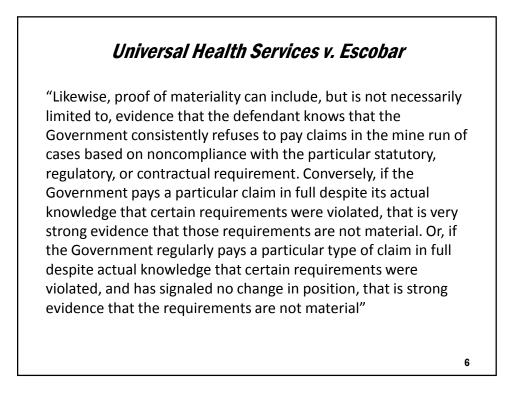
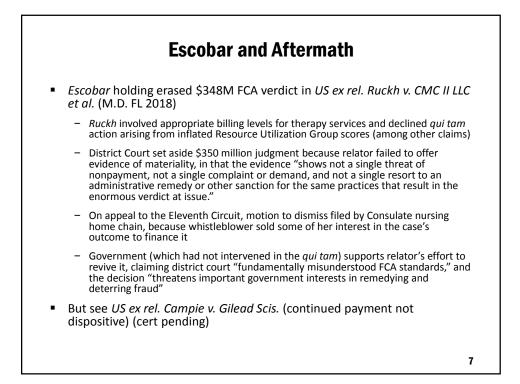
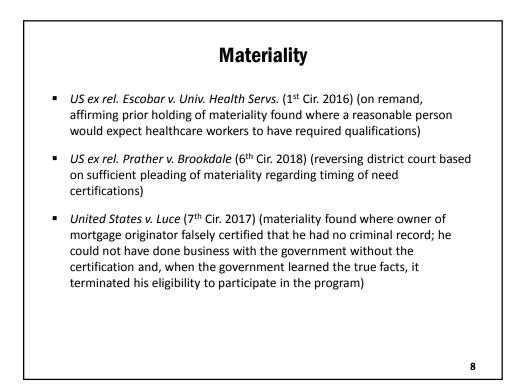


## Hot Topics Legal Issues: Does the alleged violation matter to the government? Materiality Does the Complaint have enough detail? Fed. R. Civ. P. 9(b) Medical Necessity and Objective Falsity Scienter - Did the Defendant have the requisite intent? Do recent Department of Justice memos change the landscape?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







# *United States v. Triple Canopy, Inc.* (7<sup>th</sup> 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.* (8<sup>th</sup> 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 istory of policing violations) *US ex rel. Campie v. Gilead Scis.* (9<sup>th</sup> 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**

- United States v. Sanford-Brown, Ltd. (7<sup>th</sup> 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. (9<sup>th</sup> 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 (1<sup>st</sup> 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 (6<sup>th</sup> 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)

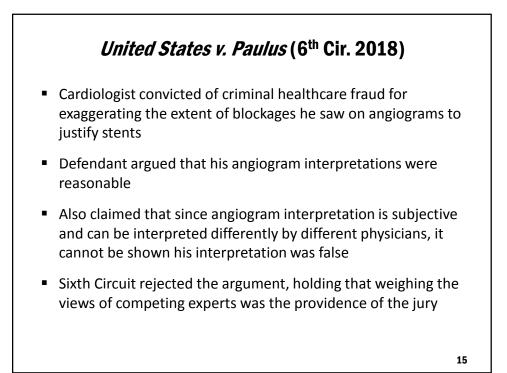
### Rule 9(b): What does it mean to plead fraud with particularity?

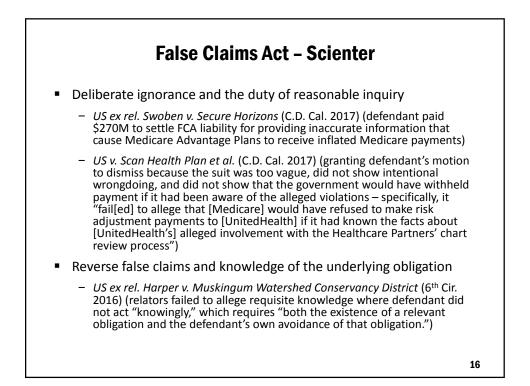
- Second, Fifth Circuit
  - Relator need not plead details of specific alleged false billings, only allege facts leading to a strong inference that specific claims were submitted and that information about them are peculiarly within the defendant's knowledge
  - Chorches v. American Medical Response, 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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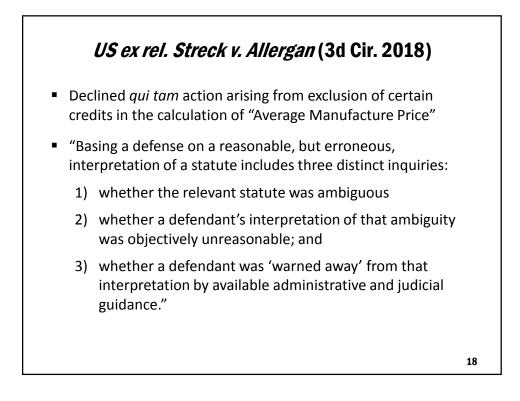
### Rule 9(b): What does it mean to plead fraud with particularity?

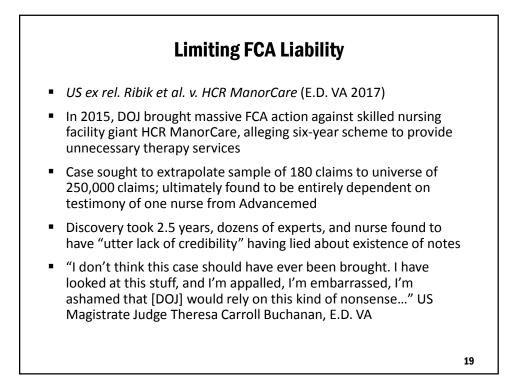
- Tenth Circuit
  - Seemingly an exception to 9(b) standard: can "excuse deficiencies" if relator does not have enough access to crucial information
- Polukoff v. St. Marks Hosp. (10<sup>th</sup> Cir. 2018)
  - Declined *qui tam* action alleging unnecessary patent foramen ovale closure procedures
  - 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]."

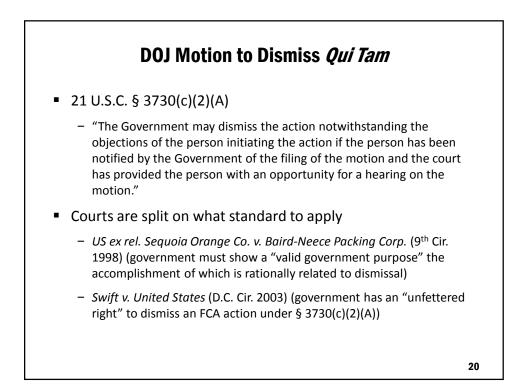




### **False Claims Act – Scienter** Reasonable interpretation of ambiguous rule - US ex rel. Purcell v. MWI Corp. (D.C. Cir. 2015) (reversing multimillion dollar jury verdict for government and holding there can be no violation of the FCA where (1) the law or regulation at issue is ambiguous, (2) the 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)



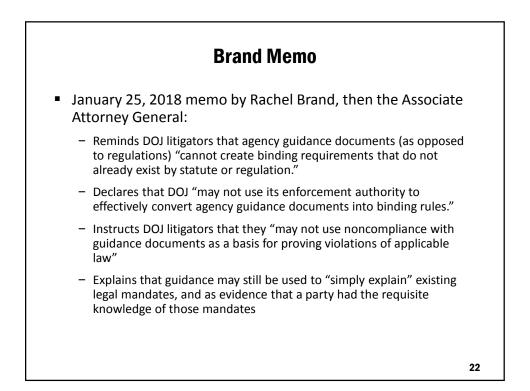


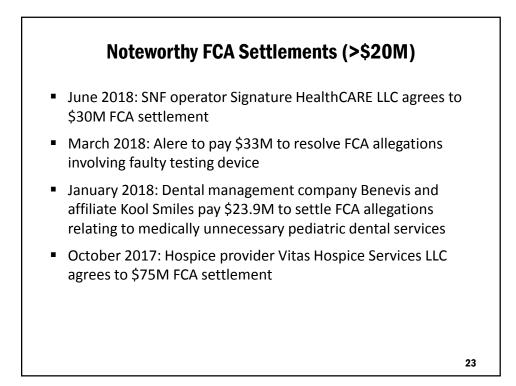


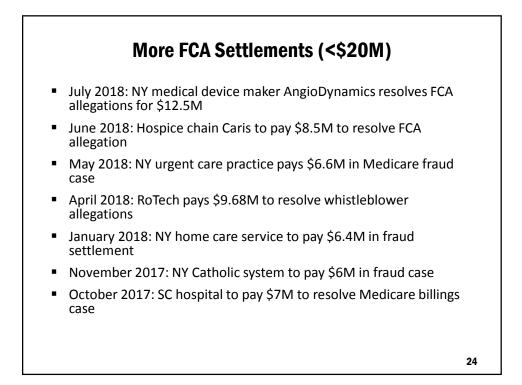
### **Granston Memo**

- 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









## 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 perdiem 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

