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# Implied Certification Liability Under the FCA: Guidance for Healthcare Counsel to Navigate the Circuit Split

Minimizing the Likelihood of Penalties, Cost of Litigation and Damages; Ensuring Regulatory or Contractual Compliance

THURSDAY, FEBRUARY 4, 2016

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Today's faculty features:

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# Implied Certification Liability Under the FCA: Guidance for Healthcare Counsel to Navigate the Circuit Split

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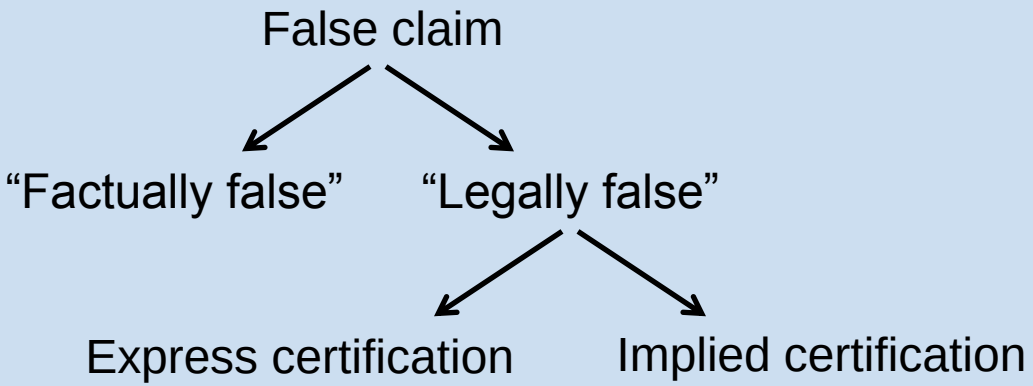
February 4, 2016

# Implied Certification Theory




- Under the "implied certification theory" of FCA liability, a person who submits a claim for payment to the government impliedly certifies that the party has complied with all applicable statutory, regulatory, and contractual requirements.
- Thus, the United States or a relator may allege that any failure to comply with the myriad of applicable statutory, regulatory, and contractual requirements is an FCA violation because compliance with those requirements is a "condition of payment."

# Conditions of Participation vs. Conditions of Payment

***The success of a false certification claim depends on whether it is based on "conditions of participation" in the Medicare program (which do not support an FCA claim) or on "conditions of payment" from Medicare funds (which do support FCA claims).***

- *United States ex rel. Hobbs v. MedQuest Associates, Inc.* (6th Cir. 2013)

***A provider's compliance with the [conditions of participation] COPs is determined by the CMS Regional Office based on the State survey agency recommendation. If during a review, any contractor believes that a provider does not comply with conditions of participation, the reviewer shall not deny payment solely for this reason.***

- Centers for Medicare & Medicaid Services, Medicare Program Integrity Manual

# Conditions of Participation vs. Conditions of Payment, cont'd

- Conditions of Participation
  - Requirements imposed by statute, regulation, or contract as preconditions to participation in a federal government program (*e.g.*, Medicare) in the first instance.
  - For example, CMS has promulgated minimum health and safety standards applicable to most health care organizations that provide patient care to Medicare beneficiaries (*e.g.*, Reform of Hospital and Critical Access Hospital Conditions of Participation, 42 C.F.R. §§ 482, 485 (2012)).
- Conditions of Payment
  - Requirements imposed by statute, regulation, or contract as preconditions to reimbursement under a federal government program.
  - For example, the Sixth Circuit in *Hobbs* identified the provision in 42 C.F.R. § 410.33(a) that "carriers will pay for diagnostic procedures under the physician fee schedule only when performed by a physician, a group practice of physicians, . . . or an independent diagnostic testing facility," as a condition of payment.

# Circuit Split

- Circuit split as to the scope and validity of the implied certification theory:
  - The First, Second, Third, Fourth, Sixth, Ninth, Tenth, Eleventh, and D.C. Circuits have found that implied certification is a valid theory of FCA liability.
  - The Fifth and Seventh Circuits have found that implied certification is not a valid theory of FCA liability.

# Expansive Views of Implied Certification

- *United States ex rel. Hutcheson v. Blackstone Med., Inc.* (1st Cir. 2011)
  - Favorably cited the D.C. Circuit's 2010 decision in *United States v. Sci. Applications Int'l Corp.* to reject the argument that FCA liability requires "the existence of express contractual language specifically linking compliance to eligibility for payment."
  - Refused to "adopt any categorical rules as to what counts as a materially false or fraudulent claim under the FCA."
  - The court focused on whether the claims misrepresented compliance with a precondition of payment and whether the misrepresentations were material.
    - Found that in this case, the Provider Agreements and Hospital Cost Reports drafted by CMS make "clear" that compliance with the Anti-Kickback Statute is a precondition of Medicare payment.
  - Expanded scope of liability to include non-submitting parties, holding "[w]hen the defendant in an FCA action is a non-submitting entity, the question is whether the entity knowingly caused the submission of either a false or fraudulent claim or false records or statements to get such a claim paid."

# Restrictive Adoption of Implied Certification

- *Mikes v. Straus* (2d Cir. 2001)
  - The FCA "was not designed for use as a blunt instrument to enforce compliance with all medical regulations – but rather only those regulations that are a precondition to payment – and to construe the impliedly false certification theory in an expansive fashion would improperly broaden the [FCA's] reach."
  - Allowing relators to bring FCA claims for alleged failures to meet a medical standard of care would "promote federalization of medical malpractice, as the federal government or the *qui tam* relator would replace the aggrieved patient as plaintiff."
  - But the theory can apply in limited circumstances where a statute or regulation expressly requires compliance as a condition of payment.
  - Found that the Medicare statute conditions payment on services that are medically necessary, but does not condition payment on services meeting a particular standard of care.

# Restrictive Adoption of Implied Certification, cont'd

- The Sixth Circuit in *Chesbrough v. VPA* (2011) similarly recognized the implied certification theory while limiting its use in the healthcare context.
  - Medicare "does not require compliance with an industry standard as a condition to payment."
  - "[R]equesting payment for tests that allegedly did not comply with a particular standard of care does not amount to a 'fraudulent scheme' actionable under the FCA."
- In *United States ex rel. Ebeid v. Lungwitz* (9th Cir. 2010), the court endorsed the implied certification theory and found that the Stark Act conditions payment on compliance with its prohibitions, but found that the relator in this case failed to plead sufficient facts to establish a prohibited self-referral arrangement.

# Restrictive Adoption of Implied Certification, cont'd

- *United States ex rel. Wilkins v. United Health Group* (3d Cir. 2011)
  - Described the implied certification theory as "premised on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment," but cautioned against applying the theory too expansively.
  - Partially affirmed dismissal of relator's complaint, holding that compliance with Medicare marketing regulations is not a condition of payment.
  - However, the Third Circuit held that compliance with the Anti-Kickback Statute (AKS) is a condition of receiving payment under Medicare parts C and D, and thus submitting a claim for reimbursement despite a knowing violation of the AKS could result in FCA liability.

# Rejections of Implied Certification

- *United States v. Sanford-Brown, Ltd.* (7th Cir. 2015)
  - Relator alleged that institution impliedly certified compliance with the "panoply of statutory, regulatory, and contractual requirements" related to Title IV every time it received a payment from the federal government.
  - "[D]istilled to its core [the implied certification] theory of liability lacks a discerning limiting principle."
  - "[U]nder the FCA, evidence that an entity has violated conditions of participation after good faith entry into its agreement with the agency is for the agency – not a court – to evaluate and adjudicate."

# Rejections of Implied Certification, cont'd

- *United States ex rel. Steury v. Cardinal Health, Inc.* (5th Cir. 2010)
  - Relator alleged that Cardinal Health impliedly certified that infusion pumps sold to the U.S. Department of Veterans Affairs met the warranty of merchantability.
  - No false claim unless payment is specifically conditioned on compliance with a warranty of merchantability.
  - This "prerequisite requirement" is important to "maintain a crucial distinction between punitive FCA liability and ordinary breaches of contract."

# Supreme Court To Take Up Implied Certification

- On December 4, 2015, the U.S. Supreme Court granted certiorari in *Universal Health Services, Inc. v. United States ex rel. Escobar* to address two questions:

  1. Whether the "implied certification" theory of legal falsity under the FCA is viable; and

  2. If the "implied certification" theory is viable, whether a reimbursement claim can be legally "false" under that theory if the provider failed to comply with a statute, regulation, or contractual provision that does not state that it is a condition of payment.

- The First Circuit, again recognizing the implied certification theory, held that a clinic's receipt of Medicaid funds could be conditioned on compliance with state regulations requiring proper supervision of staff.

# What's at Stake?

- Treble damages assessed on a per claim basis
- Civil penalties of up to $11,000 per claim
- Exclusion from participation in federal health care programs
- Payment suspension
- Potential criminal liability
- Follow-on suits under state false claims acts
- Reputational harm (DOJ announcements; SEC and other mandatory public disclosures)
- Legal costs
- Increased scrutiny and monitoring (*e.g.*, Corporate Integrity Agreements)

# Focus on Healthcare Enforcement

- In March 2007, OIG established the Medicare Fraud Strike Force to combine Federal, State, and local law enforcement resources to combat fraud.
- Operational areas:  Los Angeles, Chicago, Detroit, Brooklyn, Dallas, southern Texas, southern Louisiana, Tampa, and Miami.
- In May 2009, HHS and DOJ created the Health Care Fraud Prevention and Enforcement Action Team (HEAT).

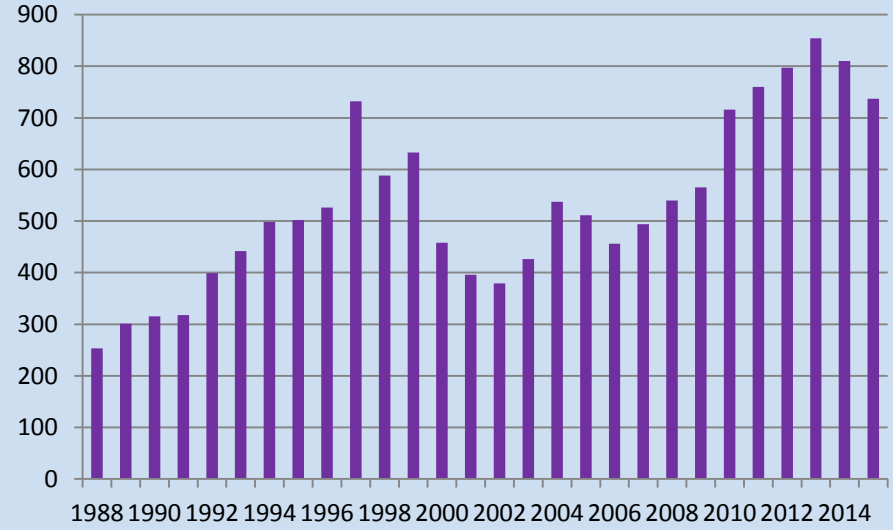
# Focus on Healthcare Enforcement, cont'd

- The government's focus on healthcare fraud has resulted in a large number of lawsuits against individuals and institutions.
- With the exception of 2004, the government has collected more than $1 billion per year in judgments and settlements since 2001.
- Since the formation of HEAT in 2009 and passage of the ACA in 2010, the DOJ has collected more than $2 billion per year.
- In 2014, the Criminal Division implemented a procedure so that all new *qui tam* complaints are shared by the Civil Division with the Criminal Division as soon as the cases are filed.
- On June 30, 2015, HHS-OIG announced the creation of a new 10-lawyer litigation team focusing solely on levying fraud-based civil monetary penalties and excluding providers from Medicare and Medicaid for fraud.

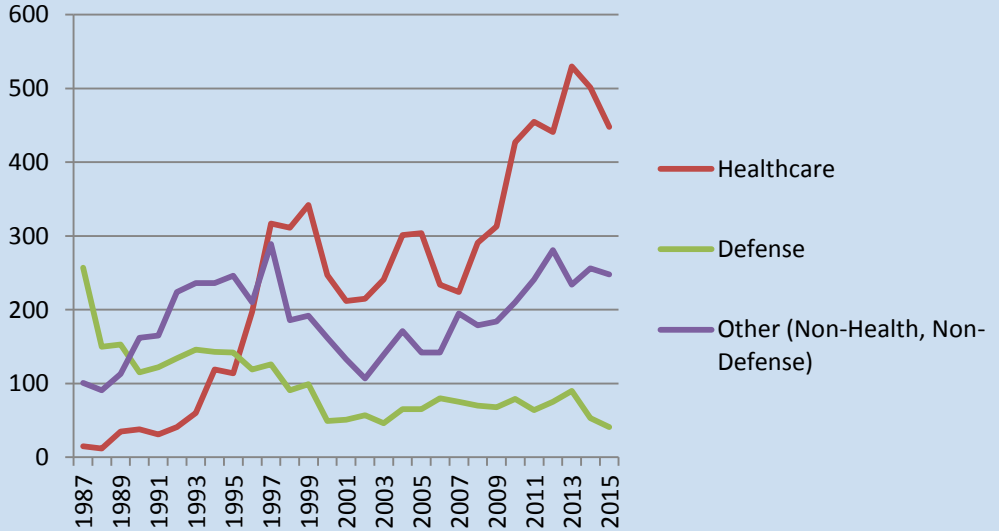
# Increased Number of Healthcare FCA Cases

- Since the 1986 revisions to the False Claims Act, the number of FCA cases (*qui tam* and non-*qui tam*) have risen dramatically.
- The number of healthcare FCA cases has grown faster than any other type and now make up the majority of cases.

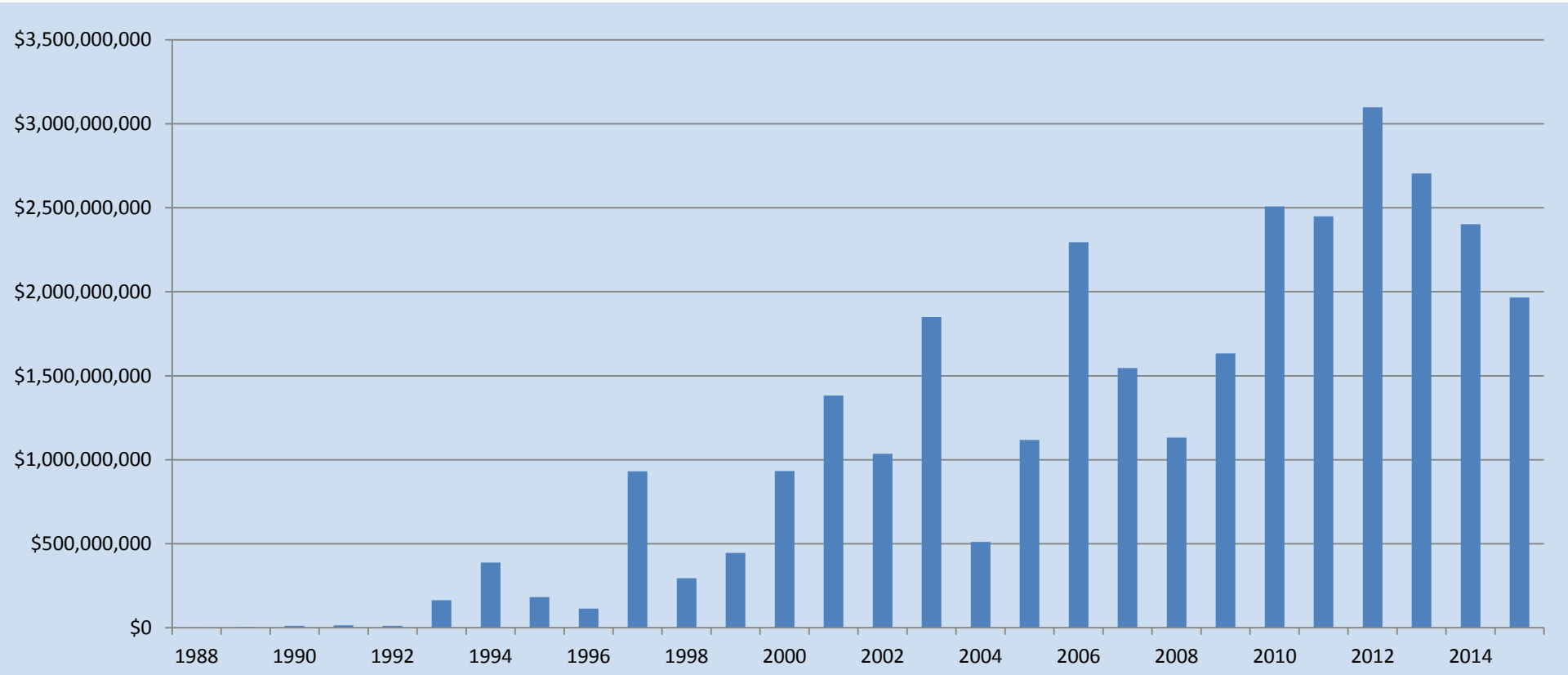
**New DOJ FCA Matters by Year**




**New DOJ FCA Matters by Industry**



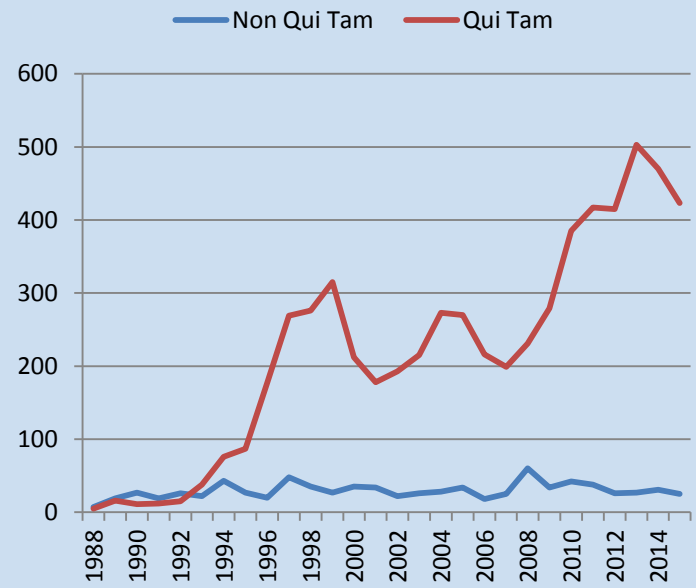
# Results: Settlement and Judgment Amounts

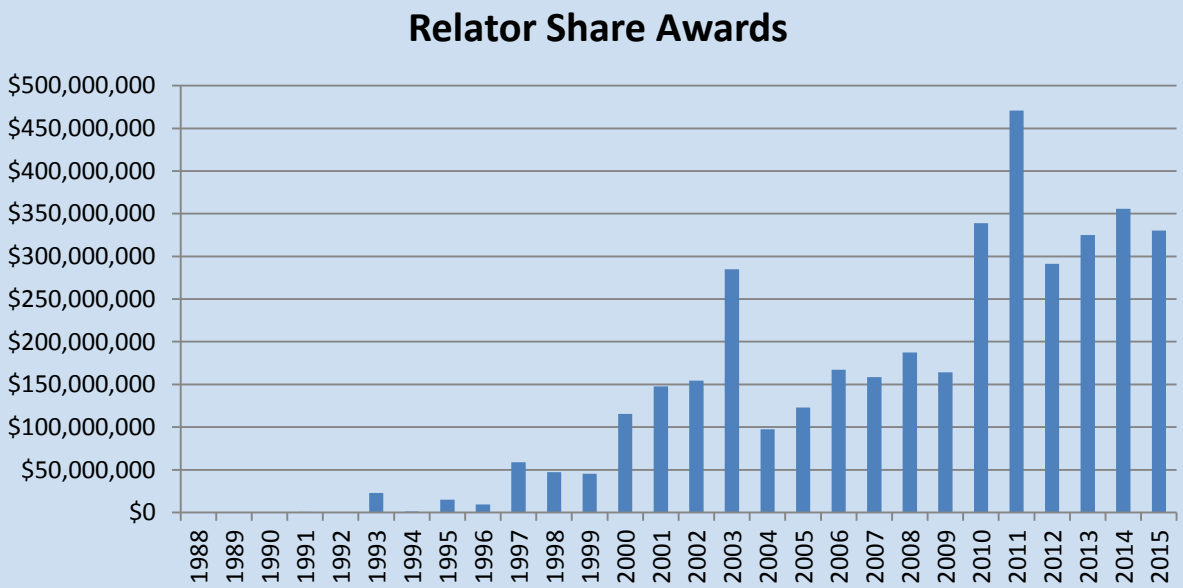



Source: U.S. Dep't of Justice, Civil Div., Fraud Statistics (Oct. 1, 1987 – Sept. 30, 2015), *available at* http://www.justice.gov/opa/file/796866/download.

# *Qui Tam* Actions

- The number of FCA *qui tam* actions filed has far exceeded the number of non-*qui tam* actions for healthcare-related FCA cases since 1993.
- Financial incentives of up to 30% of the total award in FCA cases has caused an overall increase in the number of *qui tam* cases.



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# Implied Certification Liability Under The False Claims Act: Practical Guidance For Defendants

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# Introduction

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- Most FCA cases start with a *qui tam* relator filing a complaint under seal. The government investigates and decides whether to intervene
- Even if the government does not intervene, the relator can still pursue the case
  - Increasingly, relators pursue declined cases
  - Implied certification theory attractive to relators, who argue that *all* claims submitted by defendant while in violation of a regulation, statute or contract were false
    - Potentially huge damages and penalties, with significant relator's cut
    - Relators lacking firsthand knowledge of the actual claims contend that their complaints are nonetheless viable

# Introduction

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- If served with an FCA complaint asserting implied certification claims, a defendant should be thinking about:
  - A robust motion to dismiss strategy
  - Limiting excessively broad discovery, while making effective, offensive use of discovery
  - Setting up a powerful, multi-faceted summary judgment motion
  - Considerations for potential settlement

# Motion to Dismiss

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- First check on meritless *qui tam* cases
- Numerous grounds for dismissal on the pleadings are available in an implied certification case:
  - Rule 9(b): Lack of particularity
  - Rule 12(b)(6): Failure to plead:
    - Falsity
      - Given that implied certification theory is itself on review by Supreme Court, every defendant should challenge it
    - Materiality
    - Causation
    - Knowledge
  - Relator-specific and other defenses, e.g., public disclosure bar, first to file bar, statute of limitations

# Motion to Dismiss: Rule 9(b)

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- Courts recognize that the FCA is a fraud statute and is thus subject to FRCP 9(b)
- Rule 9(b) remains a critical defense in implied certification cases
- Relators must set forth with particularity the “who, what, when, where, and how” of an alleged fraud
- But many “implied certification” relators lack firsthand knowledge of key details of the alleged fraud, often relying almost entirely on vague and conclusory allegations of regulatory, statutory or contractual violations

# Motion to Dismiss: Rule 9(b)

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- Defendants should mine such a complaint, and attack it based on (as applicable):
  - Lack of detail regarding  the “false” claims
  - Lack of detail regarding the defendant’s billing process
  - Lack of detail regarding the allegedly fraudulent scheme to violate the regulation, statute or contractual provision
  - Lack of detail regarding whether the provision was even violated, when, where, by whom, and how often

# Motion to Dismiss: Rule 9(b)

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- Implied certification cases particularly ripe for Rule 9(b) dismissal
  - No allegation that the claim for payment contained an untrue statement
  - Burden lies with relators to specifically plead fraud
- Case-specific inquiry, with varied results depending on the jurisdiction. For example:
  - Courts differ on how specific allegations about the claims must be
- Court may dismiss without prejudice, but defendants should request dismissal with prejudice: futility
  - Many relators clearly cannot improve on their lack of specificity, even if given a second chance

# Motion to Dismiss: Rule 9(b)

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- *U.S. ex rel. Gage v. Davis S.R. Aviation, LLC* (5th Cir. 2015)
  - To plead the "what" of an implied certification claim, relator must state with particularity the statute, regulation, or contract provision with which defendants have certified compliance – Gage did not allege that defendants violated a statute, but rather, that they violated several FAR and DFARS provisions. Gage did not plausibly allege, however, that the contract contained these provisions, nor did he identify any contract provision that was violated
  - Must state with particularity *how* the statute, regulation, or contract provision was violated – even if FAR and DFARS provisions applied to defendants' actions, Gage failed to plead how they were violated (e.g., how the parts deviated from government standards)
  - Must state with specificity when and where invoices were presented for payment – Gage's allegation that defendants submitted $4 million of false invoices to the government between 2009 and 2011 was not specific enough to comply with Rule 9(b)

# Motion to Dismiss: Rule 12(b)(6) (Falsity)

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- Given that the validity of the implied certification theory is an open question pending before the Supreme Court, defendants should move to dismiss on the grounds that it is not a legally valid theory
  - As such, a relator relying on the theory cannot plead falsity – an essential element of an FCA claim

# Motion to Dismiss: Rule 12(b)(6) (Falsity)

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- A defendant should also seek dismissal if the regulation, statute or contractual provision allegedly violated does not expressly state it is a condition of payment
  - Jurisdictions recognizing implied certification theory are currently split on whether condition must be “express”
  - Express condition of payment issue also pending before Supreme Court

# Motion to Dismiss: Rule 12(b)(6) (Falsity)

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- Even in jurisdictions that hold a condition of payment need not be express, a relator still must plead that a condition of payment (albeit implied) was violated
- Defendants should move to dismiss on the grounds that the regulation is not a condition of payment. E.g.:
  - Regulatory (or statutory, or contractual) scheme may designate other regulations as conditions of payment, but not the one at issue
  - Regulatory infraction may be so minor that it could not conceivably be a condition of payment
  - Government payor may have its own remedies for redressing violations, demonstrating payor did not condition payment on compliance

# Motion to Dismiss: Rule 12(b)(6) (Falsity)

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- Resist relators' attempt to characterize these issues as unresolvable prior to discovery. E.g.:
  - *USA ex rel. Harris v Dialysis Corp Amer.* (D. Md. 2013):
    - Relators claimed that defendant issued bills to the government with altered digits in patients' Social Security numbers, and that this resulted in bills for services that were never rendered to the individuals whose altered Social Security numbers were being used
    - Issue before the court was whether the allegedly inaccurate Social Security numbers were material to the Government's decision to pay or approve the claims
    - Court found that relator's allegations did not allow a plausible inference that inaccurate Social Security numbers on any Medicare claims filed by defendant had any natural tendency to influence agency action or were capable of influencing agency action
    - Court thus could not infer that DCA made false, material statements to the Government when it allegedly included incorrect Social Security numbers on these claims

# Motion to Dismiss: 12(b)(6) (Falsity v. Materiality?)

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- Some courts view the condition of payment issue as a question of falsity, while others view it as a question of materiality
  - Guidance in case law is varied and inconsistent, even within single jurisdictions
- Defendants should argue that the absence of a condition of payment requires dismissal for failure to plead both FCA elements

# Motion to Dismiss Under Rule 12(b)(6): Was There Even a Violation?

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- Defendants should not lose sight of fact that a relator cannot state an implied certification claim if the regulation, statute or contract was not actually violated
  - A defendant should scrutinize the provision at issue to see if, in fact, the defendant was compliant
  - May present a fact question difficult to resolve on the pleadings, but in some instances, it may be clear that no violation occurred

# Discovery Strategy

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- Relators often propound broad discovery requests in FCA cases in an attempt to fish and force settlement
  - True regardless of the theory of liability
  - Often follows on heels of defendant having spent significant $$ responding to an investigative subpoena
- New proportionality test of FRCP 26 important tool for defendants:
  - *"Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense* ***and proportional to the needs of the case,*** *considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit…."*

# Discovery Strategy

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- Discovery is also a key tool for defendants to set up summary judgment in implied certification cases
- Defendants should make aggressive use of discovery to show, for example, that:
  - The government payor did not condition payment on compliance with the regulation at issue
  - The regulation does not mean what the relator says (and thus that the defendant did not violate it) or that the regulation was ambiguous
  - The government knew about the defendant's practices
  - In healthcare cases in particular, that reasonable medical minds may differ on a service or treatment
- Well-organized discovery is critical to negate falsity, materiality, and knowledge in an implied certification case

# Discovery Strategy: Government

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- May need third-party discovery from the government payor to prove above points:
  - Be prepared to deal with *Touhy* regulations, and give ample time
    - Propound discovery to the government early
- Consider use of FOIA. For example:
  - In healthcare implied certification cases, consider obtaining competitor utilization data to show that defendant's alleged violation did not cause overutilization of services or medications

# Discovery Strategy: Experts

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- Hiring the right expert is critical and defendants should do so early
- For example, in a case where the parties disagree about what the allegedly violated regulation requires, an expert is important to help show:
  - Defendant's interpretation is correct or that, at a minimum, reasonable minds can interpret the requirement differently
    - Many courts hold that a claim cannot be false if a regulation lends itself to two different, but reasonable, interpretations

# Summary Judgment

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- The last stop before trial
- Crucial stage, particularly for corporate defendants who often will settle rather than risk trial
  - Relators keenly aware of this
- Good discovery choices lay foundation for a strong summary judgment motion, which should broadly attack the implied certification claim:
  - Falsity
  - Materiality
  - Knowledge
  - Causation
  - No Loss to Government
  - Sampling/extrapolation

# Settlement Considerations

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- Settlement considerations in implied cert cases mirror those in other types of FCA cases. These include:
  - How broadly will the release be drawn?
    - Need broadest possible release against future claims
  - How will the purported damages be defined?
    - Extrapolation?
  - Can all parties get on the same page?
    - Relator, defendant, and government
  - Will there be a CIA and if so, how rigorous?
    - If a healthcare case, will there be a quality of care component?
- These are just some of the considerations that a defendant must take into account if considering settlement

# Compliance Best Practices

- Entities should have a robust compliance program that is more than window-dressing.
  - A strong program designed to ensure compliance with regulations and other legal requirements is crucial to ensure no legal violations *and* to rebut evidence of recklessness.
    - Without an underlying legal violation → no implied certification claim.
    - Without at least recklessness → no viable FCA claim.
  - The government increasingly uses absence of an effective compliance program to show recklessness.

# Compliance Best Practices, cont'd

- Courts have repeatedly found that compliance efforts can negate a finding of recklessness.
  - *United States ex rel. Hefner v. Hackensack University Medical Center*, 495 F.3d 103, 110 (3d Cir. 2007) (noting that defendant's lack of recklessness was demonstrated, "at least indirectly," by defendant's hiring of a compliance consultant).
  - *United States ex rel. Gillespie v. Kaplan University*, No. 09-20756-CIV, 2013 WL 3762445, at *7 (S.D. Fla. Jul. 16, 2013), ***aff'd in part***, 780 F.3d 1039 (granting summary judgment to the defendant and finding that the defendant did not act with "reckless disregard" because it "had employees, including attorneys, who were tasked with ensuring compliance with the Rehabilitation Act and who, together with outside counsel, developed policies, procedures, and training to ensure compliance").

# Compliance Best Practices, cont'd

- Regularly conduct compliance audits and surveys to identify risk areas and solicit employee feedback.
- Train employees about compliance policies and procedures, especially the process for internal reporting of potential FCA issues.
- While it is virtually impossible to stop all regulatory and other legal violations, take steps to eliminate low-hanging fruit.
  - For example, when the need for a refund becomes apparent, make it.
    - Avoids liability under reverse false claims theories, which may be pursued alongside implied certification theories.