

The Salcido Report: False Claims Act Public Disclosure Alert

October 9, 2017

Key Points

- How have appellate courts applied the Supreme Court's ruling in *Escobar*?
- If the government is aware of the relator's allegation, but does not undertake any administrative action to address the defendant's alleged violation of law or contract, does that show that the relator's allegations are not material to the government's determination to pay?
- If the government is aware of the relator's allegation, but continues to pay for the defendant's product, does that show that the relator's allegations are not material to the government's determination to pay?
- If the government is aware of the relator's allegation, and investigates and concludes that the relator's allegations are unfounded, does that show that the relator's allegations are not material to the government's determination to pay?



Under What Circumstances Can a Private *Qui tam* Plaintiff Overtake Government Agency Experts' Use of Administrative Discretion to File False Claims Act Actions in the Post-*Escobar* FCA World?

The False Claims Act (FCA) *qui tam* provisions authorize private citizens, known as “relators”, to file lawsuits where they have suffered no personal injury. Instead, they allege that the federal government has been defrauded and obtain a substantial bounty if there is ultimately a recovery. A number of courts have described the FCA *qui tam* process as one where a “posse of ad hoc deputies” is unleashed to enforce the legal obligations of the United States.¹ But what if the posse actually supplants the efforts of law enforcement rather than supplementing them?

One instance in which the relator's action may thwart effective law enforcement rather than enhance it occurs when the relator contends that knowingly material false statements or claims were tendered to the government, but the government itself either believes that there is no violation of law or agency experts

¹ *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 184 (5th Cir. 2009); *United States ex rel. Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 876 (6th Cir. 2006); *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 224 (1st Cir. 2004).

would prefer, to better administer the programs they are charged with overseeing, that the violation be addressed through administrative sanctions.

In these instances, it is, obviously, the politically accountable, expert government official's policy preferences regarding how the law should be enforced, not the nonpolitically accountable, financially self-interested, nonexpert private relator's, that should govern. Indeed, courts recognize that the FCA's purpose is to advance the government's interest, and not merely the interests of the relators or their counsel.² Courts, including the Supreme Court, recognize that, in FCA actions, the United States is the real party in interest.³ They also recognize that relators have an interest in pursuing their own private interests rather than the public good⁴ and that the prospect of recovery draw out relators "like moths to a flame"⁵ that cause them to urge overly expansive theories that could undermine the government's interest.⁶

To reign in relators' overly broad theories of FCA liability that undermine law enforcement, courts historically have adopted different approaches. Before the Supreme Court's decision in *Universal Health Servs. v. United States ex rel. Escobar*,⁷ in determining whether a violation of a rule or regulation could potentially trigger an FCA violation, courts distinguished between whether the violation constituted a "condition of payment"⁸ (which triggered potential FCA liability) and violations that are "conditions of

² See, e.g., *United States v. Health Possibilities*, P.S.C., 207 F.3d 335, 340 (6th Cir. 2000) ("The FCA is not designed to serve the parochial interests of relators, but to vindicate civic interests in avoiding fraud against public monies") (citation omitted); *United States v. Northrop Corp.*, 59 F.3d 953, 968 (9th Cir. 1995) ("The private right of recovery created by the provisions of the FCA exists not to compensate the *qui tam* relator, but the United States. The relator's right to recovery exists solely as a mechanism for deterring fraud and returning funds to the federal treasury").

³ *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 930 (2009) (United States is "a real party in interest" in a case brought under the FCA).

⁴ *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 949 (1997) ("[a]s a class of plaintiffs, *qui tam* relators are different in kind than the Government. They are motivated primarily by prospects of monetary reward rather than the public good").

⁵ *United States ex rel. LaCorte v. Wagner*, 185 F.3d 188, 191-92 (4th Cir. 1999) (construing the FCA first-to-file rule to bar relators from intervening in a subsequent *qui tam* and noting that prohibiting "intervention in this case is fully consistent with Congress' purposes in enacting sections 3730(b)(5) and 3730(c)(5). Settlements in *qui tam* actions can draw intervenors like moths to the flame. Congress therefore struck a careful balance between encouraging citizens to report fraud and stifling parasitic lawsuits . . . The only way to preserve the balance that Congress struck is to apply the unqualified congressional mandate of Section 3730(b)(5) to bar all would-be intervenors other than the government") (citation omitted).

⁶ *United States v. Everglades Coll., Inc.*, 855 F.3d 1279, 1287-88 (11th Cir. 2017) (ruling that the government acted reasonably in consummating settlement with defendant notwithstanding relators' objections that the government's settlement was only a small fraction of the amount the relators sought under their theory of liability because, unlike relators, the government's interest was not solely to maximize its recovery, and the relators' theory of liability relied on an unsettled proposition which if the proposition was rejected by the appellate court would actually limit the government's enforcement efforts).

⁷ 136 S. Ct. 1989 (2016).

⁸ Conditions of payment "are those which, if the government knew they were not being followed, might cause it to actually refuse payment." *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1220 (10th Cir. 2008) (citation omitted).

participation”⁹ (which did not create FCA liability). This distinction ensured that relators would not be able to supplant the exercise of administrative discretion in the enforcement of regulations because, if the regulatory scheme permitted regulators to exercise their discretion to impose administrative sanctions, then courts found that the violation was nothing more than a condition of participation, which did not result in FCA liability.¹⁰

In *Escobar*, the Supreme Court rejected the distinction between conditions of payment and conditions of participation, a distinction which does not have textual support in the FCA, and noted that the concerns of an overly broad construction of the FCA could be addressed in other ways—namely “through strict enforcement of the [FCA’s] materiality and scienter requirements.”¹¹ In the place of the prior condition of participation versus condition of payment analysis, the *Escobar* Court applied a “rigorous” materiality standard.¹² The Court found that, in general, “materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.”¹³ Specifically, under the FCA:

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 a 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.¹⁴ Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were

⁹ Conditions of participation are those where violations may trigger administrative sanctions (like the imposition of a corrective action plan), but will not necessarily result in the government’s denial of payment. See, e.g., *United States ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791, 799 (8th Cir. 2011) (ruling that the relator “must plead and prove that [the defendant’s] allegedly false Certifications were conditions of payment – “those which, if the government knew they were not being followed, might cause it to actually refuse payment” and noting that, by contrast, “if the regulatory violations were only conditions of . . . participation, they ‘are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program”).

¹⁰ For a detailed discussion regarding how courts applied the condition of participation doctrine, see The Salcido Report: When a Violation of a Rule or Regulation Becomes an FCA Violation: Understanding the Distinction Between Conditions of Payment and Conditions of Participation (Oct. 1, 2015).

¹¹ 136 S. Ct. at 2002. The Court’s rejection of the condition of participation versus condition of payment distinction in favor of a robust, demanding, textually based materiality element actually narrows the FCA’s scope. This is because, if the sole issue were whether the compliance with a regulation constituted a condition of payment, the government would simply state in the regulation, as it began to do, that compliance with the regulation is a condition of payment regardless of whether the government would actually deny payment when an infraction occurred. See, e.g., CMS Enrollment Forms (noting that compliance with conditions of participation is a condition of payment); see generally Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6407, 124 Stat. 119, 769-70 (2010) (mandating as an express “condition of payment” that the physician certify and document in a specified fashion a face-to-face encounter with a patient for the patient to be eligible for home health services). In rejecting the principle that the government’s mere statement that compliance with a regulation is a condition of payment as dispositive of the issue, the Court instead looked to the government’s actual conduct, that is, whether the government did, in fact, treat the violation as a condition of payment by actually rejecting payment. If not, then, in most cases, the violation is not material, and the relator cannot prevail.

¹² *Id.* at 2004 n.6.

¹³ *Id.* at 2002 (internal quotation marks and brackets omitted).

¹⁴ *Id.* at 2003-04.

*violated, and has signaled no change in position, that is strong evidence that the requirements are not material.*¹⁵

By refocusing the analysis to the FCA's materiality element, the Supreme Court has continued to ensure that the relator's lawsuit cannot result in permitting FCA actions to supplant administrative discretion or permit juries to overrule agency experts. This is true because, by focusing on the **effect** of the government's behavior—such as whether regulators, notwithstanding the relator's allegation of wrongdoing, determined that no administrative sanction is necessary; or that any breach should not result in the denial of payment; or that payment under the contract or for the service should be made; or that the contract should be renewed—to determine whether the defendant's alleged breach was material to the government, the relator will not be able to second-guess the regulator's determination because the lawsuit will be dismissed based upon a lack of materiality, even though the relator disagrees with the expert administrator's exercise of discretion.

Since the Supreme Court's decision in *Escobar*, multiple courts of appeal have applied the Court's ruling. In these cases, the courts have carefully reviewed the government's conduct to determine whether the defendant's alleged breach was, in fact, material to the government's determination to pay. If the government's experts are aware of the underlying allegations and do not undertake administrative action, or continue to pay under the arrangement, or conclude that the defendant's conduct did not violate the law, circuit courts have concluded that the relator cannot establish FCA materiality. Set forth below is a description of those cases, together with questions that defendants should ask in light of those decisions to defend FCA lawsuits:

I. Post-*Escobar* FCA Appellate Case Law

To prevent *qui tam* relators from second-guessing expert government administrators or short-circuiting the remedial process the government has established to address noncompliance with regulations, appellate courts, post-*Escobar*, have ruled that the relator cannot establish the FCA's materiality element when evidence shows that, notwithstanding the relator's allegations, regulators did not act to impose readily available administrative sanctions on the defendant, continued to pay for the defendant's product, or investigated the relator's allegations and found no violation.

A. No Materiality is Found When the Government Is Aware of Relator's Allegation, but Does Not Impose any Administrative Sanction in Light of the Allegation.

In *United States ex rel. D'Agostino v. EV3, Inc.*, the 1st Circuit ruled that permitting the relator to proceed would undermine the agency's regulatory process when the agency was aware of the relator's allegations but did not impose any administrative sanction, and the agency's inaction demonstrated that the relator's allegation was not material to the government's determination to pay.¹⁶

¹⁵ *Id.* at 2003-04.

¹⁶ 845 F.3d 1 (1st Cir. 2016).

In *D'Agostino*, the defendant manufactured medical devices and sought Food and Drug Administration (FDA) premarket approval of the devices.¹⁷ Under that process, the device manufacturer “supplies the FDA with extensive information regarding the device—including its design, manufacturing, packing, labeling and testing—to satisfy the agency that the device is safe and effective.”¹⁸ Once a sufficiently complete application is submitted, FDA personnel conduct a substantive review, which, in this case, included an advisory panel of outside experts.¹⁹ The panel holds a public meeting to review the application before making a recommendation to the FDA.

The relator claimed that the defendants made three lies during the approval process: they disclaimed uses for the device that they later pursued, overstated the training that they later provided, and omitted critical safety information about the device.²⁰ But the court ruled that the relator could not state an FCA cause of action asserting that any of those alleged lies to the FDA caused Centers for Medicare & Medicaid Services (CMS) to make payments that it would not have made had it known the purported true facts. The court ruled that the causal link between the alleged fraud and payment was lacking because, in the six years since the relator surfaced the alleged fraud, the FDA demanded neither recall nor relabeling of the device.²¹ The court reasoned that the “FDA’s failure actually to withdraw its approval of [the device] in the face of [the relator’s] allegations precludes [the relator] from resting his claims on a contention that the FDA’s approval was fraudulently obtained. To rule otherwise would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so.”²² The FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies’ judgments about whether to rescind regulatory rulings.”²³

¹⁷ *Id.* at 3-4.

¹⁸ *Id.* at 3-4 (citation omitted).

¹⁹ *Id.* at 4.

²⁰ *Id.* at 7.

²¹ *Id.* at 8.

²² Even before *Escobar*, courts had cautioned against permitting the relator’s lawsuit to overrule the decisions of politically accountable agency officials. *See, e.g., United States ex rel. Smith v. Boeing Co.*, No. 05-1073, 2014 U.S. Dist. LEXIS 142982, at *74-77 (D. Kan. Oct. 8, 2014) (noting that the FAA has “exceptionally broad remedial powers to enforce the regulations if it believes a violation has occurred” and its “agents and officers are accountable for their actions (as members of the Executive Branch) and the agency is subject to oversight by Congress” and that federal “judges and juries, by contrast, have no such expertise or restraints, and allowing them to decide whether aircraft are airworthy has the potential to derail the oversight system devised by Congress and implemented by the President” and that an “FCA action is not the appropriate vehicle for challenging a federal agency’s construction and application of its regulations”), *aff’d*, No. 14-3247, 2016 U.S. App. LEXIS 10649 (10th Cir. June 13, 2016).

²³ 845 F.3d at 8 (citations omitted). *Cf. United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 34-35, 40 (1st Cir. 2017) (finding that, because of the FDA’s failure to apply any administrative sanction in the wake of the relators’ allegations, the relators’ fraud on the FDA assertions were “implausible,” and noting that ruling “otherwise would turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so,” but also holding that the relators’ nonfraud on the FDA claims that the defendant “palmed off”

The court concluded that permitting the relator to proceed could undermine the FDA's ability to effectively administer its program.²⁴

Similarly, in *United States ex rel. Petratos v. Genentech Inc.*,²⁵ the 3rd Circuit also looked at the government's action—continued approval of the drug, no initiation of administrative action and declination in *qui tam* action—as proof of no materiality.

In *Petratos*, the relator alleged that the defendant concealed information about a drug's health risks that would have shown that the drug's side effects for certain patients were more common and severe than reported and would have required the company to file adverse-event reports with the FDA.²⁶ The relator filed his action in 2011.²⁷ The relator noted that he disclosed the defendant's "campaign of misinformation" to the FDA and Department of Justice in 2010 and 2011.²⁸ Notwithstanding this disclosure, the FDA continued to approve the drug "for the at-risk populations that [the relator] claims are

latently defective versions of its FDA-approved product on unsuspecting doctors who sought government reimbursement to be a viable theory of liability).

²⁴ *Id.* at 8-9. Even before *Escobar* hammered home the "rigorous" nature of FCA materiality, courts had ruled that *qui tam* actions should not be "used as a back-door regulatory regime to restrict practices that the relevant federal and state agencies have chosen not to prohibit through their regulatory authority" or to "short-circuit the very remedial process the government has established to address non-compliance with those regulations." See, e.g., *United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 620 (2d Cir. 2016) ("The False Claims Act, even in its broadest application, was never intended to be used as a back-door regulatory regime to restrict practices that the relevant federal and state agencies have chosen not to prohibit through their regulatory authority It is the FDA's role to decide what ought to go into a label, and to say what the label means, and to regulate compliance. We agree with Judge Cogan that there is an important distinction between marketing a drug for a purpose obviously not contemplated by the label (such as, with respect to Lipitor, 'to promote hair growth or cure cancer') and marketing a drug for its FDA-approved purpose to a patient population that is neither specified nor excluded in the label An FCA relator alleging off-label marketing might be able to satisfy Rule 9(b) and surmount the impediment of implied certification in a case in which it would be obvious to anyone that the use promoted is one that is not approved, but this is emphatically not such a case") (internal quotation and citation omitted); *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir. 2014) ("Were we to accept relator's theory of liability based merely on a regulatory violation, we would sanction use of the FCA as a sweeping mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct. When an agency has broad powers to enforce its own regulations, as the FDA does in this case, allowing FCA liability based on regulatory non-compliance could short-circuit the very remedial process the Government has established to address non-compliance with those regulations") (citation and internal quotation omitted); *United States ex rel. Provuncher v. Angioscore*, No. 09-12176, 2012 U.S. Dist. LEXIS 108487 at *3-*6 (D. Mass. Aug. 3, 2012) (rejecting relator's contention that defendant's EX Catheter was "defective" or "misbranded" or "medically unnecessary or worthless" and resulted in *ipso facto* a "false claim" because "[u]nlike the deliberate sale of batches of say, contaminated beef or nonfunctioning munition to the U.S. military, the provision of a sophisticated medical device that almost inevitably will be subject to a statistically predictable failure rate, is not the evil that Congress sought to root out by passage of the False Claims Act," especially where the FDA audited the relator's contentions and "chose not to suspend or withdraw its consent for the device, and in fact approved the PMA Supplements, thereby authorizing continued marketing of the EX Catheter" and concluding, instead, that "the issue is one properly committed to the policing power of the FDA") (emphasis supplied).

²⁵ 855 F.3d 481 (3d Cir. 2017).

²⁶ *Id.* at 485.

²⁷ *Id.* at 486.

²⁸ *Id.* at 490.

adversely affected by the undisclosed data, but has added three more approved indications for the drug,” and the FDA did not initiate proceedings to enforce its adverse-event reporting rules.²⁹ In fact, the court noted in the six years since the relator filed that “the Department of Justice has taken no action against [the defendant] and declined to intervene in this suit.”³⁰ The Court noted that, since the relator concedes that the expert agencies and government regulators have deemed these violations insubstantial, the relator could not satisfy the FCA materiality standard under *Escobar* and that, under these circumstances, it is not “appropriate for a private citizen to enforce [the relevant] regulations through the False Claims Act.”³¹

B. Several Circuits Have Also Ruled that the Government’s Knowledge of the Relator’s Underlying Allegation and Continuation of Payment or Other Acts Affirming Defendant’s Conduct Demonstrate that Relator’s Allegations Are Not Material.

Several appellate courts have also found that strong evidence exists that the relator’s allegations are not material to the government’s determination to pay when, notwithstanding the relator’s allegation, the government continues to pay under the contract, renews the contract or provides an additional fee under the contract.

For example, the D.C. Circuit in *United States ex rel. McBride v. Halliburton Co.*,³² looked to the government’s provision as an award fee on the defendant’s contract as additional evidence that the relator’s allegation was not material.

In *McBride*, the relator alleged that defendant had inflated the “headcount” data used to track how many U.S. troops frequented recreation centers at certain camps in Iraq from July 2004 to March 2005.³³ The relator also alleged that the defendant destroyed sign-in sheets to conceal the falsity of the headcount data.³⁴ After the relator filed the lawsuit, the Defense Contract Audit Agency (DCAA) investigated the relator’s allegations.³⁵ The DCAA did not issue any formal findings, but neither the DCAA nor any other government agency disallowed or challenged any of the amounts that the defendant had billed.³⁶

The relator contended that the defendant deprived the government of the opportunity to examine records to determine the reasonableness or allowability of the costs.³⁷ Moreover, the relator pointed out that a government representative stated that knowledge of alleged infraction “might” have caused the government to disallow costs. But the court ruled that this representation was insufficient to establish FCA

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.* (citations omitted).

³² 848 F.3d 1027, 1033-34 (D.C. Cir. 2017).

³³ *Id.* at 1028.

³⁴ *Id.* at 1029

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.* at 1033.

materiality because the “statement amounts to the far-too-attenuated supposition that the Government *might* have had the ‘option to decline to pay,’” which does not satisfy the “rigorous” and “demanding” materiality standard under *Escobar* and noting that, moreover, the court has “the benefit of hindsight and should not ignore what actually occurred: the [government agency] investigated [the relator’s] allegations and did not disallow any charged costs.”³⁸ Additionally, the defendant continued to receive an award fee for exceptional performance even after the government learned of the allegations.³⁹ The court noted that this is “very strong evidence” that the requirements allegedly violated by the maintenance of inflated headcounts are not material.⁴⁰

Similarly, the 9th Circuit in *United States ex rel. Kelly v. Serco, Inc.* looked to the government’s continuation of payment, notwithstanding the relator’s allegations, as proof that the relator did not establish materiality. In *Kelly*, the relator alleged that the defendant’s monthly cost reports were unreliable because they tracked costs manually and with a single charge code in violation of the American National Standards Institute/Electronic Industries Alliance Standard 748 (“ANSI-748”).⁴¹ The relator informed the government of this contention prior to filing his *qui tam* lawsuit.⁴² The court concluded that the relator could not satisfy the FCA’s “demanding” materiality standard because of “the government’s acceptance of [defendant’s] reports despite their non-compliance with ANSI-748” and because of “the government’s payment of [defendant’s] public vouchers for its work.”⁴³

³⁸ *Id.* at 1034.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.* at 329.

⁴² *Id.*

⁴³ *Id.* at 334. Even before *Escobar*, courts had emphasized that the government’s failure to impose sanctions, or continuation of payment, or renewal of contracts were all strong evidence that the relator’s allegations were not material to the government’s determination to pay. See, e.g., *United States ex rel. Thomas v. Black & Veatch Special Projects*, 820 F.3d 1162, 1171 & 1174 (10th Cir. 2016) (finding that, where the relators contended that the defendant altered documents to obtain visas and work permits from the Afghan government and then falsely certified that it had complied with applicable laws to obtain payment under its contract with the government, the relators could not establish materiality because, to establish materiality, the relators would need to prove that the defendant “violated a contractual or regulatory provision that undercut the purpose of the contract[.]” and not simply a “tangential or minor contractual provision” and ruling that the relators could not satisfy that standard because, even though the government knew about the relators’ allegations, the government “did not withhold payment pending the outcome of the investigations of the altered documents,” and did not reserve any rights with attempting to confirm the truth of relators’ allegations, but instead paid defendant’s “invoices in full and without reservation” and thus, this establishes that the falsehoods “were merely tangential to the purpose of the Contract”) (citation and internal quotation omitted); *United States ex rel. Am. Sys. Consulting, Inc. v. ManTech Adv. Sys. Int’l*, 600 F. App’x 969, 972, 976 (6th Cir. 2015) (no materiality where agency “chose to continue under its contract” after learning of alleged misrepresentations and noting that statements “by the actual decision-makers may be (and often are) the best available evidence of whether alleged misrepresentations had an objective, natural tendency to affect a reasonable government decision-maker, especially if they are consistent with a rational decision-making process and a common sense reading of the record as a whole”); *United States ex rel. Marshall v. Woodward, Inc.*, 812 F.3d 556 (7th Cir. 2015); *United States ex rel. Stephenson v. Archer W. Contractors, L.L.C.*, No. 13-30327, 2013 U.S. App. LEXIS 23987, at *7–*8 (5th Cir. Dec. 2, 2013) (finding that violation of certification could not be material when the government was aware of violation and that remedy under contract was for the government to issue “stop work order,” but the government issued no order and continued to pay because “[h]ow could ‘fraud’ be material to

C. No Materiality is Found When the Government's Investigation Confirms no Violation of Law.

Finally, the 5th Circuit in *United States ex rel. Abbott v. BP Explorations & Prod.*,⁴⁴ reached the seemingly obvious conclusion that the alleged falsity could not have been material to the government when the government, upon review, concludes that there was no violation of law.

In *Abbott*, the relators alleged that the defendant did not have all necessary documentation to maintain a floating oil production facility platform (the "Platform") and that engineers did not approve some necessary documents as required by applicable regulations.⁴⁵

As a result of the lawsuit, the Department of Interior (DOI) began reviewing the defendants' compliance with these regulatory requirements.⁴⁶ The DOI also received inquiries from Congress and indicated to Congress that it would conduct a full investigation.⁴⁷ As a result of that investigation, DOI prepared a report that concluded that the relators' allegations were unfounded and that there were no grounds for suspending the operations of the Platform.⁴⁸

The district court granted defendants' motion for summary judgment. The relators contended that summary judgment was inappropriate because evidence existed that drawings were missing markings in accordance with defendant's internal procedures and testimony from a DOI official stating that the Platform would not have been approved if defendants had not certified compliance with various

payment if the defrauded party knows about it and remains satisfied with the work?"); *United States ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 828, 831 (7th Cir. 2011) (finding that defendant's failure to remind the government of information set forth in some detail in a contract that the government had recently reviewed could not reasonably be deemed material to the government's decision and ruling that, if the government learned of the alleged misstatements and it neither altered nor suspended payment, "speculative testimony about how [the government] might have acted if it had discovered that misrepresentation earlier cannot raise a genuine issue of fact as to materiality") (citation omitted); *United States ex rel. Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 733 (7th Cir. 1999) (ruling that the relator's allegation that the defendant violated federal testing standards for blood plasma could not have been found material by a reasonable jury because the "Department of Justice has conspicuously declined to adopt [the relator's] position or to prosecute this claim on its own behalf" and "the federal government is 100% satisfied with the blood products it receives from [the defendant] and with the representations made in connection with the sales."); *United States v. Intervest Corp.*, 67 F. Supp. 2d 637, 649 (S.D. Miss. 1999) ("The controlling issue in this case is whether the certifications of the Defendants as to the condition of the property were material to [the government]. Clearly they were not. [The government] has continued to pay . . . vouchers since 1994 when it knew from its own inspection reports that the certifications were false. For this reason, the Court finds that Defendants are entitled to judgment at [sic] a matter of law on the claims asserted against them by the Government"). Cf. *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890, 906 (9th Cir. 2017) (rejecting defendant's contention that, given the fact that the government continued to pay, the relator's allegations could not have been material because the continued payment came after the alleged noncompliance had terminated and "the government's decision to keep paying for compliant drugs does not have the same significance as if the government continued to pay despite noncompliance").

⁴⁴ 851 F.3d 384 (5th Cir. 2017).

⁴⁵ *Id.* at 386.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

regulations.⁴⁹ But the court ruled that these facts do not create a triable issue of fact as to materiality. The court noted that *Escobar* “debunked the notion that a Governmental designation of compliance as a condition of payment by itself is sufficient to prove materiality” and ruled that, notwithstanding a government official’s testimony that the platform would not be approved had defendant not certified its compliance with government regulations, materiality was not established because the government report found no violation and found no grounds to suspend defendant’s operations.⁵⁰ The court noted that, as “recognized in *Escobar*, when the DOI decided to allow the [Platform] to continue drilling after a substantial investigation into Plaintiffs’ allegations, that decision represents ‘strong evidence’ that the requirements in those regulations are not material.”⁵¹

II. Questions to Ask in Determining Whether the Relator’s Alleged Breach of Law is Material To the Government’s Determination to Pay

In most cases, the relator will disclose the allegations underlying the lawsuit to the government even before filing an action.⁵² At a minimum, statutorily, relators must disclose the material evidence underlying their lawsuit at the time in which the lawsuit is filed,⁵³ and the government must investigate.⁵⁴

⁴⁹ *Id.* at 388.

⁵⁰ *Id.* at 387-88.

⁵¹ *Id.* at 388. Even before *Escobar*, courts had refused to allow the relator’s opinions to supplant the findings of agency experts. See, e.g., *United States ex rel. Smith v. Boeing Co.*, No. 05-1073, 2014 U.S. Dist. LEXIS 142982, at *86-87 (D. Kan. Oct. 8, 2014) (finding that, where the relators alleged that the defendant falsely certified that it manufactured aircraft parts in compliance with applicable Federal Aviation Administration (FAA) regulations and in response, FAA opened two investigations, met with the relators, and ultimately determined that the parts were manufactured and approved in accordance with the approved data, processes and procedures, and that the parts are considered approved, the court concluded that “Boeing’s asserted failures were not material to the government’s purchase decision” because “FAA initially certified the planes and has twice now rejected relators’ claims of safety problems and regulatory non-compliance” and that any “lingering doubt on that question is dispelled by the actions of the government purchasers after learning of relators’ claims” because a “number of the aircraft at issue were delivered to the military after relators filed their first FCA action in 2002 The government did not terminate the leases or contracts after learning of relators’ allegations, nor did it seek any contractual remedies,” but, on “the contrary, the Air Force decided to go ahead and purchase the leased aircraft on which it had an option to buy,” the “most recent such purchase occurred in 2010”) (citations omitted), *aff’d other grounds*, No. 14-3247, 2016 U.S. App. LEXIS 10649 (10th Cir. June 13, 2016). See also *United States ex rel. Thurman v. Woodward, Inc.*, 85 F. Supp. 3d 973, 982-84 (N.D. Ill. 2015) (finding that, where the record shows that after the relators’ counsel independently disclosed the allegations to the Department of Defense (DoD) and the government understood the relators’ allegations, conducted an extensive review, determined that there was no problem and that the relators’ concerns were unfounded, and continued to purchase the relevant parts from the defendant, the relators could not satisfy the materiality element and rejecting the relators’ contentions that the government was not fully informed and should have conducted a more intensive investigation because these contentions “cannot be reconciled with *Luckey*, *Yannacopoulos*, and *Lusby*, which teach that, where the government knows about the allegedly false statements, looks into them, concludes that nothing is wrong, and continues doing business with the defendant anyway, there is no materiality despite what the relator thinks the government should have done”), *aff’d*, 812 F.3d 556 (7th Cir. 2015).

⁵² Many relators will notify the government of the allegations prior to the lawsuit to increase the likelihood that they will qualify as original sources. Under the FCA’s public disclosure bar, an action can be dismissed if the underlying allegations were publicly disclosed and the relator does not qualify as an original source. See 31 U.S.C. § 3730(e)(4). To qualify as an original source, the relator must voluntarily provide the allegations to the government either prior to the public disclosure or prior to filing the action. *Id.* Thus, in the event that the allegations had been previously publicly disclosed before the relator filed the lawsuit, many relators, prior to filing the action, will present

Thus, in every *qui tam* lawsuit, the government will have learned, and had the opportunity to fully investigate, the relator's allegations. In light of *Escobar* and its progeny the questions to ask in any FCA litigation to determine whether the relator can satisfy the FCA materiality element include:

- When did the government first become aware of the allegations?
- Did it learn of the allegations before the relator filed?
- Did it learn after the relator filed?
- What tangible actions occurred next?
- Is payment overseen by an administrative agency where agency personnel exercise discretion regarding whether any sanction should be imposed in light of the relator's allegations?
- Did the government impose any administrative sanction? For example, after review, did the government undertake action short of denial of payment (e.g., institute a corrective action plan, impose a civil monetary penalty)?
- Did the government decline to impose any sanction?
- Did the government continue to pay the claims?
- Did the government continue to pay on claims that relate to the subject matter of the relator's complaint?
- Did the government renew any existing contract?
- Did the government pay any incentive payments or reward fees under the contract?

III. Conclusion

As the Supreme Court recently reminded us, the FCA “is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations.”⁵⁵ And while the FCA addresses acts

the underlying allegations to the government to maximize the odds that a court will find that they may qualify as original sources.

⁵³ Relators must serve the government their statement of material evidence in support of their claims at the time that they file their action. 31 U.S.C. § 3730(b)(2).

⁵⁴ Under the FCA, the “Attorney General diligently shall investigate a violation.” 31 U.S.C. § 3730(a).

⁵⁵ 136 S. Ct. 1989, 2004 (2016). See also *United States ex rel. Dunn v. N. Mem'l Health Care & N. Mem'l Med. Ctr.*, 739 F.3d 417, 419 (8th Cir. 2014); *United States ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 829 (8th Cir. 2013) (no FCA liability because relators alleged “nothing more than regulatory noncompliance”); *United States ex rel. Onnen v. Sioux Falls Indep. School Dist. No. 49-5*, 688 F.3d 410, 414 (8th Cir. 2012) (“The FCA is not concerned with regulatory noncompliance”); *United States ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791, 795–96 (8th Cir. 2011) (finding that the FCA is not concerned with regulatory noncompliance, but “serves a more specific function, protecting the federal fisc by imposing severe penalties on those whose false or fraudulent claims cause the government to pay money”); see generally *United States ex rel. Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1045 (11th Cir. 2015) (“Liability under the False Claims Act arises from the submission of a fraudulent claim to the government, not the disregard of government regulations or failure to maintain proper internal procedures”) (quoting *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1012 (11th Cir. 2005)); *United States ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707, 717 (6th Cir. 2013) (noting that the FCA “is not a vehicle to police technical compliance with complex federal regulations” and that the “blunt[ness] of the FCA’s hefty fines and penalties

of fraud against the government that drains the federal treasury, the Supreme Court has also reminded us that it is definitively not “an all-purpose antifraud statute” to enforce every regulation on the books.⁵⁶ Instead, as the Court has made clear in a series of cases even before *Escobar*, the FCA applies only when the alleged breach would result in the government denying or reducing payment.⁵⁷

Thus, in any FCA action, to ensure that the statutory language related to a “claim” that is “material” to the government’s determination to pay is applied in the rigorous fashion, as the Supreme Court directed, defendants should take discovery to inquire into the government’s actual conduct **after** it learned of the underlying allegations. By undertaking this inquiry, defendants will ensure that, consistent with the FCA’s plain language and purpose, that nonexpert, financially self-interested relators who believe that the government should recover treble damages based upon a regulatory infraction will not be able to displace executive branch agency experts who are charged with enforcing and administering the law, and believe that no repayment should be made.

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makes them an inappropriate tool for ensuring compliance with technical and local program requirements”) (citation omitted); *United States ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 532 (6th Cir. 2012) (the FCA “is not a vehicle to police technical compliance with complex federal regulations”); *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 268 (5th Cir. 2010) (“The FCA is not a general ‘enforcement device’ for federal statutes, regulations, and contracts”) (citations omitted).

⁵⁶ 136 S. Ct. at 2003. See also *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488, 496 (D.C. Cir. 2004) (rejecting FCA construction that would result in “almost boundless” reach). See generally *United States ex rel. Hopper v. Solvay Pharms., Inc.*, 588 F.3d 1318, 1328 (11th Cir. 2009) (noting that the FCA is not “an all-purpose antifraud statute”) (quoting *Allison Engine Co., Inc. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)).

⁵⁷ See *United States v. McNinch*, 356 U.S. 595, 599 (1958) (finding that, “[e]ssentially, then, only those actions by the claimant **which have the purpose and effect of causing the United States to pay out money it is not obligated to pay . . . are properly considered ‘claims’ within the meaning of the FCA**” and noting that the “False Claims Act was not designed to reach every kind of fraud practiced on the Government”) (emphasis supplied). Indeed, in multiple cases, the Supreme Court has been careful to link application of the FCA to actual claims for payment. See, e.g., *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 551 (1943) (stating that the purpose of the FCA “was to provide for restitution to the government of **money taken from it** by fraud”) (emphasis supplied); *Rainwater v. United States*, 356 U.S. 590, 592 (1958) (“It seems quite clear that the objective of Congress was broadly **to protect the funds and property of the government** from fraudulent claims.”) (emphasis supplied); *United States v. Bornstein*, 423 U.S. 303, 309 n.4 (1976) (“[t]he conception of a claim against the government normally **connotes a demand for money or for some transfer of public property.**”) (emphasis supplied). Indeed, even in *United States v. Neifert-White*, which is generally cited as the Supreme Court’s endorsement of an expansive interpretation of the FCA, because it speaks to the FCA reaching “all fraudulent attempts,” the remainder of the oft-quoted passage dramatically limits the FCA by linking the fraudulent attempts to causing “the Government to pay out sums of money.” *United States v. Neifert-White Co.*, 390 U.S. 228, 233, 19 L. Ed. 2d 1061, 88 S. Ct. 959 (1968) (False Claims Act reaches to “all fraudulent attempts **to cause the Government to pay out sums of money.**”) (emphasis supplied).

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September 25, 2015 - *False Claims Act Public Disclosure Alert.*

About the Author

Robert Salcido is a leading FCA practitioner.

Mr. Salcido has been lead counsel in several FCA actions in which he successfully defended clients in FCA actions that the government filed at trial or summary judgment. Some of those cases include:

- Mr. Salcido was lead counsel for Golden Living in an FCA action where the federal government had sued Golden Living's predecessor company, Beverly Enterprises ("Beverly"), for \$895 million, alleging that Beverly had engaged in an unlawful kickback scheme with McKesson Corp. in violation of the Anti-Kickback Act and the FCA. After 14 days of trial, the court ruled that Beverly and McKesson did not violate the FCA or the Anti-Kickback Act because their business negotiations were fair, reasonable and conducted in good faith. *See United States of America ex rel. Jamison v. McKesson Corp.*, 900 F. Supp. 2d 683 (N.D. Miss. 2012).
- Mr. Salcido was lead counsel for Aegis Therapies and a Golden Living skilled nursing facility where the federal government had alleged that defendants provided medically unnecessary rehabilitation therapy. The district court granted defendants' summary judgment motion, ruling that the government had used the wrong standard to assess whether the services were medically necessary and failed to prove that defendants' certification regarding medical necessity was objectively false. *See United States ex rel. Lawson v. Aegis Therapies, Inc.*, 2014 U.S. Dist. LEXIS 45221 (S.D. Ga. Mar. 31, 2015).
- Mr. Salcido was lead counsel for a defendant physician and multispecialty group practice that the government accused of FCA violations. The district court dismissed all the government's claims on summary judgment. Ultimately, because the United States' action lacked "substantial justification," the United States was ordered to pay defendants more than \$500,000 in legal fees. In making the ruling, the court ruled that Medicare fraud law is an area of expertise and ruled that it was undisputed that Mr. Salcido possessed such expertise. *See United States v. Prabhu*, 442 F. Supp. 2d 1008 (D. Nev. 2006).
- Mr. Salcido was lead counsel for Golden Living in an action where the relator and the government sued multiple defendants alleging that they violated the FCA because they knowingly created and operated a supply company in violation of Medicare Supplier Standards. The district court granted defendants' FCA summary judgment motion regarding the Supplier Standards allegations, finding

that the government's prior administrative proceedings demonstrated that the defendant supply company was entitled to payment. See *United States ex rel. Jamison v. McKesson Corp.*, 784 F. Supp. 2d 664 (N.D. Miss. 2011).

Mr. Salcido has authored a number of books and chapters in leading publications (including the American Health Lawyers Association, BNA Books and Bloomberg BNA) regarding the application of the FCA, including:

- *False Claims Act & the Health Care Industry: Counseling & Litigation* (2d ed. American Health Lawyers Ass'n 2008) (3d edition forthcoming in 2018)
- *2014 Supplement to False Claims Act and the Health Care Industry: Counseling and Litigation* (American Health Lawyers Ass'n 2014)
- "The False Claims Act in Health Care Prosecutions: Application of the Substantive, *Qui tam* and Voluntary Disclosure Provisions," in *Health Care Fraud and Abuse: Practical Perspectives*, Ch. 3 (3d ed. BNA Books 2013) (with annual supplements)
- "False Claims Act: Health Care Applications and Defenses" in *Bloomberg BNA Health Law and Bus. Series No. 2650* (2012) (with annual supplements).

Because of his work successfully defending a number of FCA lawsuits, Mr. Salcido has been recognized in:

- *The National Law Journal* in its 2014 Litigation Trailblazers & Pioneers as one of 50 "people who have made a difference in the fight for justice" for his outstanding work in defending FCA lawsuits
- *Chambers USA: America's Leading Lawyers for Business* (2006-2017), in the 2011-2017 editions of *Chambers USA*, listed under Health Care: Regulatory and Litigation, Leading Individuals (Nationwide) (Band 1) and as Health Care Leading Individuals (District of Columbia) (Band 1)
- *Law360*, which selected Mr. Salcido as one of the four Health Care MVPs for 2012 based upon a successful trial verdict obtained in the Golden Living FCA/Anti-Kickback Act lawsuit
- Before entering private practice, Mr. Salcido served as trial counsel for the U.S. Department of Justice Civil Fraud Section, which has nationwide jurisdiction over the FCA, where he led several successful prosecutions of the FCA on the United States' behalf.

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