

2017 YEAR IN REVIEW – THE FALSE CLAIMS ACT

January 2018

haynesboone

Clients and Friends,

The False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (FCA), continued to be a significant focus of government and whistleblower activity in 2017. This Year in Review highlights several key developments, including:

- The recovery by the government of more than \$3.7 billion in settlements and judgments in FCA cases in 2017.
- The aftermath of the Supreme Court’s landmark decision in *Escobar* and the varying interpretations of “materiality” under the FCA.
- Significant judicial decisions regarding the first-to-file rule, the public disclosure bar, and pleading requirements for FCA cases, among other issues.

In 2017, Haynes and Boone, LLP represented healthcare providers, defense contractors, and individuals in FCA investigations and lawsuits. We successfully resolved matters before lawsuits were filed, negotiated favorable settlements, and continued to defend our clients in active litigation. We also advised a number of contractors and healthcare providers regarding FCA compliance and other related issues.

If you have any questions about the issues covered in this year’s *Review*, please let us know. We look forward to working with our friends and clients in 2018.

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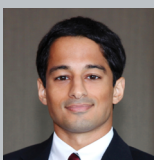
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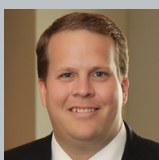


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A. 2017: A LOOK BACK AT THE NUMBERS

1. 2017 Was Another Record-Breaking Year

On December 21, 2017, the DOJ reported that the United States recovered more than \$3.7 billion in settlements and judgments from FCA cases during fiscal year 2017.¹ Although this amount was significantly less than last year's recovery, it continued DOJ's eight-year record of obtaining recoveries in excess of \$3 billion.

DOJ further reported:

- Of the \$3.7 billion recovered, \$2.4 billion came from the healthcare industry.
- \$543 million came from the financial industry as a result of the housing and mortgage fraud crisis.
- Although up from \$120 million last year, the defense industry contributed only about \$220 million of the total recovery.
- Of the \$3.7 billion recovered, a staggering \$3.4 billion related to cases filed by private whistleblowers, with whistleblowers receiving \$394 million for their share of the award.

Among the cases resolved in 2017, there were several notable settlements and judgments, including:

- A \$465 million settlement with drug manufacturer Mylan Inc. to resolve allegations that it underpaid rebates to the Medicaid Drug Rebate Program for EpiPens.
- A \$350 million settlement with Shire Pharmaceuticals LLC to resolve kickback and off-label marketing allegations related to its bioengineered skin substitute.
- A \$145 million settlement with Life Care Centers of America Inc. to resolve allegations that it caused

skilled nursing facilities to submit claims for services that were not reasonable, necessary, or skilled. This is the largest settlement on record with a skilled nursing facility chain.

- A jury in the Southern District of Texas found that Allied Home Mortgage Capital Corporation and Allied Home Mortgage Corporation violated the FCA while participating in the Federal Housing Administration mortgage insurance program. The judge trebled the damages found by the jury and imposed additional penalties under the FCA and the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, resulting in a \$296 million judgment.
- A \$95 million settlement with Agility Public Warehousing Co. KSC to resolve allegations that it overcharged the Department of Defense for food supplied to U.S. soldiers.

2. The Government Continued to Prioritize Individual Accountability in FCA Enforcement

As noted in the last several issues of our *Review*, the DOJ has continued its pursuit of *individuals* involved in alleged fraud, not just the *companies* for whom they work. For example, in the \$155 million settlement involving eClinicalWorks, several of its employees agreed to joint and several liability, along with the company. Three additional employees entered into separate settlement agreements to resolve their personal involvement in the conduct. Similarly, the owner of Life Care Centers of America Inc. agreed to joint and several liability (along with the company) in the \$145 million settlement mentioned above.

The DOJ also reported that it recovered over \$60 million in settlements and judgments with individuals under the FCA. For example, a urologist paid \$3.8 million to settle allegations that he referred unnecessary tests to a lab owned by 21st Century Oncology (which paid nearly \$20 million to resolve FCA allegations against it).

¹Available [here](#).

3. Other Enforcement Updates

Other notable enforcement trends from 2017 included a focus on Medicare and Medicaid electronic health record incentive programs, which provide incentive payments to healthcare providers that show a “meaningful use” of certified electronic health record technology. Both the 21st Century Oncology and eClinicalWorks settlements mentioned above involved allegedly false statements to electronic health record incentive programs. A June 2017 report from the Department of Health and Human Services Office of Inspector General (HHS OIG) stated that the Centers for Medicare and Medicaid Services (CMS) inappropriately paid \$729 million under the programs, with states erroneously paying another \$66 million under the programs.² Not surprisingly, HHS OIG indicated that electronic health record incentive programs would continue to be a focus in 2018.

Last year also brought the DOJ’s first interventions in whistleblower cases related to Medicare Advantage plans. The lawsuits, both against UnitedHealth Group, Inc., involved allegations that the insurance plan inflated patients’ health risk scores in order to increase payments. See *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, No. 2:16-cv-08697 (C.D. Cal.); *United States ex rel. Swoben v. United Healthcare Ins. Co.*, No. 2:09-cv-05013 (C.D. Cal.). Although one of the lawsuits has been dismissed, CMS has estimated that it improperly paid over \$14 billion to Medicare Advantage plans in recent years,³ and thus Medicare Advantage plans will likely remain a target in FCA cases in 2018.

Finally, a lawyer from the DOJ Civil Division caused a splash in October after giving a speech indicating that the DOJ would exercise its statutory authority under 31 U.S.C. § 3730(c)(2)(A) to move to dismiss meritless whistleblower actions (known as “*qui tam*” actions). Although the defense bar was hopeful for a policy shift that could avoid the time and expense of frivolous litigation, the DOJ later clarified that the speech was merely an affirmation of the DOJ’s existing statutory authority, rather than a change in policy.

4. Notable Defense Victories

The defense bar also enjoyed a few notable victories in 2017. Our firm was privileged to assist Trinity Industries, Inc. in the appeal of a \$663 million judgment resulting from a 2014 jury trial in which a Trinity competitor had alleged that the company provided false information about a guardrail system that is sold to state departments of transportation and reimbursed by the Federal Highway Administration. *United States ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645 (5th Cir. 2017). On September 29, 2017, the Fifth Circuit reversed the judgment and held that Trinity did not commit fraud as a matter of law. *Id.* That decision, which vindicated Trinity on every element that it argued—materiality, falsity, intent, and damages—is discussed in more detail below.

As discussed in greater detail below, the DOJ walked away from the closely watched *ManorCare* case, which accused the national nursing home operator of engaging in a massive overbilling scheme. *United States ex rel. Ribik v. HCR ManorCare, Inc.*, No. 1:09-cv-00013 (E.D. Va. 2017). The DOJ agreed to dismiss the case with prejudice after the district court excluded the testimony of the DOJ’s star expert witness.

²Available [here](#).

³Available [here](#).

B. LEGISLATIVE UPDATE

Last year was relatively quiet in terms of legislative developments impacting the FCA, but HHS OIG did make several important regulatory modifications to its permissive exclusion authority, including:

- Expanding permissive exclusion authority to individuals or entities convicted of obstructing investigations or audits related to federal health care program funds.
- Expanding permissive exclusion authority to individuals or entities that *refer* or *certify the need* for items or services that they themselves do not provide.
- Expanding permissive exclusion authority to individuals or entities that knowingly make or cause to be made “any false statement, omission, or misrepresentation of material fact in any application, agreement, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program.”
- Adopting a 10-year limitations period.

These regulations took effect on February 13, 2017. 82 Fed. Reg. 4100 (Jan. 12, 2017).

C. SIGNIFICANT JUDICIAL DECISIONS

Federal courts continued interpreting and applying the FCA in various contexts in 2017. The following is a brief summary of some of those key decisions, organized by issue.

1. Post-*Escobar*: Materiality and Implied Certification

The Supreme Court’s 2016 decision in *Universal Health Servs., Inc. v. United States ex rel. Escobar* has continued to receive significant attention from the lower courts. 136 S. Ct. 1989, ___ U.S. ___ (2016).

By way of background, the *Escobar* Court issued two key holdings. First, the Court resolved a circuit split by confirming the validity of the “implied false certification theory of liability,” under which a defendant’s failure to disclose noncompliance with a statute, regulation, or contract requirement can render a claim “false or fraudulent”—even if the claim does not expressly certify such compliance. See *id.* at 1995-96. The Court clarified that “not every undisclosed violation of an express condition of payment automatically triggers liability.” *Id.* Instead, the misrepresentation about compliance “must be *material* to the government’s payment decision.” *Id.* at 2002 (emphasis added).

Second, the Court held that determining materiality is a “rigorous” and “demanding” fact-based inquiry of whether a noncompliance has a natural tendency to influence, or be capable of influencing, the government’s payment decision. See *id.*; *United States ex rel. Gelman v. Donovan*, 2017 WL 4280543, at *5 (E.D.N.Y. Sept. 25, 2017) (“[After *Escobar*,] materiality is essentially a matter of common sense rather than technical exegesis of statutes and regulations.”).

Since the Supreme Court issued its opinion in *Escobar*, numerous district and appellate courts have attempted to apply these two key holdings. The following is a brief summary of some of the key decisions issued in 2017.

a. Interpretations of *Escobar* Regarding Implied Certification Claims

Escobar did not resolve “whether all claims for payment implicitly represent that the billing party is legally entitled to payment.” 136 S. Ct. at 2000. This left the question of whether the Supreme Court intended to outline two *mandatory* elements of an implied false certification claim—(1) a request for payment with specific representations and (2) the failure to disclose material noncompliance—or simply one possible way FCA liability could arise. We noted the growing disagreement among district courts in last year’s issue. In 2017, courts of appeals have weighed in to deepen the divide.

In *United States ex rel. Kelly v. Serco, Inc.*, the Ninth Circuit stated in dicta that the implied certification theory can be a basis for liability where both elements outlined in *Escobar* are satisfied. See 846 F.3d 325, 332 (9th Cir. 2017). The court then analyzed each element in turn—finding no evidence for either—before moving on to the issue of materiality. This was reiterated in dicta in *United States ex rel. Campie v. Gilead Sciences, Inc.*, where the court stated that the “two conditions *must* be satisfied” for the implied certification theory to be a basis for FCA liability. 862 F.3d 890, 901 (9th Cir. 2017) (emphasis added).

Kelly and *Campie* appear to establish that the two-part test for falsity is mandatory in the Ninth Circuit, and district courts have since cited the two cases to dismiss complaints that fail to identify specific representations in the defendant’s claims for payment. See, e.g., *United States ex rel. Mateski v. Raytheon*, 2017 WL 1954942 (C.D. Cal. Feb. 10, 2017). This view also aligns with that of courts in the Second, Third, and Seventh Circuits. See, e.g., *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447-48 (7th Cir. 2016); *United States ex rel. Forcier v. Computer Sci. Corp.*, 2017 WL 3616665, at *12 (S.D.N.Y. Aug. 10, 2017); *United States ex rel. Schimelpfenig v. Dr. Reddy’s Labs. Ltd.*, 2017 WL 1133956, at *4-5 (E.D. Pa. Mar. 27, 2017).

Interestingly, *Kelly* and *Campie* depart from the earlier view of district courts in the Ninth Circuit. See *United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1044 (C.D. Cal. 2016) (*Escobar*’s two conditions were not intended to describe “the outer reaches of FCA liability”); *Rose v. Stephens Inst.*, 2016 WL 5076214, at

*5 (N.D. Cal. Sept. 20, 2016) (“*Escobar* did not establish a rigid two-part test for falsity that must be met every single implied certification case.”). *Rose* was appealed to the Ninth Circuit to address the question directly, *United States ex rel. Rose v. Stephens Inst.*, No. 17-1511 (9th Cir.), and oral argument was heard in December 2017.

In contrast, the Fourth Circuit has noted that the lack of a “specific representation” in a claim does not alter the fact that “half truths . . . can be actionable misrepresentations.” *United States ex rel. Badr v. Triply Canopy, Inc.*, 857 F.3d 174, 178 (4th Cir.) (quoting *Escobar*, 136 S. Ct. at 2000), *cert. denied*, 138 S. Ct. 370 (2017). The court thus held that *Escobar*’s two conditions were *not* required for a valid implied certification claim. This view aligns with that of the district courts in the D.C. Circuit. See, e.g., *United States v. DynCorp Int’l, LLC*, 253 F. Supp. 3d 89, 99-100 (D.D.C. 2017) (clarifying that requiring “specific representations” for an implied certification claim “is not the law of the D.C. Circuit”). We will be monitoring for further developments as courts continue to grapple with this issue.

b. Interpretations of *Escobar* Regarding Materiality

i. Continued payment by the government is strong evidence of non-materiality

In *Escobar*, the Court clarified that if the government pays a particular claim in full—or regularly pays that type of claim in full—despite actual knowledge of the key allegations, then the government’s payment is strong evidence of *non-materiality*. 136 S. Ct. at 2003-04. Several circuits weighed in on this issue in 2017.

In *Coyne v. Amgen, Inc.*, the Second Circuit affirmed the dismissal of an FCA suit because it held that the concealment of clinical trial data from CMS was not material to CMS’s decision to pay. 2017 WL 6459267, at *2 (2d Cir. Dec. 18, 2017). Since the drug in question was approved by the Food and Drug Administration (FDA) and prescribed consistently with its FDA-approved indication, it was “presumptively ‘reasonable and necessary’ for the purposes of CMS reimbursement.” *Id.* The lack of materiality was confirmed by the fact that CMS did not alter its

reimbursement practices after the defendant updated the drug's label to contain the allegedly concealed clinical trial information. *Id.* at *2-3.

In *United States ex rel. Petratos v. Genentech, Inc.*, the Third Circuit affirmed the dismissal of an FCA suit because the relator did not allege that the government would not have reimbursed the claims if it had known about the alleged noncompliance. 855 F.3d 481, 490 (3d Cir. 2017). The relator had disclosed evidence of the defendant's conduct to the DOJ and FDA in 2010 and 2011. *Id.* Since that time, the FDA not only left undisturbed its approval of the defendant's product, but it also approved three more indications for the drug. *Id.* The court determined that the alleged fraud did not affect CMS's payment decision and, thus, was not material. *Id.* at 492.

The Third Circuit came to the same conclusion in *United States ex rel. Spay v. CVS Caremark Corp.*, a case involving the defendant's alleged submission of pharmacy claims with "dummy" Prescriber IDs—required by CMS to process prescription drug event records and payments. 875 F.3d 746, 750-51 (3d Cir. 2017). Because CMS continued paying the defendant's claims despite actual knowledge of the claims having dummy IDs, the Third Circuit held that this was strong evidence that the IDs were not material. *Id.* at 764. The court characterized the dummy IDs as "precisely the type of 'minor or insubstantial' misstatements where '[m]ateriality . . . cannot be found.'" *Id.* (quoting *Escobar*, 136 S. Ct. at 2003).⁴

In *United States ex rel. McBride v. Halliburton Co.*, the D.C. Circuit found no materiality in a case alleging that a contractor providing recreation services to the U.S. military inflated "headcounts" of personnel served. 848 F.3d 1027, 1028 (D.C. Cir. 2017). The relator could not point to a contractual, regulatory, or other legal

requirement that defendant had to maintain accurate headcounts. *Id.* at 1032. Instead, she pointed to a regulation requiring costs charged to the government to be "reasonable," and alleged that inflated headcounts could be used to justify excessive staffing levels and increased—and therefore "unreasonable"—costs. *Id.* at 1033. But the relator did not offer any evidence that accurate headcount data was relevant to determining the reasonableness of costs; in fact, the government did not disallow any costs charged by the defendant after investigating the allegations, and even later gave the defendant an award fee for exceptional performance. *Id.* at 1033-34. As such, the D.C. Circuit held that there was "very strong evidence" that the requirements allegedly violated by the inflated headcounts were not material. *Id.* at 1034.

Finally, in *United States ex rel. Harman v. Trinity Industries Inc.*, the Fifth Circuit examined several of the aforementioned appellate court decisions and determined that the defendants in that case did not submit materially false statements as a matter of law. 872 F.3d 645, 663-64 (5th Cir. 2017). The court noted that the government was aware of the relator's allegations and yet "never retracted its explicit approval [of Trinity's product], instead stating that an 'unbroken chain of eligibility' has existed since 2005." *Id.* The Fifth Circuit therefore reversed a \$663 million judgment against the defendants, noting that "[w]hen the government, at appropriate levels, repeatedly concludes that it has not been defrauded, it is not forgiving a found fraud—rather it is concluding that there was no fraud at all." The Federal Highway Administration's consistent approval of Trinity's product represented "very strong" and "unrebutted" evidence that any alleged false statements were not material. *Id.* at 664-65, 668; see also *Abbott v. BP Expl. & Prod., Inc.*, 851 F.3d 384, 386, 388 (5th Cir. 2017) (holding that there was "strong evidence" of

⁴ *Spay* is notable for two additional holdings. First, the Third Circuit held that the FCA's materiality standard applies to conduct before the adoption of the Fraud Enforcement and Recovery Act of 2009 (FERA). FERA reversed *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008), which expressed a narrow scope of FCA liability, and introduced a materiality standard for the first time. Second, the district court in *Spay* had granted summary judgment in the defendant's favor on the basis of the "government knowledge inference" doctrine: "[w]hen the government knows and approves of the facts underlying an allegedly false claim prior to presentment, an inference arises that the claim was not knowingly submitted, regardless of whether the claim itself is actually false." 2015 WL 5582553, at *24 (E.D. Pa. Sept. 22, 2015). In other words, CMS knew about the use of the dummy IDs but paid all the claims anyway and did not seek repayment, so the defendant did not have the "requisite scienter of falsely submitting a claim." *Id.* at *26. The Third Circuit affirmed the grant of summary judgment, but on the grounds of materiality instead of the "government knowledge inference" doctrine. The appellate court held that the doctrine requires (1) the government knowing about the alleged false statement(s), and (2) the defendant knowing that the government knows. In *Spay*, however, there was insufficient evidence of the defendant's knowledge that CMS knew of the dummy Prescriber IDs practice, so the second prong was not met.

non-materiality where, among other things, a Department of the Interior investigation deemed the relator's allegations "without merit" and "unfounded" and the defendant was allowed to continue its activities).

ii. Other government action supporting non-materiality

While *Escobar* discussed the relationship between materiality and continued payment of claims by the government, it did not directly address other governmental actions. Since *Escobar*, some courts have looked beyond the government's payment decision to actions such as the decision to intervene, debarment, and regulatory certifications.

In *Badr*, for example, the Fourth Circuit found that the government's decision not to renew its contract with the defendant and instead intervene in the litigation suggested the noncompliance was material to the government's decision to pay. See 857 F.3d at 179. Correspondingly, the government's decision not to intervene or take action against the defendant in *Petratos* was viewed by the Third Circuit as additional evidence that the alleged false certifications were not material to the government's decision to continue to pay. See 855 F.3d at 490.

In *United States v. Luce*, the government sued the defendant for falsely certifying that no officers of his mortgage company had been subject to criminal proceedings so that the company could continue to qualify for insurance under the Fair Housing Act—even though the defendant himself had previously been indicted. 873 F.3d 999, 1002 (7th Cir. 2017). In addressing the element of materiality, the Seventh Circuit held that the false certifications were material in part because the government presented evidence showing that the certification was a "threshold eligibility requirement" for program participation—and in fact the government "actual[ly] debar[ed]" the defendant when it learned of the falsity. See *id.* at 1008.

Finally, in *A1 Procurement, LLC v. Thermcor, Inc.*, the court held that the agency's continuing approval of the defendant for participation in its program—despite knowing of the defendant's alleged noncompliance—

meant that any misrepresentation about that compliance was not material. 2017 WL 2881350, at *6-7 (E.D. Va. May 5, 2017). In *Thermcor*, the defendant allegedly failed to comply with various program eligibility requirements for certification by the Small Business Administration (SBA), which allowed the defendant to bid on contracts from government agencies. *Id.* at *2. After learning of the defendant's noncompliance, however, the SBA did not terminate the defendant from its program. *Id.* at *6. As with inaction by the government despite actual knowledge of noncompliance (in the form of continued payment of claims), the court held that inaction by a certifying body was evidence of non-materiality. See *id.* at *6-7.

iii. Conclusory allegations of materiality are insufficient to state an FCA claim

Following the Supreme Court's reinvigoration of the materiality element in *Escobar*, several courts have held that conclusory allegations of materiality are inadequate at the pleading stage. See, e.g., *Coyne*, 2017 WL 6459267, at *2 (holding that a conclusory allegation that the defendant's failure to disclose clinical trial information to CMS was material to payment was insufficient, and instead "the complaint must present concrete allegations from which the court may draw the reasonable inference that the misrepresentations . . . caused the government to make the reimbursement decision"); *United States ex rel. Swoben v. Scan Health Plan*, 2017 WL 4564722, at *6 (C.D. Cal. Oct. 5, 2017) (dismissing government's Complaint-in-Partial-Intervention because it "includes only conclusory allegations that the [defendants'] conduct was material, and fails to allege that CMS would have refused to make . . . payments to the [defendants] if it had known the facts . . ."); *United States ex rel. Payton v. Pediatric Servs. of Am., Inc.*, 2017 WL 3910434, at *10 (S.D. Ga. Sept. 6, 2017) (holding that a relator's complaint "must do something more than simply state that compliance is material").

Similarly, a conclusory statement that the government would not have paid the claim had it been aware of the alleged false statement is insufficient. For example, one district court characterized "barebones allegations regarding materiality" that "d[id] not show how [the defendant's] misrepresentations were material" as "completely conclusory," "insufficient,"

and “requir[ing] dismissal even without considering the government’s knowledge.” *United States ex rel. Mateski v. Raytheon*, 2017 WL 3326452, at *7 (C.D. Cal. Aug. 3, 2017).

In contrast, complaints alleging more than merely conclusory statements of materiality satisfied the pleading requirements:

- Complaint “allege[d] enough information on materiality to make it past the motion-to-dismiss stage” where it pleaded sufficient information about how the defendant’s misrepresentations would cause the government to bear more financial risk than it bargained for, which “would have affected the government’s payment decision.” *United States ex rel. Hussain v. CDM Smith, Inc.*, 2017 WL 4326523, at *8 (S.D.N.Y. Sept. 27, 2017).
- Complaint satisfied the materiality requirement by, among other things, citing cases in which CMS canceled participation in and eligibility for the Medicare program for violations similar to those alleged. *United States v. Visiting Nurse Serv. of N.Y.*, 2017 WL 5515860, at *10 (S.D.N.Y. Sept. 26, 2017).
- Government letters indicating the materiality of the disclosure of interested persons “support a finding that both [the state’s] Medicaid administrators and HHS would have refused to pay the [defendant’s] claims had they known of [the interested person’s] involvement. *Smith v. Carolina Med. Ctr.*, 2017 WL 3310694, at *11 (E.D. Pa. Aug. 2, 2017).
- Complaint adequately pleaded materiality by alleging that the defendant’s “claims for government reimbursement . . . included false certifications rendering the claims ‘ineligible for reimbursement’” (in contrast to the complaint in *Petratos* above). *United States v. Johnson & Johnson*, 2017 WL 2367050, at *6 (D.N.J. May 31, 2017).

A plaintiff may also be able to adequately plead materiality by showing that the misrepresentation was an “essential feature” of the government program in

question or went to the “essence of the bargain” with the government—language from *Escobar* itself. 136 S. Ct. at 2003 n.5 (“[A] misrepresentation is material if it went to the very essence of the bargain”) (citation omitted). Below are a few examples:

- Complaint adequately pleaded materiality where it cited contractual provisions and references to show that the defendant’s contractual violations went to the “essence of the bargain” with the government. *United States ex rel. Fisher v. IASIS Healthcare LLC*, 2016 WL 6610675, at *14 (D. Ariz. Nov. 9, 2016). The court ruled that the defendant’s compliance with the provisions were “the *sine qua non* of government payment.” *Id.*
- Complaint adequately pleaded materiality where it alleged that, among other things, the defendant-lender’s certifications with statutory underwriting requirements went to the “essence of the bargain” with the federal department and agency in question. *See United States v. Quicken Loans Inc.*, 239 F. Supp. 3d 1014, 1039-40 (E.D. Mich. 2017).
- Complaint adequately pleaded materiality where, among other things, “courts have routinely found the various statements and regulations at issue to be central to the government’s Medicare and Medicaid programs.” *United States v. Am. at Home Healthcare & Nursing Servs., Ltd.*, 2017 WL 2653070, at *9 (N.D. Ill. June 20, 2017).
- Complaint alleging claims for payment of off-label pharmaceuticals adequately pleaded materiality where disclosure of a medically accepted indication was “an essential feature” of the Medicare Part D program. *United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1049 (C.D. Cal. 2016). The court reasoned that *Escobar* “does not foreclose the possibility that a statutory requirement may be so central to the functioning of a government program that noncompliance is material as a matter of law.” *Id.*

Although ruling on a motion for summary judgment, not a motion to dismiss, a 2017 case examining exceptions to the Stark Law is also worth mentioning. *See United States ex rel. Emanuele v. Medicor Assocs.*, 242 F. Supp. 3d 409, 431 (W.D. Pa. 2017),

reconsideration denied, 2017 WL 3675921 (W.D. Pa. Aug. 25, 2017). There, the court denied the defendants' motion for summary judgment, finding the writing requirement present in various Stark law exceptions represented a "material" component of the exceptions for the purposes of establishing liability under the FCA as the requirement was not "minor or insubstantial" and meeting each element of an applicable exception went "to the very 'essence of the bargain' between the government and health care providers." *Id.*

2. Pleading with Particularity

One of the first hurdles for plaintiffs in an FCA suit is the heightened pleading standard associated with allegations of fraud. See Fed. R. Civ. P. 9(b). Under this standard, a complaint must "state with particularity the circumstances constituting fraud" to provide sufficient notice of the relator's claims and protect the defendant against baseless allegations.

As we have discussed in previous *Reviews*, courts have long been divided over the standard's application and the necessity of pleading representative claims. The First, Fourth, Sixth, and Eleventh Circuits previously held that the FCA generally imposes a strict pleading standard requiring particularized allegations of specific false claims. Conversely, the Third, Fifth, Seventh, Eighth, Ninth, and D.C. Circuits have applied a more flexible, case-specific approach under which a representative sample claim may not be necessary. Instead, it may be sufficient to, for example, allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." See, e.g., *United States ex rel. Colquitt v. Abbott Labs.*, 858 F.3d 365, 372 (5th Cir. 2017). In 2017, some circuits attempted to bridge the circuit split while others doubled down on their determination of the appropriate pleading standard under Rule 9(b).

a. Circuit courts apply the Rule 9(b) pleading standard in a variety of cases

The Second Circuit noted that it "generally held FCA claims to the higher pleading standard of Rule 9(b), which requires that plaintiffs state with particularity

the specific statements or conduct giving rise to the fraud claim." *United States ex rel. Takemoto v. Nationwide Mutual Ins. Co.*, 674 F. App'x 92, 95 n.1 (2d Cir. 2017) (citations omitted). But the Second Circuit later recognized that information regarding specific false claims may sometimes be "peculiarly within [the defendant's] knowledge" and thus inaccessible to relators without discovery. *United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 82-83 (2d Cir. 2017). In such circumstances, Rule 9(b) can be satisfied by "plausible and particularized factual allegations leading to a strong inference that [the defendant] did in fact submit false claims to the government," even without the identification of specific false claims submitted to the government. *Id.* at 85-86.

Chorches appears to place the Second Circuit among those circuits that have adopted a "more lenient" pleading standard. The court did not, however, believe circuits on the other side of the split would necessarily disagree with its position. It noted that even those circuits consistently applying the "stricter" pleading standard sometimes retreated from it where specific circumstances—such as a relator having personal knowledge of the defendant's claims submission and billing processes—could support a strong inference that specific false claims were submitted. *Id.* at 90-91 (citing *United States ex rel. Prather v. Brookdale Senior Living Cmty., Inc.*, 838 F.3d 750, 773 (6th Cir. 2016)).

The Sixth Circuit clarified that the identification of at least one false claim with specificity remained "an indispensable element" of Rule 9(b), and that a "relaxed" standard is only appropriate where the relator has sufficient personal knowledge of when, where, and how the defendant submitted claims. See *United States ex rel. Hirt v. Walgreen Co.*, 846 F.3d 879, 881-82 (6th Cir. 2017) (affirming dismissal of the relator's complaint where it failed to "identify a single false claim" and instead pleaded only "inferences and implications"). In *United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, the Sixth Circuit confirmed that this "personal knowledge" exception is limited and applies only when a "relator alleges specific knowledge that relates directly to billing practices." 874 F.3d 905, 915 (6th Cir. 2017). The court further held that since the relators in that case alleged a complex scheme

involving a “long chain of causal links from defendants’ conduct to the eventual submission of claims,” Rule 9(b) required “a representative claim that describes *each step* with particularity.” *Id.* at 914 (emphasis added).

Similarly, the Fourth Circuit unequivocally affirmed its earlier holding that Rule 9(b)’s heightened pleading standard required identification of specific false claims or allegations of a scheme that *necessarily* resulted in the submission of false claims. See *United States ex rel. Szymoniak v. Am. Home Mortgage Servicing, Inc.*, 679 F. App’x 299, 303 (4th Cir. 2017) (declining to revisit *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451 (4th Cir. 2013)). Allegations of a scheme that *could* have led, but *need not necessarily* have led, to the submission of false claims are insufficient. *Nathan*, 707 F.3d at 457. At least one district court in the Fourth Circuit has already relied on *Szymoniak* to dismiss a complaint that alleged the maker of a false representation and the time and place of the false representation but did not include “a description of the content of the alleged misrepresentation” or “the nature of the fraud.” See *Thomas v. Ocwen Loan Servicing, LLC*, 2017 WL 2645721, at *5 (D. Md. June 19, 2017).

While the Sixth and Fourth Circuits affirmed their strict Rule 9(b) standards, the First Circuit took an affirmative step away from its own similar standard. In *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, the relator alleged that the defendant induced unsuspecting doctors to purchase defectively manufactured devices and submit claims for their use. 865 F.3d 29, 37 (1st Cir. 2017). The complaint included only one example of an actual sale of a defectively manufactured product to a doctor who submitted claims. *Id.* But since the defendant had not submitted false claims itself—instead allegedly inducing third parties to submit claims—the court applied a “more flexible” pleading standard. See *id.* at 39. The defendant’s indirect fraud meant the “relator could satisfy Rule 9(b) by providing factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim.” *Id.* (citations omitted). Thus, *Nargol* recognized an exception to its strict pleading standard in cases involving evidence of indirect fraud paired with “reliable indicia that lead to a strong inference that claims were actually submitted.” *Id.* (citation omitted).

b. District courts continue to grapple with Rule 9(b)

Since the Supreme Court has yet to resolve the circuit split, district courts continue to wrestle with Rule 9(b)’s pleading requirements. Below are a few key cases analyzing FCA complaints for compliance with Rule 9(b):

- Complaint failed to satisfy Rule 9(b) where relators stated that “they ha[d] become aware of specific claims” for improper services and would later identify them during discovery. *United States v. CareFlite*, No. 4:16-cv-00410, at 8 (N.D. Tex. Apr. 17, 2017), ECF No. 90. The court held that “[t]his statement provides no additional facts supporting an inference that false claims were actually submitted and it is too vague to qualify as pleading the presentment of a specific claim.” *Id.* at 13.
- Complaint satisfied Rule 9(b) where the relator alleged falsity of claims based on physicians’ findings of a lack of medical necessity, provided nine specific examples of the defendant’s actions causing a patient’s admission and a related claim to be submitted to Medicare, and alleged personal knowledge of the defendant’s scheme. See *United States ex rel. Graziosi v. Accretive Health, Inc.*, 2017 WL 1079190, at *7 (N.D. Ill. Mar. 22, 2017). Even though the relator did not attach records showing that claims were in fact submitted to the federal government, her “factual allegations, taken as a whole, provide enough detail to support her belief that the claims were or likely were submitted.” *Id.*
- Complaint satisfied Rule 9(b) where it “adequately describes the market for radiology services prior to and after [the defendant’s] formation, highlights the structure of the joint venture agreement, details the valuation process, and identifies specific components of [the defendant’s] continued operation central to the claims.” *United States ex rel. Rembert v. Bozeman Health Deaconess Hosp.*, 2017 WL 514205, at *5 (D. Mont. Feb. 7, 2017). These factual allegations pleaded the existence of the claimed fraudulent scheme with sufficient particularity to meet the Ninth Circuit’s lenient pleading standard. See *id.* (citation omitted).
- Complaint satisfied Rule 9(b) where relators

alleged “firsthand knowledge of the fraudulent billing practices” through their privileged positions and access to medical records and billing summaries while working for the defendant.

United States ex rel. Napoli v. Premier Hospitalists PL, 2017 WL 119773, at *5 (M.D. Fla. Jan. 12, 2017).

The complaint’s “detailed description of the allegedly fraudulent schemes” and the relators’ “insider knowledge” provided sufficient indicia of reliability to meet the Eleventh Circuit’s strict pleading standard, even though relators did not identify a specific false claim submitted to the government. See *id.* at *6.

- Complaint failed to satisfy Rule 9(b) where the relator provided detailed allegations regarding marketing schemes but did not link the scheme to the actual submission of false claims. See *United States ex rel. Stepe v. RS Compounding LLC*, 2017 WL 5178183, at *6 (M.D. Fla. Nov. 8, 2017). The relator also focused on her status as an insider, but because the relator was a sales representative rather than a billing department employee, she could not allege firsthand knowledge of the defendant’s billing practices (unlike *Napoli* above). See *id.* The United States’ Complaint in Partial Intervention, however, satisfied Rule 9(b) where the government provided “numerous sample claims for specific patients,” calculations comparing the defendant’s pricing on prescriptions paid for by TRICARE and by cash payors, and a detailed explanation of how the defendant allegedly used a software to conceal its actual pricing. See *United States ex rel. Stepe v. RS Compounding LLC*, 2017 WL 5998992, at *6-7 (M.D. Fla. Dec. 4, 2017).

3. Public Disclosure and Original Source

The public disclosure bar prohibits *qui tam* suits based on publicly disclosed allegations of fraud, unless the relator has sufficient knowledge of the fraud to qualify as an “original source.” 31 U.S.C. § 3730(e)(4). This defense is continually a source of litigation, as courts attempt to strike the congressionally intended balance between discouraging parasitic lawsuits and properly

incentivizing true whistleblowers. In 2017, a number of appellate courts addressed the public disclosure bar and the original source exception. The significant decisions are summarized below.

a. When is the public disclosure bar triggered?

This year, several circuits addressed the timing and details of disclosures sufficient to trigger the public disclosure bar.

- **Seventh Circuit.** The Seventh Circuit held that a relator’s allegations were substantially similar to publicly disclosed allegations, even though the allegations related to an entirely different time period. *Bellevue v. Universal Health Servs. of Hartgrove, Inc.*, 867 F.3d 712, 720 (7th Cir. 2017), *petition for cert. filed*, No. 17-842 (U.S. Dec. 12, 2017). The relator’s allegations involved conduct occurring both before and after a letter published by CMS in May 2009. *Id.* at 718-19. The district court held that the allegations concerning conduct up through May 2009 were substantially similar to the publicly disclosed conduct and barred by the public disclosure bar, but that the allegations concerning conduct after May 2009 were not barred because they concerned a different time period. *Id.* at 719. On appeal, the Seventh Circuit agreed as to the pre-May 2009 conduct, but held that the post-May 2009 allegations *were also substantially similar* to the publicly disclosed conduct. *Id.* at 720. The Seventh Circuit found that the “conclusory allegations” pertained to the same entity and described the same scheme and, thus, merely pleading a “continuing practice” could not circumvent the public disclosure bar. See *id.*; see also *United States ex rel. Lisitza v. Par Pharm. Cos., Inc.*, 2017 WL 3531678, at *13 (N.D. Ill. Aug. 17, 2017) (citing *Bellevue* for the proposition that “expansion of time period over which fraud scheme operated insufficient to clear substantial similarity hurdle”), *appeal filed*, No. 17-2915 (7th Cir. Sept. 18, 2017).
- **Sixth Circuit.** The Sixth Circuit also addressed claims of continuing conduct, but instead held that allegations that a fraudulent off-label promotion scheme continued or restarted could survive the public disclosure bar. *United States ex*

rel. Ibanez v. Bristol-Myers Squibb Co., 874 F.3d 905, 919 (6th Cir. 2017). The court reasoned that “[i]t cannot be assumed that the government is aware a fraudulent scheme continues (or was restarted) simply because it had uncovered, and then resolved, a similar scheme before.” *Id.* To the extent relators are able to describe *with particularity* post-agreement, off-label promotion of the drug, the court held that the mere resemblance of those allegations to a scheme resolved years earlier is not by itself enough to trigger the public disclosure bar. *See id.* Thus, whether allegations of continuing conduct are enough to preclude application of the public disclosure bar depends heavily on the specific nature of the post-public disclosure facts pleaded and whether those facts, pleaded with particularity, exceed the scope of the previous public disclosure.

- **Eighth Circuit.** The Eighth Circuit addressed the details necessary to establish a public disclosure and explained that a disclosure need not explicitly identify defendants or the specific fraud at issue in order for the bar to apply. *See United States ex rel. Lager v. CSL Behring, LLC*, 855 F.3d 935, 944 (8th Cir. 2017). The Eighth Circuit held that, viewed collectively, the public disclosures in various governmental and media sources “provide[d] enough information about the participants in the scheme to directly identify the defendants and the subject drugs.” *Id.* at 946 (citation omitted). The public disclosures “would have ‘set the government squarely on the trail’ of the defendants’ participation in the purported fraudulent reporting of prices for DME infusion drugs.” *Id.* (quoting *In re Nat. Gas Royalties*, 562 F.3d 1032, 1041 (10th Cir. 2009)).
- **Ninth Circuit.** The Ninth Circuit similarly held that a public disclosure in a patent infringement lawsuit contained enough detail to bar allegations against a drug manufacturer even where the disclosure did not expressly reference any false claims or the FCA, or contain every specific detail regarding the alleged fraud. *Amphastar Pharm. Inc. v. Aventis Pharma S.A.*, 856 F.3d 696, 704 (9th Cir. 2017). Because the allegations in the two cases were “nearly identical,” with the exception

of the one new allegation in the FCA suit that the government also bought the drug, the Ninth Circuit held that the allegations were substantially similar and that the public disclosure bar was triggered. *Id.*

b. Who is an original source?

If the public disclosure bar is triggered, the court must dismiss the *qui tam* suit unless the relator is an “original source” of the information underlying the complaint. 31 U.S.C. § 3730(e)(4). To qualify as an “original source,” the relator must have knowledge that is “independent of and materially adds to” the public disclosure and must have voluntarily provided that information to the government before filing a *qui tam* suit. In 2017, the circuit courts opined on both the pre-suit disclosure requirement and the independent knowledge requirement.

- **Fifth Circuit.** The Fifth Circuit addressed the pre-suit disclosure requirement, holding that relators were not original sources where they failed to establish that their pre-suit disclosure contained “the information on which the allegations are based” as required by the statute. *United States ex rel. King v. Solvay Pharm., Inc.*, 871 F.3d 318, 326 (5th Cir. 2017). The court explained that for relators to satisfy the FCA’s voluntary pre-suit disclosure requirement, “their disclosure must—at a minimum—connect direct and independent knowledge of information about [the defendant’s] conduct to false claims submitted to the government, i.e., suggest an *FCA violation*.” *Id.* at 327. Because the declaration merely referred to discussions the relators had with the FDA about the off-label marketing and kickbacks at issue and did not indicate that relators *actually connected* the information with any false claims presented to the government, the court held that the claims as to one of the drugs at issue were barred by the public disclosure bar.

The Fifth Circuit also addressed the independent knowledge requirement, reiterating that a relator is not an original source unless he contributes firsthand knowledge that strengthens the government’s case. *See United States ex rel. Colquitt v. Abbott Labs.*, 858 F.3d 365, 366 (5th

Cir. 2017). In *Abbott*, the Fifth Circuit held that the district court did not err in limiting the timeframe of the false presentment theory presented to the jury because the relator, who was a former employee, was not an original source as to the pre- and post-employment timeframe. *Id.* at 366. As to those time periods, the relator had relied on secondhand facts such as those learned from conversations with a former co-worker. *Id.* The court held that these secondhand facts did not constitute new evidence of wrongdoing or strengthen the government’s case so as to support treating the relator as an original source. *Id.* at 366-77. To proceed as an original source, a relator must have direct, independent, firsthand knowledge. *Id.* at 377.

- **Eighth Circuit.** The Eighth Circuit clarified that a relator need only have “direct knowledge of the true state of the facts” in order to proceed as an original source, and need not be aware of *all* elements of a cause of action. *In re Baycol Prods. Litig.*, 870 F.3d 960, 962 (8th Cir. 2017). The district court granted a motion to dismiss, finding that the relator was not an “original source” of the allegations because she failed to demonstrate direct or independent knowledge of any communication between the defendant and the government forming the basis of her claim. *Id.* The Eighth Circuit reversed, stating that the relator was not required to have direct or independent knowledge of the defendant’s allegedly false communications to the government. *Id.* The Eighth Circuit explained that the original source provision requires the relator “to possess direct and independent knowledge of the ‘information’ on which her allegations are based, not of the ‘transaction,’ a term used earlier in the same provision.” *Id.* (citing *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 656 (D.C. Cir. 1994)). It was enough that the relator had direct knowledge of the facts, “even though her knowledge of the misrepresentation is not first-hand.” *Id.* (citation omitted).

4. First-to-File Rule

The FCA’s first-to-file rule prevents anyone other than the government from bringing “a related action based

on the facts underlying [a] pending action.” 31 U.S.C. § 3730(b)(5). Courts have interpreted the phrase “related action” to mean actions based on the same “material” or “essential” facts. *See, e.g., United States ex rel. Johnson v. Planned Parenthood*, 570 F. App’x 386, 389 (5th Cir. 2014). The Supreme Court previously resolved a circuit split regarding the meaning of “pending,” holding that the first-to-file rule does not bar new claims in perpetuity but instead only applies if the first-filed case is still alive. *See Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970, 1978-79 (2015). In other words, an FCA case ceases to be “pending” once it is dismissed. *Id.* at 1979. In 2017, the Fourth Circuit and the D.C. Circuit both strengthened the first-to-file rule, holding that the rule bars a later-filed suit if an earlier-filed related action is pending *at the time the later suit is filed*, even if the first-filed action is later dismissed.

On remand in *Carter*, the Fourth Circuit ruled that the first-to-file rule mandated dismissal of the relator’s case because it was brought while two related actions—filed four years before the relator’s action—were pending. *United States ex rel. Carter v. Halliburton Co.*, 866 F.3d 199, 207-08 (4th Cir. 2017). The two earlier-filed cases were dismissed several months *after* the relator filed his case, but the court held that this did not matter. Instead, “the appropriate reference point for a first-to-file analysis is the set of facts *in existence at the time that the FCA action under review is commenced.*” *Id.* at 207 (emphasis added). The relator in *Carter* sought to amend his complaint pursuant to *United States ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1 (1st Cir. 2015)—a case we discussed in our two previous *Reviews*. *Gadbois* held that a first-to-file defect can be cured by a Rule 15(d) supplement clarifying that an earlier-filed, related action has been dismissed. The proposed amendments in *Carter* did not, however, address the dismissals of the earlier-filed actions. So, the Fourth Circuit deemed *Gadbois* factually distinguishable and affirmed the district court’s denial of leave to amend.

The D.C. Circuit issued an opinion mere days before *Carter* in which it reached the same conclusions regarding the appropriate reference point for a first-to-file analysis and the inability to cure first-to-file defects by amendment. In *United States ex rel. Shea v. Cellco Partnership*, the same relator filed two cases.

863 F.3d 923, 926 (D.C. Cir. 2017). The first ended in a settlement, but the second suit was brought while the first was still pending. As in *Carter*, the D.C. Circuit held that the first-to-file rule mandated dismissal since bringing a related action while one's first-filed case remains pending—regardless of what ultimately happens to the first-filed case—triggers the first-to-file rule. *Id.* at 929. The relator in *Shea* also sought leave to amend his complaint rather than re-file a new suit to avoid running afoul of the statute of limitations. But the D.C. Circuit held that amendment of the complaint would be futile since the first-to-file rule rendered the action “incurably flawed from the moment [the relator] filed it.” *Id.* at 930. Thus, Shea arguably takes a stronger position than *Carter* against *Gadbois* by ruling that an amendment or supplement to a complaint cannot, *as a matter of law*, cure a first-to-file defect. See *Carter*, 866 F.3d at 212 (Wynn, C.J., concurring). This remains an issue that divides courts across the country. See, e.g., *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 795-800 (S.D.N.Y. 2017) (holding that, as a matter of first impression, a violation of the first-to-file rule is curable by amending or supplementing a complaint after an earlier-filed action is dismissed), *appeal filed*, No. 17-2191 (2d Cir. July 17, 2017).

The Fourth Circuit also broadly interpreted the first-to-file rule with regard to alleged conduct occurring in different states and consolidation of claims made by separate relators, concluding that the bar applied in both circumstances. *United States ex rel. Carson v. Manor Care, Inc.*, 851 F.3d 293, 303-05 (4th Cir. 2017). *Carson* involved two *qui tam* actions filed separately by two different relators, but later consolidated by the district court. See *id.* at 301. Both complaints alleged that ManorCare implemented a scheme of overbilling for medical and physical therapy costs, but the second relator provided additional factual allegations and alleged that the conduct occurred in Pennsylvania rather than Virginia. *Id.* at 304. The district court dismissed the second complaint, concluding that it was based upon the same “material elements” of alleged fraud as the first-filed complaint and therefore was barred by the first-to-file rule. *Id.* at 301. On appeal, the second relator argued that the first-to-file bar did not apply for two reasons: (1) his allegations went well beyond those in the first-filed complaint; and

(2) even if his complaint included substantially the same claims as the first-filed complaint, it should not be dismissed because the government had intervened in the consolidated action. *Id.* at 303-05.

The Fourth Circuit applied the “material elements test” and held that the factual additions as to how ManorCare overbilled the government and the fact that the second relator alleged conduct occurring in a different state *were not enough* to save him from the first-to-file bar. *Id.* at 305. Further, the court held that the second relator’s argument that the first-to-file rule should not be applied because the complaints were consolidated—while a novel argument—had no merit in light of the plain language of the statute. *Id.* The Fourth Circuit explained that the first-to-file rule does not include an exception for consolidated complaints. *Id.* Rather, the first-to-file rule “is ‘an absolute, unambiguous, exception-free rule.’” *Id.* (quoting *United States ex rel. Carter v. Halliburton Co.*, 710 F.3d 171, 181 (4th Cir. 2013)).

Courts also remain split over whether the first-to-file rule is jurisdictional. Most recently, the Second Circuit joined the D.C. Circuit in holding that the rule is not jurisdictional and instead bears on whether a relator has properly stated a claim. See *United States ex rel. Hayes v. Allstate Ins. Co.*, 853 F.3d 80, 85-86 (2d Cir. 2017), *cert. denied*, 2017 WL 2868652 (U.S. Oct. 02, 2017); *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 120-21 (D.C. Cir. 2015). The First, Fourth, Fifth, Sixth, and Tenth Circuits have come to the opposite conclusion. See *United States ex rel. Wilson v. Bristol-Myers Squibb, Inc.*, 750 F.3d 111, 117 (1st Cir. 2014); *United States ex rel. Carter v. Halliburton Co.*, 710 F.3d 171, 181 (4th Cir. 2013); *United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 376-77 (5th Cir. 2009); *Walburn v. Lockheed Martin Corp.*, 431 F.3d 966, 970 (6th Cir. 2005); *Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1278 (10th Cir. 2004). Interestingly, district courts in the circuits that have deemed the rule non-jurisdictional are not unanimous in holding that violations of the rule are curable by amendment. Compare *Wood*, 246 F. Supp. 3d at 795-800 with *United States ex rel. Shea v. Verizon Commc'ns*, 160 F. Supp. 3d 16, 28-30 (D.D.C. 2015) (“Although it is . . . clear that the first-to-file rule is not jurisdictional, . . . [t]he only way to cure [a

first-to-file] defect is for the Court to dismiss Plaintiff’s action—not merely his Complaint . . .”).

5. Government-Action Bar

The government-action bar prohibits a relator from bringing a *qui tam* action that is “based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the government is already a party.” 31 U.S.C. § 3730(e)(3). This year in a case of first impression, the Ninth Circuit broadly interpreted the government-action bar, holding that it “applies even when the government is no longer an active participant in an ongoing *qui tam* lawsuit.” *United States ex rel. Bennett v. Biotronik, Inc.*, 876 F.3d 1011, 1016 (9th Cir. 2017).

The *Bennett* case involved a *qui tam* suit filed against a medical device supplier that had already settled a separate, substantially similar *qui tam* case in which the government had elected to intervene. *Id.* at 1014. With respect to the United States, the previously settled suit was dismissed with prejudice as to the “covered conduct” but without prejudice as to any other conduct. *Id.* The medical device manufacturer filed a motion to dismiss the second *qui tam* action in the district court, arguing that the case was barred by the government-action bar. *Id.* at 1015. The relator made two arguments in response: (1) the statutory language of § 3730(e)(3) is present tense and should not prohibit a subsequent suit, since the settled case was no longer pending (and so the government “is” no longer a party to it); and (2) the government had only intervened in part of the previously settled case (the “covered conduct”). *Id.*

The district court disagreed and granted the motion to dismiss, reasoning that (1) the second relator’s allegations were substantially the same as the settled allegations; and (2) because the government was a party to the settled case, which was based upon the same “allegations or transactions” as the second case, the second case was barred by the government-action bar. *Id.* The Ninth Circuit affirmed, holding that “the government-action bar applies even when the government is no longer an active participant in an ongoing *qui tam* suit.” *Id.* at 1016. The Ninth Circuit

further explained that the government-action bar precludes *all* overlapping claims, not only those claims that were part of the government settlement and dismissed with prejudice. *Id.* at 1020. The court noted that the key determination is whether the government is made aware of the claims it ultimately chose not to settle, and concluded that the “government becomes a ‘party’ to the suit as a whole when it intervenes. It does not become a ‘party’ to a particular claim or number of claims.” *Id.* at 1021; *see also United States ex rel. Estate of Gadbois v. PharMerica Corp.*, 2017 WL 5466659, at *6 (D.R.I. Nov. 13, 2017) (holding that the government becomes a party to the whole action even if it elects only to proceed with and ultimately settle certain claims).

Under *Bennett*, claims that are addressed in a previously settled case involving the government but that were not ultimately included in the definition of “covered conduct” may still be barred by the government-action bar.

6. Falsity

As the name implies, the FCA imposes liability for presenting a false or fraudulent claim or making a false record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(A)-(B). Although the terms “false” and “fraudulent” are not defined in the statute, a number of courts provided helpful guidance in 2017.

In an important decision in an off-label marketing case, the First Circuit reiterated “that evidence of an actual false claim is the sine qua non of a False Claims Act violation” and therefore “where relators only offer aggregate expenditure data by the government for the drug at issue, without identifying specific entities who submitted claims much less times, amounts, and circumstances, their claim falls far short” at the summary judgment phase. *United States ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52, 57-58 (1st Cir. 2017) (citation omitted). Because the relators had not proffered evidence of actual false claims submitted to the government after six years of litigation, the First Circuit agreed that they were not entitled to present their case to a jury. *Id.* at 58; *see also United States ex rel. Lisitza v. Par Pharm. Cos., Inc.*, 2017 WL 3531679, at

*18 (N.D. Ill. Aug. 17, 2017) (“It is not enough to say given this scheme, surely there were false claims submitted; the plaintiff is required to prove that to be the case.”) (citation omitted).

In a case that expands the reach of last year’s *AseraCare* decision, a district court in Utah held that an alleged false statement must be based on an “objectively verifiable fact” in order to survive a motion to dismiss. See *United States ex rel. Polukoff v. St. Mark’s Hosp.*, 2017 WL 237615, at *10 (D. Utah Jan. 19, 2017). In *Polukoff*, the relator alleged that the defendants made false representations to the government that certain cardiac procedures were medically reasonable and necessary. *Id.* at *9. In holding that the complaint did not allege a falsity, the court explained that “[o]pinions, medical judgments, and conclusions about which reasonable minds may differ cannot be false for purposes of an FCA claim.” *Id.* (citation omitted). In other words, a “difference of opinion between physicians, without more, is not enough to establish falsity.” *Id.* Accordingly, the court dismissed the complaint and denied the relator leave to amend.

A district court in D.C. reached the opposite conclusion, however, declining to address potential differences in clinical opinions on a motion to dismiss. See *United States ex rel. Groat v. Boston Heart Diagnostics*, 255 F. Supp. 3d 13, 28-29 (D.D.C. 2017). In *Groat*, the relator alleged that Boston Heart encouraged non-cardiologists to order medically unnecessary tests and then billed the government for those tests. Taking the relator’s allegations as true, the court concluded “that the relator has sufficiently alleged that Boston Heart’s claims were false, based on her allegation that it sought payment for medically unnecessary services.” *Id.* at 29.

7. Reverse False Claims

A defendant may be liable under the FCA for a “reverse false claim” if the defendant knowingly makes or uses a false record or statement for the purpose of avoiding or decreasing an “obligation” owed to the United States. See 31 U.S.C. § 3729(a)(1)(G). Two courts provided clarity on what qualifies as an “obligation” under this provision in 2017.

In *United States ex rel. Petras v. Simparel, Inc.*, the Third Circuit held that a contingent obligation was insufficient to state a reverse false claim. 857 F.3d 497, 506 (3d Cir. 2017). The court explained that there were two events that would have triggered the defendant’s obligation to pay money to the SBA, but neither of those events had actually materialized. As a result, the court held that no obligation had accrued. *Id.* The court further explained that “the legislative history of the statute’s other relevant language—whether or not fixed—suggests a reference to whether or not the amount owed was fixed at the time of the obligation, not whether an obligation to pay was fixed.” *Id.* (citation omitted).

The district court for the District of Columbia similarly held that an “unassessed, contingent penalty” did not qualify as an “obligation” under the statute. *United States ex rel. Kasowitz Benson Torres LLP v. BASF Corp.*, 2017 WL 4803906, at *4-8 (D.D.C. Oct. 23, 2017). There, the relator alleged that the defendants did not report “substantial risk information” to the Environmental Protection Agency (EPA) as required by the Toxic Substances Control Act (TSCA), which could have led to the imposition of civil penalties. The court focused on the EPA’s broad discretion under the TSCA in determining the amount of penalties, along with the discretion to compromise, modify, or remit any penalties, and concluded that the alleged obligation was contingent in nature. *Id.* at *7. Citing to the Third Circuit in *Petras*, the court explained that “an FCA obligation does not include a duty that is dependent on a future discretionary act.” *Id.* The court also agreed that the phrase “whether or not fixed” meant that a dollar amount need not be fixed, so long as there is an established duty to repay money to the government. *Id.*

While the cases above show the challenges facing FCA plaintiffs, there was a 2017 settlement agreement under the Affordable Care Act’s 60-Day Rule that demonstrates the dangers of the reverse false claim provision. In *United States ex rel. Malie v. First Coast Cardiovascular Institute, P.A.*, First Coast Cardiovascular agreed to pay nearly half a million dollars for failing to report and refund overpayments received from federal healthcare programs within 60 days. No. 3:16-cv-01054 (M.D. Fla. Oct. 13, 2017). The

defendants settled the matter for two and a half times the alleged overpayment amount.

8. Scienter

Under the FCA, the plaintiff must show that a defendant “knowingly” submitted a claim that was false or fraudulent. 31 U.S.C. § 3729(a)(1). “Knowingly” is defined as having “actual knowledge of the information” or acting in “deliberate ignorance” or “reckless disregard” of the “truth or falsity of the information.” 31 U.S.C. § 3729(b)(1). While the law does not require that the plaintiff show a specific intent to defraud, gross negligence is not enough. As a result, defendants frequently argue there is no scienter where the evidence shows that they acted in good faith or had a reasonable interpretation of a governing regulation.

In *United States ex rel. Phalp v. Lincare Holdings, Inc.*, however, the Eleventh Circuit held that the district court went too far in finding that “a defendant’s reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA.” 857 F.3d 1148, 1155 (11th Cir. 2017). The Eleventh Circuit cautioned that the lower court’s interpretation could allow defendants to manufacture a reasonable interpretation of a regulation post hoc and that a jury could still find scienter where the defendant knowingly disregarded the proper interpretation of an ambiguous regulation. *Id.*; see also *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 288 (D.C. Cir. 2015) (“[A] jury might still find knowledge if there is interpretive guidance that might have warned [the defendant] away from the view it took.”), *cert. denied*, 137 S. Ct. 625 (2017).

The district court for the Southern District of Florida was similarly not persuaded that a defendant’s compliance program prevented it from acting with reckless disregard or deliberate ignorance. See *Graves v. Plaza Med. Ctrs., Corp.*, 2017 WL 1102907 (S.D. Fla. Mar. 20, 2017). According to the court, the existence of a compliance program and a special investigation unit were not enough to defeat scienter as a matter of law in that case, holding that there were “genuine issues of material fact as to whether the shortcomings of the design and application of [defendant’s] compliance program met the CMS regulations or constituted

reckless disregard.” *Id.*

Yet, not all of the cases analyzing scienter went in the plaintiff’s favor in 2017. In the closely watched Medicare Advantage case *United States v. Scan Health Plan*, the court granted the defendant’s motion to dismiss, in part, because the government failed to allege the defendants’ risk adjustment attestations were knowingly false. 2017 WL 4564722, at *5-6 (C.D. Cal. Oct. 5, 2017). The court found the government’s general allegations of collective corporate scienter insufficient and explained that the government must identify the corporate officers who signed the false risk adjustment attestations and explain how those individuals knew or should have known the information was false. *Id.* Despite being given an opportunity to re-plead, the government agreed to dismiss the case.

9. Retaliation Against Whistleblowers

The FCA’s whistleblower provisions prohibit employers from retaliating against employees who initiate and pursue FCA actions or otherwise attempt to stop violations of the FCA. 31 U.S.C. § 3730(h). To maintain a retaliation action, the employee must prove that (1) she engaged in a protected activity; (2) her employer knew about these acts; and (3) she suffered adverse action as a result of these acts.

Courts in 2017 primarily focused on the first prong of the FCA retaliation analysis: the circumstances under which an employee engages in a “protected activity” sufficient to trigger anti-retaliation provisions. Several courts followed the general rule that to qualify as a protected activity, litigation must be a “distinct possibility.” *United States ex rel. Ribik v. HCR ManorCare, Inc.*, 2017 WL 3471426, at *3 (E.D. Va. Aug. 10, 2017). Under this standard, reporting general concerns about billing and treatment practices to management was not enough to survive a motion to dismiss. *Id.* According to the *Ribik* court, “expressing concerns and objections to management without anything more does not create a distinct possibility that litigation is pending.” *Id.*; see also *United States ex rel. Morison v. Res-Care, Inc.*, 2017 WL 468287, at *4-5 (S.D. Ind. Feb. 3, 2017) (“Simply informing one’s employer that certain actions are illegal, improper, or fraudulent, without any explicit mention that the

employee may sue will not suffice to show the Relator was acting in furtherance of an FCA enforcement action.”) (citation omitted).

In contrast, some courts applied an arguably less stringent standard and required only that the employee’s actions be aimed at matters that could reasonably lead to a viable FCA claim. *See Fakorede v. Mid-S. Heart Ctr., P.C.*, 2017 WL 4217230, at *2 (6th Cir. Sept. 22, 2017). In other words, the plaintiff “must allege conduct directed at stopping what he reasonably believed to be fraud committed against the federal government.” *Id.* Under this standard, at least one court found that reporting “illegal conduct” to his superiors on two occasions qualified as a protected activity. *See United States ex rel. Doe v. Lincare Holdings Inc.*, 2017 WL 752288, at *8 (S.D. Miss. Feb. 27, 2017) (mem. op.). On the other hand, expressing general concerns to management about the calculation of expenses and reminding management it “should check for compliance with federal law” did not qualify as a protected activity. *Fakorede*, 2017 WL 4217230, at *2; *see also United States ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52, 60 (1st Cir. 2017) (reporting regulatory failures alone is insufficient to qualify as a protected activity; the relator must report concerns of a fraud on the government).

Even under the more flexible approach, the underlying conduct the employee is complaining about must be unlawful. *See United States ex rel. Endicott v. Oakbend Med. Ctr.*, No. 4:16-cv-01835, at 5-7 (S.D. Tex. Jan. 30, 2017), ECF No. 24. In *Endicott*, for example, the plaintiff alleged she was terminated after she complained that Oakbend improperly used funds it legitimately obtained from Medicare and Medicaid to pay its IT employees. The defendants moved to dismiss, arguing that the alleged whistleblowing activity was not protected because the plaintiff’s allegations did not state a claim under the FCA. In other words, the plaintiff did not allege that defendants “submitted false claims to the United States government, but that Oakbend improperly used funds it legitimately obtained from the government.” *Id.* at 7. Because the alleged conduct did not lead to a viable FCA claim, the court held that the plaintiff had not engaged in a protected activity by raising her concerns. *Id.*

Judicial decisions in 2017 have also helped to clarify who may be pursued for retaliation under the FCA. Since 2009, courts have grappled with the amendments to the FCA whistleblower provisions, which removed the requirement that an employee endure retaliatory action from “his or her employer.” Some in the plaintiffs’ bar have argued that the change allowed whistleblowers to sue individuals in supervisory positions. The district court for the Southern District of New York recently disagreed and explained that Congress likely removed the word “employer” to avoid “confusion in cases involving a contractor or agent rather than an employee.” *Diffley v. Bostwick Labs., Inc.*, No. 1:17-cv-01410, at 5-9 (S.D.N.Y. Dec. 6, 2017), ECF No. 28 (citation omitted). The district court stated that it was joining “the overwhelming majority of courts . . . that have held that the current version of § 3730(h) does not create a cause of action against supervisors sued in their individual capacities.” *Id.* at 4 (citation omitted).

10. Damages, Penalties, and Costs

Under the FCA, violators are not only liable for treble the amount of actual damages, but also face civil penalties of \$11,000 to \$21,000 per false claim. 31 U.S.C. § 3729(a). A jury verdict from the Middle District of Florida demonstrates the potency of these provisions. *See United States ex rel. Ruckh v. CMC II, LLC*, No. 8:11-cv-01303 (M.D. Fla. Feb. 15, 2017), ECF No. 430. In *Ruckh*, the jury found that a nursing home operator had submitted 446 false claims to the government, resulting in \$115 million in damages. *Id.* The court then trebled that amount and applied an additional \$2.4 million in penalties, for total verdict of \$347 million. In early 2018, however, the district judge overturned the verdict on materiality grounds.

With so much at stake, the measure of actual damages will be a critical factor in the resolution of any FCA case. Although not frequently litigated, the district court for the District of Columbia recently provided some helpful guidance on this point in *United States ex rel. Landis v. Tailwind Sports Corp.*, 234 F. Supp. 3d 180, 198-201 (D.D.C. 2017). As many know, Lance Armstrong’s former cycling teammate Floyd Landis had alleged that Armstrong and others violated the FCA by seeking sponsorship payments from the

United States Postal Service (USPS) while violating anti-doping commitments. The government intervened in the case and claimed it sustained \$32 million in actual damages—the total amount the USPS paid out in sponsorship dollars. Armstrong argued that the government sustained no actual damages because the benefits the USPS reaped from the sponsorship far outweighed the cost. *Id.* at 199. The court found that the government was “not entitled to the return of all of its money, tripled no less, simply because it never would have sponsored a doping team.” *Id.* at 201. Instead, the jury should conduct a benefit of the bargain analysis and decide “what, if any, monetary value the government received or used from the delivered services based on the particular circumstances of the case.” *Id.*

11. ManorCare

The government suffered a highly publicized loss this year as it dropped its high-profile case against national skilled nursing home operator, HCR ManorCare, Inc. (ManorCare), after pre-trial motions resulted in an unfavorable ruling and sanction of government lawyers.

The government had claimed that ManorCare directed or encouraged its employees to provide services that were not medically necessary in order to bill Medicare at a higher rate. The government sought to prove its overbilling allegations through statistical sampling, a method often attempted in large-scale FCA cases that involve high volumes of claims. Typically, an expert reviewer will evaluate a sample of claims, determine the “error rate,” and then use that determination to estimate the total number of false claims. Here, the government’s key expert reviewer, Rebecca Clearwater, examined the medical necessity of services provided to 180 ManorCare patients, which was then extrapolated to a total damage calculation of over \$500 million. ManorCare moved to exclude Ms. Clearwater’s testimony and also moved for sanctions based on Ms. Clearwater’s failure to timely disclose

handwritten notes.

On October 27, 2017, the magistrate judge overseeing discovery in the case granted ManorCare’s motion for sanctions and took care to explain why the case, which she called a “house of cards that was resting on Ms. Clearwater’s testimony,” was a “huge waste of money” that should have never been brought. Transcript of Motion Hearing at 36, *United States ex rel. Ribik v. HCR ManorCare, Inc.*, No. 1:09-cv-00013 (E.D. Va. Oct. 27, 2017), ECF. No. 664. The magistrate judge went on to say that she was “appalled, [] embarrassed, and [] ashamed that the Department of Justice would rely on this kind of nonsense by a nurse reviewer to get involved in a *qui tam* case and cost these defendants millions of dollars in legal fees.” *Id.*

The government had initially indicated that it would appeal the sanctions order, but the chapter concluded when, on November 6, 2017, the district court entered an order granting ManorCare’s motion to exclude Ms. Clearwater’s testimony. *United States ex rel. Ribik v. HCR ManorCare, Inc.*, 2017 WL 5625559, at *1 (E.D. Va. Nov. 6, 2017). The court held that Ms. Clearwater lacked the necessary expertise to testify as to the reasonableness and necessity of the medical treatment provided because she was not a medical doctor, an occupational therapist, or a speech language pathologist, and she did not personally examine any of the ManorCare patients. *Id.* With no underlying finding of a lack of medical necessity, the court also excluded the government’s extrapolation witnesses. *Id.* The government filed a motion to dismiss the case with prejudice less than two weeks later, cementing ManorCare’s victory after five years of litigation. This case established important precedent for healthcare providers that may one day litigate medical necessity, highlighting potential challenges to expert witnesses and extrapolation models.

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