Bradley







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INTRODUCTION

2017 marked another year of significant False Claims Act (FCA) enforcement by the Department of Justice (DOJ) and legal developments in the courts. While 2017 lacked record-setting recoveries (a mere \$3.7 billion in fiscal year 2017 per DOJ statistics) or a watershed Supreme Court case like *Escobar* in 2016, the year gone by had no shortage of notable events.

As always, the headlines start with the recoveries. Although the \$3.7 billion in judgments and settlements is down from last year's \$4.7 billion, it still represents the fourth-highest annual total ever. Among recoveries originating from *qui tam* lawsuits, 2017's total (over \$3.4 billion) is the second-highest ever, while non-*qui tam*-originated recoveries (\$265.5 million) dipped to their lowest level since 2013. And among *qui tam* cases in which DOJ declined to intervene, recoveries grew significantly from 2016 to account for over \$898 million, though that figure stands to be reduced after a Florida federal judge vacated a \$350 million verdict just days ago.

The industries targeted for these recoveries remained largely the same. The healthcare industry led the way, accounting for \$2.4 billion or just under 65% of all recoveries, and the housing-and-mortgage industry (\$543 million) and defense industry (\$219.9 million) had large portions of the overall recovery total.

In the courts, litigants felt the repercussions of *Escobar*, as district and circuit courts wrestled with the Supreme Court's June 2016 decision. In particular, *Escobar*'s holding related to materiality continued to be among the most hotly and commonly argued issues. Similarly, implementation of the Yates memo—the September 2015 internal DOJ guidance refocusing prosecutors on prosecutions of individual defendants—continued to take form in 2017, with a number of FCA cases brought against individual executives.

As these and other emerging issues evolve in 2018, we take a look back at the key developments from 2017.

KEY DECISIONS & DEVELOPMENTS

I. FCA Elements

A properly pleaded FCA claim must contain four elements: First, that a claim for payment was submitted to the government. Second, that the claim (or record or statement material to the claim) was false. Third, that the defendant knew or should have known the claim was false. And fourth, that the claim or statement was material to the government's decision to pay. In the wake of

\$3.7 BILLIONIN RECOVERIES

"The healthcare industry led the way, accounting for \$2.4 billion or just under 65% of all recoveries"

Escobar, cases involving disputes over materiality were particularly common in 2017.

A. Materiality

U.S. ex rel. McBride v. Halliburton Co., 848 F.3d 1027 (D.C. Cir. Feb. 17, 2017)

Former employee Julie McBride brought an FCA suit against Halliburton Company; Kellogg Brown & Root, Inc.; Service Employees International Inc.; Kellogg Brown & Root Services, Inc.; and KBR Technical Services, Inc. (collectively, KBR). The complaint alleged that KBR billed for excess costs under KBR's contract at two camps during the Iraq War by inflating the headcount data for certain personnel. The district court granted summary judgment in favor of KBR and McBride appealed.

On appeal, McBride argued that the lower court had failed to consider whether information KBR allegedly withheld relating to headcount records could have changed the government's payment decisions. McBride argued that the Supreme Court's decision in Escobar—which found that a party could be liable if it makes a representation to the government in submitting a claim but omits its violations of a material statutory, regulatory, or contractual requirement—supported her claim. The D.C. Circuit disagreed and affirmed. The Court found that McBride could not show that maintaining the headcount data was a material statutory, regulatory, or contractual requirement for KBR to be paid under its contract with the government. Additionally, the Court noted that the Defense Contract Audit Agency had investigated the claims and had not disallowed any of the charged costs, amounting to what the court called "very strong evidence" in favor of KBR that the alleged omission was not material.

Abbott v. BP Exploration & Production, Inc., 851 F.3d 384 (5th Cir. March 14, 2017)

Abbott, a former BP employee, and Food and Water Watch, Inc., an advocacy group, brought suit alleging that BP violated the FCA by falsely certifying compliance with various regulatory requirements. Specifically, they contended that BP did not have the necessary documentation to build and maintain a certain floating oil production facility in the Gulf of Mexico and that the documents BP did possess were not approved by engineers, as required under the applicable regulations. In a harshly worded opinion, the district court granted summary judgment, stating that the plaintiffs "knew nothing, discovered nothing, and distorted what the government already knew." Abbott and Food and Water Watch appealed.

On appeal, the Fifth Circuit noted that, before the FCA suit was filed, Abbott's internal complaints led to a Department of Interior (DOI) investigation. After reiterating the FCA's demanding materiality standard, the Court reasoned that the DOI's decision to allow the production facility to continue its operations after a substantial investigation represented strong evidence that the regulation requirements proffered by the plaintiffs were not material. Furthermore, their failure to rebut that evidence led the Court to conclude that the plaintiffs failed to create a genuine issue of material fact as to materiality.

U.S. ex rel. Petratos v. Genentech Inc., 855 F.3d 481 (3d Cir. May 1, 2017)

In *Genentech Inc.*, the relator alleged that Genentech suppressed data leading to the erroneous conclusion that their drug was "reasonable and necessary" and thus wrongly entitling Genentech to reimbursement under Medicare. The district court dismissed the complaint, concluding that the drug was "reasonable and necessary" because it had been approved by the U.S. Food and Drug Administration (FDA) for a "medically accepted indication." The Third Circuit affirmed, albeit for different reasons.

Unlike the district court, the Third Circuit found that the "medically accepted" standard was not equivalent to the "reasonable and necessary" standard. The Court reasoned that the "reasonable and necessary" determination depended not just on FDA approval, but also on "accepted standards of medical practice and the medical circumstances of the individual case," as well as physicians' discretion to utilize health services. Thus, government approval was a necessary component of the determination but did not end the inquiry.

Nevertheless, the Court still affirmed, stating that materiality could not be established because the record did not demonstrate that reimbursement was dependent on the challenged claims. The Court noted that Genentech's alleged misrepresentations were reported

to both the FDA and DOJ and, in the time since, the government not only continued approval and added three more indications for the drug but also declined to intervene in the FCA suit. The Court opined that if expert agencies and government regulators deemed the alleged violations insubstantial, it was not appropriate for a private citizen to enforce the regulations through the FCA.

The Court also noted that materiality could not be established simply by demonstrating that physicians would have prescribed less of the drug "but for" the alleged fraud. The Court reasoned that establishing the alleged fraud was the "but for" cause of the submitted claim was separate from establishing materiality. For materiality to be established under the FCA, the violation must be material to the government's decision *to pay*—not to the physician's decision *to prescribe*. Because the alleged fraud did not affect the government's payment decision here, materiality was not established regardless of whether or not the alleged fraud deceived prescribing physicians.

U.S. ex rel. Harman v. Trinity Industries Inc., 872 F.3d 645 (5th Cir. Sept. 29, 2017)

In *Harman*, the Fifth Circuit reversed a \$663 million jury verdict in favor of relator Harman based on the post-*Escobar* materiality standard. After the government had declined to intervene, Harman proceeded to trial on allegations that Trinity Industries had changed the design for its guardrail end-terminal system without the approval of the Federal Highway Administration (FHWA). But both before and after trial, the FHWA reaffirmed its approval of the subject highway safety system and continued reimbursing claims for that system.

In reversing the judgment, the Fifth Circuit ruled that "the jury's findings on liability cannot stand for want of materiality." The Court reasoned that Harman could not satisfy the materiality standard because the FHWA had continued to make payments for Trinity Industries' highway safety system, even after learning of the design changes on which Harman had premised the alleged fraud and that this continued payment "substantially increases the burden on the relator in establishing materiality." According to the Fifth Circuit, a jury's "determination of materiality cannot defy the contrary decision from the government, here said to be the victim, absent some reason to doubt the government's decision as genuine." Harman is a must-read for anyone interested in the materiality standard because the opinion includes a comprehensive analysis of post-Escobar case law, including decisions from the First, Seventh, and Ninth Circuits.

U.S. ex rel. Spay v. CVS Caremark Corp., 875 F.3d 746 (3rd Cir. Nov. 16, 2017)

In 2006, Caremark employees found 4,500 prescriptions that

had already been authorized for payment but had not yet been submitted to the Center for Medicare and Medicaid Services (CMS) for payment. The delayed submission resulted from incorrect or missing prescriber identification numbers that caused errors in the computer system. To rectify this issue the company created a computer program that converted any problematic prescriber numbers into a dummy number that eliminated the error code and allowed the company to be reimbursed for the prescriptions. Spay, the relator, owned a company that performed pharmacy audits. During an audit of one of Caremark's insurance company clients, he found discrepancies in Caremark's pharmacy claims processing that led him to uncover Caremark's use of the dummy prescriber IDs.

Spay brought a *qui tam* action under the FCA against Caremark and other Medicare Part D sponsors alleging that the sponsors intentionally submitted forms containing prescriber identification numbers that did not correspond to anyone with actual prescribing authority during the reconciliation process with CMS. The district court granted Caremark's motion for summary judgment reasoning that because CMS knew that Caremark was using the dummy numbers, no fraud was intended.

On appeal, the Third Circuit affirmed the district court's dismissal but on other grounds. The Court held that the government's knowledge of the facts underlying an allegedly false statement can negate the scienter required for an FCA violation but explained that the district court erred in its application of the government-knowledge defense. It is not enough that the government knows about the alleged misrepresentation; rather, there must also be evidence that the defendant knows that the government knows about the misrepresentation. Here, the Court found insufficient evidence that Caremark knew CMS was aware of the dummy numbers.

Nonetheless, the Third Circuit still affirmed based on materiality, holding that the false claims alleged were not material to CMS' decision to pay the claims. The Court explained that although the alleged fraud occurred before the FCA was amended in 2009 to include a definition of "material," the FCA still required materiality before the 2009 amendments. And CMS' regular payment of the claims despite its actual knowledge of the dummy prescriber identification numbers strongly suggested that these alleged misrepresentations were immaterial to CMS' payment decision. The Court further noted that the dummy prescriber IDs were only a formulaic way of preventing a computer program from denying legitimate claims for reimbursement, and thus there was "nothing that would justify calling [Caremark's actions] 'fraud."

U.S. ex rel. Coyne v. Amgen, Inc., No. 17-1522-cv, 2017 WL 6459267 (2d Cir. Dec. 18, 2017)

A physician and former paid speaker for Amgen alleged that the



company misrepresented information about patient quality of life on its product Epogen's marketing and packaging materials. Specifically, he alleged that Amgen knew and concealed the information that using the product to raise hemoglobin levels above 11 grams per deciliter (g/dL) would not increase quality of life but continued to market the product as approved for usage up to 12 g/dl

The Second Circuit affirmed the dismissal of the case because the relator did not plausibly allege that the misrepresentation was material to CMS's payment determinations. Though the disputed language appeared on the "Clinical Experience" portion of the product labeling, the FDA had approved the product for usage up to 12 g/dL as shown in the "Indications and Usage" portion of the labeling, making it presumptively reasonable and necessary for the purposes of CMS reimbursement.

Further, Amgen added additional information to the "Clinical Experience" section of the Epogen label in 2007 limiting certain benefits to hemoglobin levels of 11g/dL. The Court found that the prior misrepresentations could not have been material to CMS's payment decisions because CMS did not alter its Epogen reimbursement practices once Amgen added the new information.

U.S. ex rel. Kelly v. Serco, Inc., 846 F.3d 325 (9th Cir. Jan. 12, 2017)

Kelly brought suit against his former employer, Serco, alleging that Serco made implied false certifications when it submitted

"Litigants felt the repercussions of *Escobar*, as courts wrestled with the Supreme Court's June 2016 decision."

cost reports to Navy Space and Naval Warfare Systems Command (SPAWAR) that did not comply with the format guidelines set out in American National Standards Institute/Electronic Industries Alliance Standard 748 (ANSI-748). Serco had previously advised SPAWAR that Serco's accounting systems could not accommodate the format guidelines. Both SPAWAR and DHS approved of Serco instead submitting monthly cost reports on Excel spreadsheets reflecting information compiled manually by Serco employees. Kelly contended that Serco's claims for payment impliedly certified compliance with all conditions of payment, and that under the Federal Acquisition Regulation and the Defense Federal Acquisition Regulation Supplement, the Serco contracts were required to mandate compliance with ANSI-748.

Utilizing its pre-*Escobar* standard, the district court granted summary judgment in favor of Serco, finding that neither the contracts nor the regulations expressly conditioned payment on compliance with ANSI-748.

On appeal, the Ninth Circuit applied *Escobar*, which had been issued since the district court's decision, holding that even if compliance with ANSI-748 were a condition of payment, Kelly's implied false certification claim failed as a matter of law. In key part, the Court held that Kelly failed to establish a genuine issue of material fact as to whether any implied misrepresentation about Serco's compliance with ANSI-748 was material to the government's payment decision. The Court rejected Kelly's argument that the government could lawfully have withheld payment if it knew that Serco was not complying with ANSI-748, noting that under *Escobar*, "the possibility that the government would be entitled to refuse payment if it were aware of Serco's alleged violations is insufficient by itself to support a finding of materiality." The Court observed that it was undisputed that the government agencies in question

approved the format of Serco's cost reports and accepted those cost reports despite the fact that they were not ANSI-748 compliant.

U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc., --- F. Supp. 3d ---, No. 3:12-CV-0764, 2017 WL 3034336 (M.D. Tenn. June 22, 2017) (appeal pending)

In this non-intervened *qui tam*, the Court granted Brookdale's motion to dismiss because the relator, Prather, failed to sufficiently allege materiality under *Escobar* in the complaint. The decision is notable because, although it did not intervene, the government filed a brief in support of the relator at the district court and in the still-pending appeal.

In the complaint, Prather alleged that Brookdale, a senior living company, was late in obtaining required physician signatures for home health services, in violation of a regulatory requirement. After a thorough analysis, the Court concluded that the signature timing requirement was not material to the government's payment decision. The Court noted that, even though the signature timing requirement was a condition of payment, the relator could point to no instance where the government had ever denied payment for lack of compliance with it. And while the physician *signature* requirement went to the "essence of the bargain" between Brookdale and the government, the requirement about the *timing* of that signature did not. Prather has appealed, and the case is fully briefed in the Sixth Circuit. The government has filed an amicus brief in support of Prather.

U.S. ex rel. Dickson v. Bristol-Myers Squibb Co., No. 13-cv-01039 (D.N.J. June 27, 2017)

The relator, Dickson, brought an FCA suit alleging that Bristol-Myers Squibb promoted Plavix, a prescription blood thinner, as a superior drug to aspirin for certain indicated usages, when it was no more effective and cost nearly one hundred times more than aspirin. The complaint alleged Bristol-Myers Squibb did so by marketing to prescribing physicians and to physicians and pharmacists on state formulary committees, which ultimately caused claims to be submitted to Medicaid that contained an implied false certification that Plavix complied with state Medicaid requirements. Dickson further alleged that the marketing efforts to the physicians and pharmacists on the state formulary committees fraudulently induced the committees to include Plavix on each state's Preferred Drug List (PDL) or formulary, triggering an automatic government obligation to reimburse Plavix prescriptions despite it not meeting the cost-effectiveness requirement.

The Court rejected Dickson's claims. First, it found that state Medicaid agencies would reimburse Plavix prescriptions automatically because Plavix was on each state's PDL—regardless of

any representations made by prescribing physicians—thus making such representations per se immaterial. Second, the Court held that materiality was also lacking as to the formulary allegations because of Dickson's failure to plead that any government payor actually stopped reimbursing for Plavix or took other remedial action after gaining actual knowledge of the allegations.

B. Falsity

Claims can be considered false in two different ways: factually false or legally false. A factually false claim is the "classic" type of false claim in which the government paid for goods or services that were incorrectly described or were not provided at all. By contrast, a legally false claim is not predicated on the accuracy of the claim itself; indeed, it may be factually accurate. Rather, a claim is legally false if it is predicated upon a false representation of compliance with a material statutory, regulatory, or contractual term.

Such factually false claims are further divided into two subtypes: express false certification and implied false certification claims. In an express false certification claim, the claim falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment. In an implied false certification claim, the claim is not based on any express certification but rather based on the notion that the act of submitting a claim for reimbursement itself implies compliance with some provision that is a precondition to payment.

1. Objective Falsity

U.S. ex rel. Polukoff v. St. Mark's, No. 16-cv-00304 (D. Utah, Jan. 17, 2017)

Relator Gerald Polukoff, M.D., brought a *qui tam* action under the FCA against his partner Sherman Sorensen, M.D. and the Sorensen Cardiovascular Group (collectively "Sorensen"), alleging that Sorensen performed and billed Medicare and Medicaid for unnecessary medical procedures. Specifically, Polukoff argued that Sorensen performed the procedure—patent foramen ovale (PFO) closure, which is used to close a hole in the wall between the two upper chambers of the heart—as a preventative measure for patients who had not first suffered a stroke. Polukoff further alleged that Sorensen falsely certified that the procedure was "medically indicated and necessary for the health of the patient," despite the lack of industry support for performing the procedure as a preventative measure.

In analyzing whether such representations were false, the Court considered whether Medicare had issued a National Coverage Determination (NCD) for the PFO closure procedure to provide an objective standard regarding when the procedures are reimbursable. Finding no applicable NCDs, the Court said "in the absence of an objective standard created by the government,

Dr. Polukoff can only rely upon the subjective and ambiguous 'reasonable and necessary standard.'"

The Court examined *United States ex rel. Morton v. A. Plus Benefits*, Inc., in which the Tenth Circuit held that because liability must be predicated on an objectively verifiable fact, "[e]xpressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false." It also favorably considered the factually similar district court opinion in *United States* v. AseraCare Inc., in which the Northern District of Alabama found that "a mere difference of opinion between physicians, without more," was not sufficient to show falsity. Applying this standard, the Court held that Sorensen's representations of medical necessity were not objectively false. The Court rejected Polukoff's argument that because Sorensen's performance of the PFO closure procedure did not comply with industry guidelines, the services did not satisfy the medical necessity standard, stating that "Medicare does not require compliance with an industry standard as a prerequisite to payment."

U.S. ex rel. Lisitza v. Par Pharmaceutical Companies Inc., No. 06 C 06131 (N.D. III. Aug. 17, 2017)

In *Lisitza*, the Court dismissed the relator Bernard Lisitza's FCA claims based on allegations that Par Pharmaceutical caused national pharmaceutical chains to submit false claims for reimbursement. Specifically, Lisitza alleged that Par Pharmaceutical orchestrated an illegal prescription-switching scheme by producing generic drugs in form and dosage strengths not covered by Medicaid limits and then marketed the drugs to pharmacies based on their ability to obtain higher reimbursements from Medicaid. Lisitza argued that the reimbursements were thereby fraudulent because Par Pharmaceutical failed to disclose that the drugs dispensed had been substituted not based on medical necessity but because they were more profitable. On summary judgment, Par Pharmaceutical argued that Lisitza could not meet the burden of proving falsity.

In dismissing the claims, the Court held that omitting information from the claim form regarding the course of events leading to the dispensing of the particular drug or its relative cost does not go to the truth or falsity of the representations on the claim form itself. The Court further held that there was not sufficient evidence of the identity of any specific claim that a jury could reasonably conclude was false.

2. Implied False Certification—The *Escobar* Test

Since the Supreme Court's opinion in *Universal Health Services v. U.S. ex rel. Escobar*, courts have wrestled with whether it creates a mandatory two-part test for cases asserting an implied false certification theory of liability—the theory that a claim can be false if the submitter is not in compliance with statutes and regulations

material to payment. *Escobar* said that the theory is viable "at least where two conditions are satisfied," requiring both a specific representation in the claim and a failure to disclose noncompliance that makes the representation a misleading half-truth. There have been numerous decisions in 2017 addressing whether *Escobar*'s "at least where two conditions are satisfied" language states a necessary or merely a sufficient test, including:

- U.S. ex rel. Kelly v. Serco, Inc., 846 F.3d 325, 332 (9th Cir. Jan. 12, 2017) (dismissing an FCA claim because there was no evidence that the claim for payment made any specific representations about performance).
- U.S. ex rel. Campie v. Gilead Sciences, Inc., 862 F.3d 890, 895 (9th Cir. July 7, 2017) (stating that "two conditions must be satisfied" for an implied false certification claim to proceed). Note that the Ninth Circuit's interpretation in this case and in U.S. ex rel. Kelly v. Serco has been challenged in the currently pending Ninth Circuit appeal in U.S. ex rel. Rose v. Stephens Institute, No. 17-15111.
- U.S. ex rel. Kolchinsky v. Moody's Corp., No. 12CV1399, 2017 WL 825478, at *5 (S.D.N.Y. Mar. 2, 2017) (stating that "an FCA complaint premised on implied certification must satisfy 'two conditions'...").
- U.S. ex rel. Schimelpfenig v. Dr. Reddy's Labs. Ltd., No. 11-cv-4607, 2017 WL 1133956, at *6 (E.D. Pa. Mar. 27, 2017) ("[T]he Third Circuit appears to interpret Escobar as requiring specific representations that, in conjunction with the claimant's purposeful omissions, renders the ensuing claims legally false.").
- United States v. DynCorp Int'l, LLC, 253 F. Supp. 3d 89, 100 (D.D.C. May 19, 2017) (finding the test to be merely sufficient and stating that the D.C. Circuit's broader statement of implied certification theory remains good law such that "the government can show falsity by demonstrating that (1) a contractor withheld information about its noncompliance with contractual or regulatory requirements; and (2) those contractual or regulatory requirements were material.").
- U.S. ex rel. Forcier v. Computer Sciences Corp., No. 12-civ. 1750 (S.D.N.Y. Aug. 10, 2017) (holding that the government's implied false certification claim may proceed past the motion to dismiss stage only if the defendant "made specific representations that were rendered misleading by its failure to disclose noncompliance with material regulatory requirements.").

3. Implied False Certification—General

U.S. ex rel. Searle v. DRS C3 & Aviation Co., 680 Fed. Appx. 163 (4th Cir. Feb. 23, 2017)

In *Searle*, the Fourth Circuit affirmed the district court's grant of summary judgment in favor of DRS C3 & Aviation Company, The Tolliver Group, Inc., and DRS Technical Services, Inc. (collectively "DRS"), after DRS filed declarations from relevant government officials that contradicted both Searle's factual assertions and implied certification theory of liability.

The Army had awarded DRS a contract to create technical manuals for mine-clearing vehicles. Searle, the relator, alleged that DRS falsely certified compliance with the terms of the contract. DRS then moved for summary judgment and supported its position with sworn declarations from government officials who had administered the contract. The declarations, which were accepted by the district court, rebutted Searle's claims and clarified that any changes made by DRS to the contract work "were made at the express direction of the government." The declarations also stated that that any "inaccuracy" regarding the subject work "was not the fault" of DRS and "has since been corrected" in any event. Based largely on these declarations, the district court granted summary judgment to DRS and the Fourth Circuit affirmed.

U.S. ex rel. Badr v. Triple Canopy, Inc., 857 F.3d 174 (4th Cir. May 16, 2017)

The government alleged that Triple Canopy—a defense contractor that provided security services at an airbase in Iraq—brought in guards from Uganda who could not meet a required marksmanship qualification and that Triple Canopy falsified guards' scorecards to cover up this noncompliance. Before *Escobar*, the district court had granted Triple Canopy's motion to dismiss, declining to recognize an implied certification theory, and the Fourth Circuit had reversed. Triple Canopy appealed to the Supreme Court, which granted, vacated, and remanded the Fourth Circuit's opinion for reconsideration in light of *Escobar*.

After ordering additional briefing, the Fourth Circuit stood by its previous decision and held that the complaint sufficiently alleged both falsity and materiality. As to falsity, the Court found that Triple Canopy's submission of bills listing the number of guards and hours worked was a "misleading half-truth," as described in *Escobar*, because anyone reviewing those bills would probably conclude that the guards had met the marksmanship requirement. Going further, the Court suggested in a footnote that *all* claims for payment impliedly certify that the claimant has complied with material contractual requirements.

Turning to materiality, the Court (as it had in its vacated opinion) found that Triple Canopy's alleged violations were material for

two reasons: "common sense and Triple Canopy's own actions in covering up the noncompliance." Although the Court gave little attention to the types of materiality evidence *Escobar* described, it considered the government's decision not to renew Triple Canopy's contract and its intervention in the *qui tam* FCA suit as evidence of materiality. The Court did not address the circularity of its finding that the government's decision to bring or intervene in a lawsuit could somehow be evidence of an element of its case. Triple Canopy petitioned the Supreme Court for certiorari, but the parties settled, and the Supreme Court dismissed the appeal.

U.S. ex rel. Campie v. Gilead Sciences, Inc., 862 F.3d 890 (9th Cir. July 7, 2017)

In Campie, the Ninth Circuit reversed the district court's pre-Escobar dismissal of FCA causes of action based on representations to the FDA, but remanded the issue for the district court to determine whether the allegations could survive Rule 9(b)'s heightened pleading requirements. Two former employees alleged that Gilead used unapproved, unregistered Chinese facilities for the production of its active ingredient in profitable anti-HIV drugs for at least two years prior to seeking FDA approval to use the Chinese facilities. During that time period, Gilead represented to the FDA that its active ingredient was sourced from specific registered facilities in Canada, Germany, the United States, and South Korea, and provided the drugs to payor agencies under the guise that the products were FDA-approved. Campie also brought FCA claims based on Gilead's alleged falsification or concealment of data relating to contamination in batches from the Chinese facilities when thereafter applying for and successfully obtaining FDA approval of said facilities.

In reversing the district court's dismissal, the Ninth Circuit found that the district court erroneously applied a much too lenient standard to Campie's claims. Specifically, the Court concluded that Campie had appropriately pleaded factually false certification claims under a nonconforming goods theory. A nonconforming goods theory does not require plaintiffs to aver the "worthlessness" of the product to plausibly demonstrate falsity. Rather, Campie had to plead that the drugs made using an active ingredient from Chinese facilities were not what was promised—*i.e.*, drugs made with active ingredients from registered facilities.

The Court also found that Campie's allegations constituted a viable claim under both an express and an implied false certification theory. As an express false certification, Gilead represented to the FDA that the active ingredients had been made in approved, registered facilities. To plead an implied false certification, as noted above, the Ninth Circuit held that *Escobar* requires pleading specific representations that are made misleading half-truths by the omitted regulatory violation. Here, the Court found that the drugs' names were the specific representations because they refer to

"materiality continued to be among the most hotly and commonly argued issues"

specific drugs under FDA's regulatory regime, which were rendered misleading half-truths by the failure to disclose their manufacture outside of the bounds of that FDA approval.

C. Knowledge

U.S. ex. rel. Phalp v. Lincare Holdings, Inc., 857 F.3d 1148 (11th Cir. May 26, 2017)

In recent years, several courts have held that reasonable interpretations of ambiguous regulations reflect a mental state inconsistent with the "knowing" standard in the FCA. In *Lincare*, however, the Eleventh Circuit reached a contrary conclusion, holding that defendants who articulate reasonable interpretations of ambiguous regulations may nevertheless be liable under the FCA.

The relators, Gerry Phalp and Matt Peoples, filed a *qui tam* suit alleging that Lincare, a supplier of oxygen and respiratory therapy services, submitted claims to the Medicare program in violation of regulatory requirements related to beneficiary authorization and telemarketing. The district court granted summary judgment for the defendants, finding that the relators had failed to present evidence of the defendants' scienter under the FCA because "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." In the alternative, the district court ruled that the relators' evidence of scienter did not create a genuine issue of material fact.

The Eleventh Circuit affirmed the decision but rejected the district court's conclusion that a finding of scienter can be precluded by a defendant's identification of a reasonable interpretation of an ambiguous regulation that would have permitted its conduct.

Instead, the Court concluded that the relevant inquiry is whether the defendant "actually knew or should have known that its conduct violated a regulation in light of any ambiguity at the time of the alleged violation." The Court reasoned that the district court's formulation would permit defendants to escape FCA liability by creating after-the-fact interpretations that were, on their face, reasonable, despite knowing that such interpretations were incorrect. Although the Court articulated a heightened standard for the reasonable-interpretation-of-ambiguous-guidance defense under the FCA, it went on to find that the evidence adduced by the relators in this case—largely consisting of two emails that dealt with different issues or time periods from the matter in question—was insufficient to survive the defendants' motion for summary judgment.

II. Specific Types of Claims

A. Reverse False Claims and Overpayments

Under 31 U.S.C. § 3729(a)(1)(G), the FCA also creates liability for so-called "reverse false claims," which are claims in which a defendant "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." The statute defines an "obligation" as "an established duty whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment."

Overpayments are an often related concept to reverse false claim. Ever since the 2010 Affordable Care Act established a requirement under the FCA that any overpayment from a government payor "be reported and returned [within] 60 days after the date on which the overpayment was identified," providers contracting with Medicare and Medicaid have questioned what it means to "identify" such a payment. In 2014, CMS published its final rule governing overpayments, which specified, among other things, that an overpayment to a CMS-contracted insurer under the Medicare Advantage Program would be considered "identified" when the insurer determined, or *should have determined* through reasonable diligence, that it had received an overpayment. The rule also established several other requirements for insurers, including that they undertake "proactive compliance activities conducted in good faith by qualified individuals to monitor the receipt of overpayments."

U.S. ex rel. Kasowitz v. BASF Corp., No. 16-2269 (D.D.C. Oct. 23, 2017)

Relator Kasowitz Benson Torres LLP filed suit against four manufacturers of isocyanate chemicals, alleging that the defendants' failure to report to the EPA certain information on

health and environmental risks of the chemicals they manufacture resulted in violations of the FCA's "reverse false claims" provision. Under the Toxic Substances Control Act, manufacturers of chemical substances are obligated to promptly report to the EPA any information that reasonably supports a conclusion that a substance "presents a substantial risk of injury to health or the environment." Failure to report such "substantial risk information" may lead the EPA to assess civil penalties. Kasowitz argued that the defendants' failure to report such "substantial risk information" constituted avoidance both of the defendants' obligation to transmit such information to the government and of the obligation to pay the penalties the EPA could have imposed for such failure.

The Court granted the defendant companies' motion to dismiss, considering in particular the issue of whether the definition of "obligation," as amended in 2009 by FERA, includes "contingent" obligations to pay, such as an obligation to pay a penalty that has not yet been assessed. After reviewing pre- and post-FERA case law and the legislative history, the Court concluded that an "obligation" under the reverse false claims provision at 31 U.S.C. § 3729(a)(1) (G) "refers to an established duty to pay that exists at the time of the fraudulent conduct, the amount of which may or may not be specifically known at that time. An unassessed, contingent penalty is not an FCA 'obligation' subject to suit under the reverse false claims provision." Because any penalties under the Toxic Substances Control Act were never assessed, there was no "obligation" to pay them that the defendant companies had avoided.

The Court also held that although information may be "property" within the meaning of the FCA, there is no "obligation" under the Toxic Substances Control Act to transmit data to the government absent a determination by the government that such data constitutes reportable "substantial risk information." In this case, the government had made no such determination. Finally, the Court held that neither the unassessed penalties nor the substantial risk information constituted "property or money . . . to be used by the Government" under the FCA's conversion provision at 31 U.S.C. § 3729(a)(1)(D) for the same reasons described above, and so Kasowitz also failed to state a claim under that provision.

Bradley Arant Boult Cummings LLP represents defendant Covestro LLC in this matter.

UnitedHealthcare Insurance Co. v. Price, 248 F.Supp.3d 192 (D.D.C. Mar. 31, 2017)

Last year, a collection of insurers operating under the umbrella of UnitedHealthcare Insurance Company filed a complaint against HHS, CMS, and others alleging that the final rule inappropriately applies a negligence standard to FCA liability. Defendants responded with a motion to dismiss, asserting that the plaintiff insurers did not have standing to sue regarding the rule, as they

had not been injured by its operation. The D.C. District Court disagreed, noting that while defendants had not filed an action against the insurers for violating the rule's provisions, defendants' affirmative requirements that insurers undertake significant compliance activities was sufficient to meet the injury requirement for standing. The district court did not opine on the insurance companies' substantive arguments regarding the rule's impact on the standards for FCA liability, but the decision paves the way for the case to continue to an assessment of the merits of those arguments.

B. Retaliation

U.S. ex rel. Carson v. Manor Care, Inc., 851 F.3d 293 (4th Cir. March 16, 2017)

In *Carson*, the Fourth Circuit announced that the dismissal of a relator's *qui tam* action under the FCA's first-to-file rule has no bearing on whether the relator can sustain a claim for retaliation arising from the same facts. In 2009, Christine Ribik, a former occupational therapist for Manor Care's skilled nursing facilities, filed a *qui tam* suit against the company alleging that it had overbilled Medicare for medical services. In 2011, Patrick Carson, another former Manor Care employee, filed his own *qui tam* action against the company, claiming it had billed government programs for services not provided, services performed by unqualified personnel, and "unreasonable, unnecessary and at times harmful therapy." Carson also claimed retaliation in his complaint, alleging that Manor Care had fired him less than a week after he submitted a formal complaint about the fraudulent billing practices.

The district court found that Carson's FCA claims were based on the same fraud alleged in Ribik's suit and dismissed Carson's complaint based on the first-to-file rule. On appeal, the Fourth Circuit agreed with the district court regarding Carson's FCA claims, noting that merely providing additional facts supporting earlier allegations was not sufficient to survive dismissal.

The Court, however, also emphasized that "the first-to-file rule has no relation to a claim for retaliation" under the FCA. Under the plain language of the statute, false claims and retaliation claims "stand[] independently... and deal[] with entirely different subject matter: retaliatory acts as opposed to false claims." In addition, while an action for submitting false claims effectively "belongs" to the government as the wronged party, a retaliation claim is "personal to the plaintiff." The Fourth Circuit also noted its concern that "application of the first-to-file rule to [retaliation] claims would have the effect of causing plaintiffs to hesitate to report fraud to their employers and the Government because, if another suit has already been filed, they will not have any recourse for retaliatory actions by their employers." Such a policy would be "contrary to the purpose of the FCA to encourage private citizens to act as

whistleblowers when they suspect fraudulent Government claims." The Fourth Circuit reversed and remanded Carson's retaliation claim to the district court, where it was dismissed on other grounds. A second appeal is currently pending in the Fourth Circuit.

Fakorede v. Mid-South Heart Center, P.C., No. 16-5722, 2017 WL 4217230 (6th Cir. Sept. 22, 2017)

In Fakorede, the Sixth Circuit affirmed dismissal of a retaliation claim because the relator's conduct did not rise to the level of a protected activity under the FCA in that his complaints to his employer did not sufficiently relate to fraud against the federal government. Fakorede had served as a cardiologist for a private entity, Mid-South Heart Center, and received supplemental compensation from Jackson-Madison County General Hospital District, the governmental entity that recruited him to the area. Fakorede was terminated 14 months into his employment after requesting documentation regarding the calculation of his salary, expressing concerns about some of the expenses allocated to him, and stating during the audit process that the hospital district could pay only for expenses permitted by federal law.

The Sixth Circuit affirmed the dismissal of Fakorede's retaliation claim. The FCA's anti-retaliation provision protects employees who make an "effort[] to stop 1 or more violations of [the FCA]." 31 U.S.C. \$3730(h). But any such "effort" must be based on a reasonable belief that an employer is committing fraud against the federal government. Here, Fakorede's efforts were not "directed toward preventing what he reasonably believed was ongoing federal fraud."

III. Bars and Limitations on Actions

The FCA bars or limits actions a whistleblower can bring under the Act. Among the most commonly litigated are the public-disclosure bar, the first-to-file rule, and the government-action bar.

A. Public-Disclosure Bar

Under 31 U.S.C. § 3730(e)(4), the public-disclosure bar prohibits *qui tam* actions that are based on allegations or transactions that have been publicly disclosed. That provision was modified by the Affordable Care Act to be less restrictive for the relator—limiting the applicable hearings, reports, audits and investigations to those by the federal government; requiring that the government or its agent be a party to any such hearing for the public-disclosure bar to trigger; and providing the government with the option of opposing dismissal regardless of public disclosure. As seen below, it remains a source of regular litigation.



Prather v. AT&T Inc., 847 F.3d 1097 (9th Cir. Feb. 6, 2017)

Relator John Prather, a state prosecutor, brought a *qui tam* action alleging several telecom companies fraudulently overcharged the federal government for wiretaps and related surveillance assistance. He allegedly obtained his knowledge in the course of prosecuting organized crime. The district court disagreed and dismissed the complaint. In doing so, it noted that Prather had no knowledge of how the telecoms assisted in the surveillance or how costs were incurred, never alerted the federal government of his suspicions, and only filed his action after the FCC, DOJ, FBI, and DEA began an inquiry into the costs. Prather appealed.

On appeal, the Ninth Circuit affirmed. The Court, applying the pre-2010 version of the FCA, noted a relator's action is procedurally barred if it is brought after public disclosure of the allegations unless the relator is the original source of the information (31 U.S.C. § 3730(e)(4)(A)). To be an original source, the relator must have "direct and independent knowledge" of the information underlying the allegations and have provided the information to the government prior to filing the action. The Court held Prather did not have direct knowledge of the information and therefore filed his action based on conjecture. Additionally, Prather did not voluntarily provide the information to the government prior to filing the action. Instead, he submitted his allegations in the course of his work pursuant to an FCC inquiry. Consequently, the Court held that Prather was not an original source.

Lager v. CSL Behring, LLC, 855 F.3d 935 (8th Cir. May 5, 2017)

Relator Shane Lager alleged that CSL Behring, a drug manufacturer, conspired with pharmacies to submit false claims to the government by inflating the average wholesale price "AWP" of infusion drugs. In dismissing his claims, the district court found that multiple sources had disclosed general information about reimbursement for infusion drugs, as well as specific information about the average wholesale and sale prices of the particular drugs at issue, and, consequently, that the scheme alleged by Lager had previously been made public.

On appeal, Lager argued that the public disclosures did not identify Behring nor the subject matter of the fraud. With respect to the disclosure of Behring's identity, the Eighth Circuit held that for claims against a particular defendant to be barred, the defendant must be either explicitly identified or identifiable from the disclosed information about the participants in the scheme. The Court found that information from multiple sources, here both the government and media, should be viewed collectively to determine whether there is enough to "set the government squarely on the trail" of the defendant's participation in the fraud. Viewing the collective information that had been disclosed prior to Lager filing suit, the Court held that there was enough information to identify the defendants and drugs at issue, as well as the general subject matter of the fraud. The Court affirmed the dismissal, concluding that the essential elements of Lager's claims were publicly disclosed prior to him filing suit.

U.S. ex rel. Ambrosecchia v. Paddock Laboratories, LLC, 855 F.3d 949 (8th Cir. May 5, 2017)

In *Ambrosecchia*, the Eighth Circuit affirmed the district court's dismissal of relator Ambrosecchia's claims based on the public-disclosure bar. Ambrosecchia, a former employee of defendants Paddock Laboratories and Perrigo Company, alleged that the defendants improperly reported reimbursement-eligible classification codes to CMS for certain drugs determined to be "less than effective" by the Drug Efficacy Study Implementation Program (DESI-LTE). Drugs classified as DESI-LTE are not eligible for Medicare and Medicaid reimbursement unless re-approved.

The district court found that two sources of public information barred Ambrosecchia's claim: (1) various federal reports and (2) a complaint filed in a separate district court case. Ambrosecchia, however, claimed that she qualified as an "original source" because she had independent information that "materially add[ed] to the publicly disclosed allegations or transactions." Specifically, she alleged that her relative received a reimbursement from an ineligible Paddock drug and therefore her allegation demonstrated scienter, materially adding to existing information.

The Eighth Circuit made short shrift of Ambrosecchia's allegation, concluding that "the complaint provide[d] no more than the simple, conclusory allegation that Defendants' actions were knowing." In other words, Ambrosecchia's complaint failed to satisfy the *Iqbal/Twombly* pleading standards.

Amphastar Pharmaceuticals Inc. v. Aventis Pharma SA, 856 F.3d 696 (9th Cir. May 11, 2017)

In its complaint, Amphastar alleged that Aventis Pharma committed fraud against the U.S. Patent and Trademark Office (USPTO) when it applied to patent a blood thinner called enoxaparin. Amphastar claimed that in defrauding the USPTO in its patent application, Aventis obtained an illegal monopoly on enoxaparin, and then knowingly overcharged the government for the drug. The district court dismissed the case for lack of subject matter jurisdiction based on the public-disclosure bar. Amphastar appealed.

On appeal, the Ninth Circuit held that the district court appropriately determined that Amphastar's claims were barred by the public-disclosure bar, and therefore the court lacked subject matter jurisdiction. In affirming the dismissal, the Ninth Circuit agreed with the district court's holding that the FCA allegations were nearly identical to the counterclaims that Amphastar had made in an earlier patent infringement case, and that Amphastar had not demonstrated that it had direct, firsthand knowledge of Aventis' alleged fraud nor that it had obtained this knowledge independently.

Bellevue v. Universal Health Services of Hartgrove, Inc., 867 F.3d 712 (7th Cir. Aug. 8, 2017)

The disclosures at issue in *Bellevue* were letters sent to Hartgrove, a psychiatric hospital, by the Illinois Department of Public Health and CMS detailing audit findings of regulatory violations—namely that two audits of Hartgrove revealed an excessive number of patients, establishing that Hartgrove was "over census" on multiple dates. Relator George Bellevue alleged that Hartgrove violated the FCA by submitting claims to Medicaid despite admitting patients over the hospital's licensed capacity. Treating the public-disclosure bar as jurisdictional because some of the alleged fraud occurred prior to the 2010 amendments, the Court applied a three-step analysis to determine whether or not Bellevue's suit was barred by prior public disclosure: (1) whether the allegations had been publicly disclosed; (2) whether the lawsuit was based on or was substantially similar to the publicly disclosed allegations; and (3) if so, whether Bellevue qualified as an original source of the information.

The Court held that Bellevue's allegations fell within the publicdisclosure bar and dismissed the complaint. With respect to the first step, the Court found that the Bellevue's allegations had been publicly disclosed based on the letters regarding the audit findings. The Court emphasized that because Bellevue did not have

personal knowledge of Hartgrove's billing practices, "his allegations necessarily required him to infer that Hartgrove was knowingly over census" and there was "no reason that the government could not have made the same inference based on its audits." In determining whether the suit was based on or substantially similar to the publicly disclosed allegations, the district court differentiated between the time before and time after the CMS letter, concluding that Bellevue's post-letter allegations were not barred. The Seventh Circuit disagreed and did not distinguish time periods based on the date of the letter. Rather, the Court found that Bellevue alleged a continuing practice by the same entity involving the same contested conduct that was substantially similar to the publicly disclosed allegations, and held that all of Bellevue's allegations were precluded. With respect to the final step of the analysis, the Court applied the 2010 amended definition of original source and found that Bellevue did not qualify as an original source because he did not materially add to the publicly disclosed information.0

B. First-to-File Rule

Under 31 U.S.C. § 3730(b)(5), the FCA bars anyone other than the government from bringing "a related action based on the facts underlying the pending action." Courts have interpreted the relationship necessary to trigger the first-to-file rule in different ways.

U.S. ex rel. Haynes v. Allstate Insurance Company, 853 F.3d 80 (2d Cir. Apr. 4, 2017)

Relator Haynes brought an FCA suit against several insurance companies generally alleging that they had failed to comply with obligations to reimburse Medicare for certain payments made on behalf of Medicare beneficiaries. The district court dismissed the case with prejudice as a sanction under Fed. R. Civ. P. 11, finding that Haynes had no knowledge of the allegations in the complaint and had acted in bad faith by falsely claiming to have such knowledge. Haynes appealed.

On appeal, in addition to agreeing with district court's stated basis for dismissal, the defendants also asserted that dismissal was proper because Haynes did not satisfy the first-to-file rule, and therefore the district court lacked subject-matter jurisdiction.

In a separate summary order, the Second Circuit affirmed based on the Rule 11 grounds found by the district court. In this opinion, the Court addressed the jurisdictional issue related to the first-to-file rule, concluding that the rule was not jurisdictional. In doing so, the Court joined the D.C. Circuit's similar conclusion, while declining to follow the Fourth and Sixth Circuits' holdings that the first-to-file rule is jurisdictional. In particular, the Court was persuaded that, while the FCA clearly states that certain limitations are jurisdictional, the statutory language related to the first-to-file rule does not.

U.S. ex rel. Shea v. Cellco Partnership, 863 F.3d 923 (D.C. Cir. July 25, 2017)

Shea filed a *qui tam* action against Verizon for charging the General Services Administration non-billable taxes and surcharges. That case ultimately settled, but before it did, Shea determined that Verizon had replicated the fraud in 20 other federal accounts and brought a second *qui tam* action related to those accounts. The district court dismissed the second suit under the first-to-file bar; although the first-filed suit had ended through settlement, the court reasoned that the bar prohibited a second action *brought* while the first action was still pending.

Shea successfully appealed the dismissal, but on remand, the district court dismissed the action again. Although (per the Supreme Court's ruling in *Carter*) the first-to-file bar does not prevent the bringing of a new action once the first-filed suit ends, the Court held that Shea could not simply amend his complaint to cure the first-to-file defect; he had to file a new action. The D.C. Circuit affirmed.

U.S. ex rel. Little v. Triumph Gear Systems, Inc., 870 F.3d 1242 (10th Cir. Sept. 18, 2017)

In *Little*, the Tenth Circuit held the first-to-file rule prevents a non-party from intervening in a *qui tam* action via Federal Rule of Civil Procedure 15. Relators Joe Blyn and three John Does brought an FCA suit against Triumph, a government contractor and the manufacturer of aerospace gear systems. Donald Little, Blyn's counsel, filed the original complaint as counsel of record. Almost a year later, Little—not Blyn—filed an amended complaint listing himself and Kurosh Motaghed as relators and dropping Blyn entirely. At the district court, Triumph argued the first-to-file rule prohibited new relators from intervening in a pending FCA action. The district court disagreed and denied Triumph's motion to dismiss.

The Tenth Circuit reversed. Addressing the purpose of the first-to-file rule—to prevent parasitic and duplicative lawsuits—the Court focused on the meaning of "intervention" in 31 U.S.C.

§ 3730(b)(5). Intervention, the Court noted, "takes place when a non-party becomes a party—regardless of the mechanism by which that occurs." The Court concluded that the threshold decision was simple: Prior to Little's amended complaint, neither Little nor Motaghed were parties.

In its ruling, the Court addressed an earlier Tenth Circuit decision, *United States ex. rel. Precision Company v. Koch Industries, Inc.*, 31 F.3d 1015 (10th Cir. 1994), which had allowed non-parties to intervene under Rule 15. However, in *Precision*, the *existing plaintiff*, not the new, would-be plaintiffs, amended the complaint. Here, Little—not Blyn, the original plaintiff—filed the amended complaint adding the new relators. Thus, the Court held, neither Little nor

Motaghed fit into *Precision's* narrow exception to the first-to-file rule

C. Government-Action Bar

Less commonly litigated than the other bars above, the government-action bar arises from 31 U.S.C. § 3730(e)(3), which prohibits a person from bringing an action based upon allegations or transactions that are the subject of a civil suit or an administrative proceeding in which the government is already a party.

U.S. ex rel. Bennett v. Biotronik, Inc., 876 F.3d 1011 (9th Cir. Dec. 1, 2017)

In *Bennett*, the Ninth Circuit addressed the scope of the government-action bar. In 2009, a *qui tam* claim was filed by a different relator against Biotronik. In 2014, the government intervened in the case and later reached a settlement agreement with Biotronik. That case was dismissed with prejudice as to the conduct covered in the settlement agreement and without prejudice as to the conduct not covered in the agreement.

In October 2014, Bennett filed the *qui tam* claim at issue and alleged the same conduct included in the 2009 lawsuit, but not covered by that case's settlement agreement. The government and the state declined to intervene. When Bennett continued in the case, Biotronik moved to dismiss on grounds that the case was barred under § 3730(e)(3). The district court agreed and dismissed the complaint; Bennett then appealed.

The Ninth Circuit focused on whether the government remains a "party" to a case, even after it is no longer an active participant. Bennett contended that the government is no longer a party to cases that are not ongoing, as with the 2009 case involving Biotronik that ended in settlement. The Ninth Circuit disagreed, concluding that the government remains a "party" even after a suit has concluded. The Court noted that a party remains a party after judgment in various contexts, including under Rule 60, which allows motions for relief from a final judgment. The Court further rejected Bennett's proposed distinction between the settled and unsettled claims in the 2009 case, finding that "party" does not turn on particular claims or number of claims.

IV. Pleading and Procedure

A. Rule 9(b)

Federal Rule of Civil Procedure 9(b) continues to be a fertile source of FCA litigation and a point of contention in nearly every motion to dismiss. Because FCA claims allege fraud, they must meet heightened pleading standards beyond those that apply in ordinary civil actions. Specifically, Rule 9(b) requires plaintiffs to state with particularity the circumstances constituting the fraud, a showing

that generally requires details about the time, place, and content of the misrepresentations; the fraudulent scheme; the defendants' fraudulent intent; and the injury resulting from the fraud.

U.S. ex rel. Hirt v. Walgreen Co., 846 F.3d 879 (6th Cir. Jan. 25, 2017)

In *Hirt*, the relator was the owner of two local pharmacies which competed with the area Walgreens. Hirt alleged that Walgreens offered \$25 gift cards to entice customers to fill their prescriptions at Walgreens, which he claimed was a violation of the anti-kickback statute. He further alleged that Walgreens then submitted the resultant prescription drug claims to Medicare and Medicaid in violation of the FCA. The district court granted Walgreens' motion to dismiss for, among other reasons, failure to plead fraud with particularity as required by Rule 9(b).

On appeal, the Sixth Circuit affirmed and clarified that relators are not entitled to a "relaxed" Rule 9(b) standard in the FCA context. Specifically, the Court found that Hirt's complaint was deficient because it did not identify any false claims that the pharmacy had allegedly submitted. He failed to allege the name of any customers who switched pharmacies or any facts concerning the claims submitted for patients who switched. The Court noted that the "identification of at least one false claim with specificity is an indispensable element of a complaint that alleges" a FCA violation in compliance with Rule 9(b). Significantly, the Court clarified an earlier Sixth Circuit decision which had discussed the possibility of relaxing the Rule 9(b) standard if a plaintiff, through no fault of his own, could not allege the specifics of actual false claims that in all likelihood exist.

U.S. ex rel. Booker v. Pfizer, Inc., 847 F.3d 52 (1st Cir. Jan. 30, 2017)

In *Booker*, the relator, a former Pfizer sales representative, alleged that after entering into a Corporate Integrity Agreement (CIA) with the U.S. Department of Health and Human Services, Pfizer continued to induce false claims by promoting its drug Geodon for off-label use and violated the "reverse false claims" provision of the FCA by failing to pay the government money owed it under Pfizer's CIA. The district court dismissed Booker's claim under the reverse false claims provision, and later dismissed Booker's FCA and employment retaliation claims on summary judgment.

On appeal, the First Circuit affirmed the district court's rulings. The Court found that Booker failed to provide sufficient evidence that Pfizer's alleged conduct resulted in the actual submission of fraudulent claims. Specifically, the Court noted that when FCA liability is predicated on a defendant's alleged off-label promotion of a drug to medical providers, in order to meet the requirements under Rule 9(b) of an actual false claim, a relator must identify the

medical provider responsible for submitting the false claim, the approximate time period, the location, the amount of the claim, and the government program to which the claim was made. The Court noted that evidence of aggregate data reflecting the amount expended by the government on prescriptions for alleged off-label use is insufficient on its own to support an FCA claim.

The Court similarly rejected Booker's retaliation claim based on his reporting of alleged off-label use because "absent any evidence that [] objections or reports concerned FCA-violating activity," such evidence cannot show that the employee engaged in conduct protected by the FCA. Finally, the Court also rejected Booker's reverse false claim based on an alleged breach of Pfizer's CIA because Booker failed to allege that Pfizer had determined that Booker's email to the corporate compliance department was a "reportable event" under the CIA.

U.S. ex rel. Colquitt v. Abbott Laboratories, 858 F.3d 365 (5th Cir. May 31, 2017)

In *Colquitt*, the Fifth Circuit reviewed a multitude of challenges to the lower court's decisions granting Abbott Laboratories' motion to dismiss and motion for summary judgment, as well as its trial victory on the remaining claims, ultimately affirming the trial court on all grounds.

Of most interest is the Court's Rule 9(b) holding. Although the Fifth Circuit cautioned that Rule 9(b) should not be applied too rigidly, the Court held that allegations cannot survive dismissal where a plaintiff not only fails to plead that false claims were actually submitted, but also fails to allege sufficient particular details which would make a scheme to submit false claims even plausible. Colquitt alleged that his former employers, Abbott Labs and its predecessor, Guidant Corporation, committed fraud upon the Medicare program and the FDA by encouraging the off-label use of a stent in blood vessels when the defendants had only sought FDA fast-track approval for a stent to be used in bile ducts. Physicians were purportedly encouraged by defendants to use the stents for the lucrative off-label purposes, and, in exchange, Abbott Labs and Guidant allegedly provided these physicians "benefits."

Chastising Colquitt for devoting only "a single, vague paragraph to the alleged kickback scheme," the Fifth Circuit found the lack of specifics fatal to the claims, noting that Colquitt failed to allege any particulars to show that the doctors who received the benefits caused the hospital to use Abbott Laboratories' stents. "In short," the Court wrote, "the complaint never links the alleged carrots to the purchase and use of the stents."

U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co., 874 F.3d 905 (6th Cir. Oct. 27, 2017)

In *Ibanez*, relators, former employees of Bristol-Myers Squibb Co. (BMS), alleged that BMS, together with Otsuka America Pharmaceutical, Inc. (Otsuka), engaged in a nationwide scheme to promote improperly the antipsychotic drug Abilify for unapproved, off-label uses by inducing providers to prescribe Abilify, thereby violating the Anti-Kickback Statute. The Sixth Circuit affirmed the district court's dismissal of realtors' claims for failure to plead with sufficient particularity that the alleged off-label promotion and use of kickbacks were part of a conspiracy to submit false claims.

The Sixth Circuit affirmed the dismissal of alleged violations of \$3729(a)(1)(A) of the FCA, which prohibits "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval." The Court declined to relax the Rule 9(b) pleading standard and held that relators' failure to provide any representative claim that was actually submitted to the government for payment was insufficient under this section of the FCA.

The Court also affirmed the dismissal of alleged violations of 31 U.S.C. §§ 3729(a)(1)(B), (C), and (G) of the FCA. The Court rejected relators' section 3729(a)(1)(B) claim because there were no allegations connecting the alleged false statements used to increase the number of Abilify prescriptions to any particular claims made to the government. The Court rejected the relators' reverse false claim theory because relators failed to plead facts showing BMS and Otsuka received and retained any alleged overpayment. Finally, the Court rejected relators' conspiracy claim because the alleged plan was to improperly promote Abilify to increase prescriptions, and "[w]hile this may be condemnable, it does not amount to a conspiracy to violate the FCA."

B. Pro Se Relators

U.S. ex rel. Brooks v. Ormsby, 869 F.3d 356 (5th Cir. July 20, 2017)

In *Ormsby*, the Fifth Circuit affirmed that a "non-lawyer proceeding pro se" cannot bring a *qui tam* action as relator for the United States. James Brooks, a non-lawyer, filed a pro se complaint in the United States District Court for the Western District of Texas, alleging, inter alia, violations of the FCA. The government declined to intervene in the action. The district court dismissed the action without prejudice and reasoned that Brooks could not represent himself pro se as relator for the United States. Brooks appealed the dismissal, and the Court affirmed the district court's ruling. After noting the matter to be one of first impression in the Fifth Circuit, the Court concluded that, regardless of the right to represent oneself pro se, Brooks "is not representing himself when he brings an action solely as relator for another non-intervening party, including the United States, and therefore cannot do so pro se."

V. Other Issues

A. Causation

U.S. ex rel. King v. Solvay Pharmaceuticals, Inc., 871 F.3d 318 (5th Cir. Sept. 12, 2017)

In 2006, relators John King and Tammy Drummond filed their FCA action against Solvay Pharmaceuticals, Inc., alleging that Solvay participated in an off-label marketing and kickback scheme that caused physicians to prescribe Luvox, Aceon, and AndroGel to Medicaid patients in order to receive government reimbursement. After a series of partial summary judgment rulings, the district court granted summary judgment in favor of Solvay in March 2016. On appeal, the Fifth Circuit affirmed.

The Fifth Circuit agreed with the district court's finding that King and Drummond could not overcome the FCA's public-disclosure bar with respect to the claims pertaining to AndroGel, because they failed to establish that they, and not the media, were the original source of the information. In particular, the Court noted that King and Drummond failed to rely on any of their personal knowledge as company employees to support the AndroGel allegations.

The Court also found that King and Drummond did not have sufficient evidence to demonstrate that the alleged off-label marketing of Luvox and Aceon actually resulted in any false claims being submitted to the government. Ultimately, despite some evidence that widespread off-label marketing had taken place at Solvay, King and Drummond were unable to show a causal connection between the off-label marketing and any false claims being submitted to the government for payment.

United States v. Luce, 873 F.3d 999 (7th Cir. Oct. 23, 2017)

In October, the Seventh Circuit abandoned its "but-for" causation standard for FCA claims. Under its long-standing precedent, finding causation had required only a showing that an injury would not have occurred if not for the conduct. The Seventh Circuit has been the lone outlier using a "but for" standard, with other circuits adopting the more rigorous "proximate cause" standard. The Seventh Circuit now joins the other circuits holding that causation is found when the conduct was a material element and substantial factor in bringing about the injury and that the injury is of the type a reasonable person would see as a likely result of the conduct.

In *Luce*, the government pursued FCA claims against the owner and president of a now-defunct mortgage company for submitting false certification forms to the Department of Housing and Urban Development (HUD) between 2005 and 2008. To continue to benefit from Fair Housing Act (FHA) protection, mortgagees must certify that their officers are not currently involved in criminal

proceedings. Although the owner of the mortgage company was indicted for fraud in April 2005, the company failed to notify HUD until February 2008 and failed to amend its certifications until August 2008, after the owner pleaded guilty to lesser charges. The government sought damages to compensate for losses associated with 237 FHA-covered loans originated during the three-year period, which ultimately went into default.

Applying *Escobar*, the district court found the false certifications material to the government's decision to allow the company's participation in the program, and found the mortgage company owner liable under the FCA. In addressing damages, the district court declined to hold that *Escobar* altered the jurisdiction's "but for" causation test.

On appeal, although the court emphasized that "nothing in [Escobar] directly addresses the question of FCA causation or the circuit split," the Seventh Circuit conceded that Escobar "does give us pause." Rather than acknowledging Escobar as overruling Seventh Circuit precedent, the circuit voluntarily engaged in a "careful reevaluation" of the issue based on the common-law meaning of fraud, FCA text, and the decisions of other circuits. Ultimately, the court determined that its "but-for" precedent simply could not "live in peace" with the opinions of the Third, Fifth, Tenth, and D.C. Circuits adopting a proximate cause standard.

B. Damages

U.S. ex rel. Wall v. Circle C Construction, LLC, 868 F.3d 466 (6th Cir. Aug. 18, 2017)

Circle C Construction spent seven years and \$20 million building 42 warehouses for the United States Army. A subcontractor on that project underpaid two of its electricians by \$9,916, violating the Davis-Bacon Act and rendering several of Circle C's compliance statements false. Circle C paid \$15,000 to settle the underpayment, but the government demanded \$1.66 million, arguing that the underpayment tainted all of the subcontractor's electrical work, leaving it "valueless." The Sixth Circuit reversed a judgment for \$763,000 and remanded with instructions to enter judgment for \$14,748 (triple the actual damages with an offset for the \$15,000 already paid).

On remand, the district court denied Circle C's motion for attorneys' fees under 28 U.S.C. § 2412(d)(1)(D), a fee-shifting statute that protects defendants whose ultimate liability is substantially less than the government's initial demands. Circle C appealed again, giving the Sixth Circuit the opportunity to decide whether the \$1.66 million demand was "substantially in excess" of the \$14,748 judgment, and whether that demand was therefore "unreasonable" under the facts and circumstances.



Answering "yes" and "yes," the Sixth Circuit reversed and remanded the case with orders to award Circle C its attorneys' fees. Noting that Circle C's conduct was the result of "an honest mistake" rather than a "willful violation," and that the government sought "fairyland rather than actual" damages, the Court held that the statute was *designed* to have a "chilling effect" on overly aggressive government enforcement, and, thus, Circle C was entitled to fees. While one dissenting judge would have upheld the denial of fees on abuse-of-discretion review, the majority held that, even under the deferential standard of review, it was an abuse of discretion to leave Circle C with half a million dollars in legal fees for a \$9,916 mistake simply because "the government made a demand for damages a hundredfold greater than what it was entitled to, and then pressed that demand over nearly a decade of litigation, all based on a theory that as applied here was nearly frivolous."

United States v. Americus Mortgage Corp., No. 12-cv-2676 (S.D. Tex. Sept. 14, 2017)

In September, the Southern District of Texas entered a \$298 million judgment against a mortgage originator for conduct committed largely during the era leading up to the 2008 financial crisis. The suit began in 2011 as a whistleblower action, in which the government intervened, alleging the submission of false Federal Housing Administration (FHA) insurance claims by Americus Mortgage Corporation (formerly known as Allied Home Mortgage Capital Corporation), one of its affiliates, and its CEO (collectively, "Allied") between 2001 and 2011. The matter eventually proceeded to a fiveweek jury trial, where the government proved its case in part based

upon statistical sampling and extrapolation, and Allied was found liable for multiple violations of the FCA and the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA). The conduct proven at trial included submission of 1,192 FHA insurance claims for loans that were recklessly underwritten and ineligible for FHA insurance, and submission of another 103 FHA insurance claims for loans originated in branches without proper HUD registration, using registration numbers of other, registered branches.

To reach the \$298 million judgment, the district court trebled the jury's \$93 million award and added penalties of \$10,000 per claim. The district court found Allied's conduct worthy of penalties at "the high end of the spectrum" for pre-2015 conduct, because of the many years across which the fraud occurred, the intentionality and severity of the conduct, the large amount of actual damages incurred by the government, and Allied's failure to cooperate when confronted by HUD years prior during a routine audit.

In an attempt to lessen the blow of mandatory FCA trebling, Allied argued that "net" damages, rather than "gross" damages, were the proper sum to treble, citing *United States v. Anchor Mortgage Corp.*, 711 F.3d 745, 750 (7th Cir. 2013). A "net" damages calculation would allow deduction of any payment the government had received back on the claims from the amount of loss prior to trebling. However, the district court rejected this argument, holding that that Fifth Circuit's precedent expressly prohibited such deductions until after trebling.

The Court also rejected Allied's argument that it would be unconstitutional to assess penalties under both the FCA and FIRREA for the same conduct, finding instead that the false certifications and quality control reports that formed the basis of FIRREA liability constituted different conduct than the FHA insurance claims.

C. Settlement

U.S. ex rel. Michaels v. Agape Senior Community, Inc., 848 F.3d 330 (4th Cir. Feb. 14, 2017)

Agape involved an interlocutory appeal of a *qui tam* action brought under the FCA by former employees against Agape Senior Community Inc. and 23 other defendants. The relators alleged the defendants fraudulently billed Medicare and other federal healthcare programs. After serving the complaint on the government, the government declined to intervene and the complaint was unsealed in the district court. Meanwhile, the relators, defendants, and the government mediated unsuccessfully. Subsequently, and unbeknownst to the government, the relators and defendants engaged in a second mediation session which resulted in a proposed settlement. Although the government had not intervened, the Attorney General objected to the proposed settlement. The district court concluded that the government—despite not having intervened in the action—possessed an

unreviewable veto authority over the proposed settlement. The district court sua sponte certified its ruling for interlocutory appeal.

The appeals court acknowledged that whether the government could veto a proposed settlement without having intervened in the action constituted a matter of first impression in the Fourth Circuit and an issue that divided other circuits. The statute states an "action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting" (31 U.S.C. § 3730(b)(1)). While the Ninth Circuit had previously held that the government's consent was dependent upon whether it had previously intervened, the Fifth and Sixth Circuits concluded, to the contrary, that the statute contained no such limit on the government consent requirement.

The Fourth Circuit sided with the Fifth and Sixth Circuits, concluding that government consent was required for settlement even where the government had chosen not to intervene. Rejecting the Ninth Circuit's conclusion to the contrary, the Fourth Circuit held that the consent statute was unambiguous and nothing in the statute discussed intervention. The Court reasoned that government consent was necessary to avoid settlements that unfairly enriched relators and reduced benefits to the government, including bargaining away claims on behalf of the United States. Thus, per the Fourth Circuit, the government always has absolute veto power over voluntary settlements.

U.S. ex rel. Ashton v. Everglades College, Inc., 855 F.3d 1279 (11th Cir. May 3, 2017)

In Ashton, the relators brought a qui tam lawsuit alleging that Everglade College, Inc. (d/b/a Keiser University) falsely certified compliance with a federal law banning incentive payments to university admissions counselors. After the government declined to intervene, the relators litigated the case, ultimately securing a limited trial victory of no damages and \$11,000 in penalties. Unsatisfied, relators appealed to the Eleventh Circuit. But while the appeal was pending, the government, changing its earlier decision, intervened in the case for purposes of settling with Keiser. Relators objected, arguing the settlement was insufficient and the government could not intervene so late in the proceedings. The district court rejected those arguments, allowed the government to intervene, and approved the settlement. Relators appealed those rulings.

On appeal, relators argued that the government fails to show "good cause" to intervene, as required by 31 U.S.C. § 3730(c)(3), when the government initially declines intervention but seeks to intervene later after the relator has proceeded with the case. Relying on statutory text and similar conclusions in the D.C. and Fifth Circuits, the Eleventh Circuit rejected that argument, holding that the

"good cause" requirement only applied when the government was "actually proceeding with the litigation—not when it is stepping in only for the purpose of settling and ending the case."

D. Yates Update

Despite the attention and analysis the Yates Memo generated when it was issued in 2015, examples of actions against individuals have been less than frequent. These cases span both civil and criminal fraud and have included lower-level employees, as well as executives and owners. Penalties have included fines, restitution, exclusion, licensure termination, and imprisonment. In some cases, individuals agreed to be held jointly and severally liable with their corporations for settlement payments. In other cases, the DOJ pursued settlements or convictions against individuals separately from their corporate entities.

Notable cases with individual settlements/prosecution in 2017 include:

- In January 2017, the owners of Medstar Ambulance Inc. agreed to be jointly and severally liable for a \$12.7 million settlement with their company to resolve allegations of improper billing for ambulance transfer services.
- In February 2017, a Florida urologist agreed to a \$3.8 million settlement in connection with allegations of unnecessary test referrals to a laboratory owned and operated by 21st Century Oncology. The individual settlement followed 21st Century Oncology reaching a \$19.75 million settlement for related conduct in 2015.
- Also in February 2017 a physician and owner and operator of a dermatology and skin cancer center in Florida agreed to the entry of an \$18 million consent judgment in connection with the performance of radiation therapy services.
- In addition, a February 2017 settlement with a Kentucky physician to resolve allegations that he billed federal healthcare programs for surgical monitoring services that he did not perform and for medically unnecessary diagnostic tests resulted in a \$20 million consent judgment.
- In May 2017, three of the founders and three additional employees of eClinicalWorks reached settlements. The founders agreed to joint and several liability with the company for a \$155 million settlement related to the misrepresentations of software capabilities, as well as kickback payments to customers for promoting the company's products. The three employees reached separate settlements related to their alleged personal involvement in the conduct.



- Also in May 2017, a Minnesota nonprofit and two of its principals agreed to a combined \$4.52 million settlement to resolve FCA violations for hiring unlicensed providers and batch signing thousands of claims. The individuals were also barred from participating in government healthcare programs for five and eight years respectively.
- In June 2017, the owner of a diagnostic testing center headquartered in Texas agreed to pay \$1 million to resolve liability for his alleged involvement in billing Medicare for higher and more expensive levels of cardiac monitoring services than requested by the ordering physicians.
- Also in June 2017, a former nurse supervisor at Passages Hospice LLC was sentenced to 20 months in prison and ordered to pay \$1.67 million following her conviction at trial for health care fraud.
- In addition, in June 2017, a nurse/co-owner of a home health company was sentenced to three months in prison, \$1.5 million in restitution and surrender of his nursing license for his role in a scheme to provide home health services to individuals who were not homebound.
- In July 2017, the DOJ announced settlements with three companies and two executives resolving FCA allegations concerning unnecessary rehabilitation services at skilled nursing facilities and fraudulent hospice services. Together the entities and individuals paid \$19.5 million, and one of the companies, along with its president,

entered into a five-year Corporate Integrity Agreement.

- Also in July 2017, a settlement with Freedom Health Inc. for submitting unsupported diagnosis codes resulting in inflated reimbursements from Medicare required the company's former COO to pay \$750,000.
- In addition, in July 2017, former owners and managers of the defunct Home Care Hospice agreed to pay a combined \$825,000 and to transfer personally owned assets, including two condos owned by two of the defendants.

WHAT TO WATCH IN 2018

Upcoming Eleventh Circuit Decision on Medical Judgment and Objective Falsity

In March 2016, the Northern District of Alabama granted summary judgment for AseraCare in *U.S. ex rel. Paradies v. AseraCare Inc.* after the first phase of a bifurcated trial regarding whether 123 hospice patients were eligible for the Medicare hospice benefit, with the evidence largely limited to conflicting expert testimony. The Court held that the government had failed to prove its case because it did not offer falsity evidence other than its expert's differing opinions and "[a] mere difference of opinion between physicians, without more, is not enough to show falsity." The DOJ's appeal of this decision has been fully briefed and argued before the Eleventh Circuit, and an opinion is expected in 2018.

Bradley Arant Boult Cummings LLP represents AseraCare in this matter.

Possible Increased Activity by DOJ to Dismiss Baseless Cases

In a speech during the Health Care Compliance Association's Health Care Enforcement Compliance Institute in October, the Director of the DOJ's Civil Fraud section indicated that the DOJ would move to dismiss FCA cases if it concluded that the cases were baseless. While the DOJ has always had the ability to move to dismiss these cases, it has done so very sparingly in the statute's 35-year history. The DOJ later clarified that this statement did not indicate a more aggressive approach towards dismissing cases but was merely acknowledging its policy of maximizing the use of the government's limited resources. It remains to be seen whether there will be any notable change in the DOJ's practices in this regard.

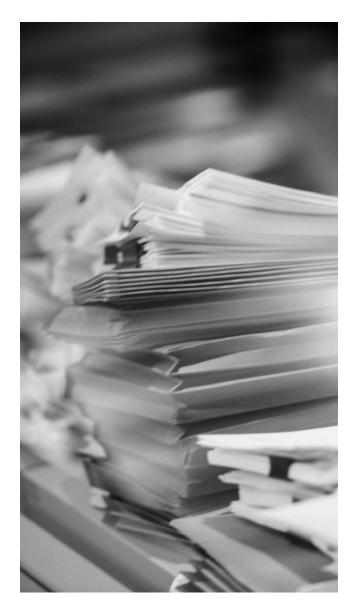
Yates Memorandum Under Review

Another issue to watch for in 2018 will be the DOJ's policy with

respect to prosecutions of individuals for their role in corporate malfeasance. In September 2017, Deputy Attorney General Rod Rosenstein suggested that the Yates memorandum, described above, was "under review." Rosenstein did not expressly indicate how the policy would change, other than to state that the DOJ will make an announcement in the "near future about what changes we're going to make."

It is unclear how the policy guidance and the focus will change. Nonetheless, it is unlikely that the focus of pursuing individuals for corporate fraud will change wholesale. Rather, as Attorney General Jeff Sessions himself stated last year—in the context of corporate compliance—it is often more just to punish the individual wrong-doers than the entire corporation.

What specific guidance the DOJ puts out remains to be seen, however, it is an issue that will attract a fair amount of attention in 2018.



The Government Enforcement and Investigations Practice Group



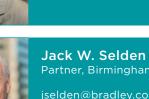
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