

False Claims Act 2018 Year in Review



CONTENTS

INTRODUCTION	1
KEY DECISIONS & DEVELOPMENTS	2
I. FCA Elements	2
A. Materiality	2
B. Falsity	2
1. Objective Falsity	3
2. Fraudulent Inducement	4
3. Implied False Certification— The <i>Escobar</i> Test	4
II. Specific Types of Claims	5
A. Anti-Kickback Statute Violations	5
B. Medicare Advantage	5
C. Reverse False Claims and Overpayments	7
D. Retaliation	8
III. Bars and Limitations on Actions	10
A. Public-Disclosure Bar	10
B. First-to-File Rule	11
C. Statute of Limitations	11
D. Government-Action Bar	12
IV. Pleading and Procedure	12
A. Rule 9(b)	12
B. Government Motions to Dismiss under Section 3730(c)(2)(a)	13
C. Government Intervention	14
D. Relator Alternate-Remedy Intervention	15
V. DOJ Memos and Policy Announcements	16
A. Dismissal of Qui Tam Suits	16
B. Limiting Use of Agency Guidance in Affirmative Civil Enforcement Cases	16
C. Avoiding “Piling On”	16
D. Corporate Monitorships	17
E. DOJ Compliance Expert	17
F. Yates Revisited	17
WHAT TO WATCH IN 2019	18
Bradley’s Government Enforcement and Investigations Practice Group	19



INTRODUCTION

Unlike some recent years, 2018 was somewhat short on headline-grabbing news related to the False Claims Act (FCA). There were, to be sure, significant developments in the courts and within the Department of Justice (DOJ), but 2018 will not be remembered for a watershed decision, record-breaking recoveries, or seismic policy change.

2018 did, however, continue the trend of DOJ's robust FCA enforcement across regulated industries—even if that enforcement lacked some of the garishly large recoveries of recent years. In fiscal year 2018, DOJ recovered over \$2.8 billion in settlements and judgments from civil FCA cases. That figure represents a second straight year of falling recoveries (down from approximately \$3.5 billion in fiscal year 2017 and \$4.9 billion in fiscal year 2016), and the lowest mark since fiscal year 2009. Notwithstanding the relative reduction, this past year is the 14th consecutive year with FCA recoveries exceeding \$1 billion, and 10th consecutive with over \$2 billion, signaling that FCA enforcement remains alive and well.

The healthcare industry again led the way among targeted industries, accounting for \$2.5 billion—about 87 percent—of all recoveries. In fact, healthcare-related recoveries continue to be remarkably consistent despite other enforcement peaks and valleys. The \$2.5 billion in fiscal year 2018 was up from \$2.1 billion last fiscal year, and it marks nine consecutive years of healthcare recoveries exceeding \$2 billion. Interestingly, while healthcare-related recoveries were up, the number of healthcare-related qui tam cases filed by whistleblowers actually fell by about 10 percent. Recoveries from the defense industry and other non-healthcare industries were significantly down in 2018 compared to recent years.

Beyond recoveries, 2018 was characterized by the courts' continued application and analysis of *Escobar* over two years after the Supreme Court's decision in June 2016. Year two of the Trump administration's DOJ also ushered in several intra-department policy changes in the Granston and Brand memos, as well as several others, that may have a significant effect on FCA litigation.

While watching those and other potential trends for 2019, we review the key decisions and developments that shaped 2018.

OVER
\$2.8 BILLION
IN SETTLEMENTS
AND JUDGMENTS
FROM CIVIL FCA
CASES WERE
RECOVERED
IN 2018.



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.

A. Materiality

***U.S. ex rel. Prather v. Brookdale Sr. Living Communities, Inc.*, 892 F.3d 822 (6th Cir. June 11, 2018)**

For the second time, the Sixth Circuit revived this non-intervened *qui tam*—this time finding that the trial court had not properly applied *Escobar* in granting Brookdale's motion to dismiss. Prather, the relator, alleged Brookdale fraudulently failed to disclose that, because of a paperwork backlog, it was late in obtaining required physician signatures for home health services it provided.

In 2016, the Sixth Circuit reversed the district court's dismissal of the case on falsity grounds. While that appeal was pending, the Supreme Court decided *Escobar*, so on remand, the district court allowed Prather to amend her complaint to strengthen her materiality allegations. But the district court thereafter dismissed the case again, agreeing with Brookdale that the amended complaint did not sufficiently allege that the timing of the physician signature was material to the government's payment decision.

On the parties' second trip to the Sixth Circuit, the court (2-1) found that Prather's allegations were sufficient under *Escobar*. Among other things, the court held that the district court incorrectly drew a negative inference from Prather's inability to allege that the government had ever denied payment based on the timing of the physician's certification. The majority found that the requirement about the *timing* of the physician's signature went to the "essence of the bargain" between Brookdale and the government because it was designed to help combat fraud. Thus, Prather met her burden under *Escobar* to show that the timing requirement was material.

In dissent, Judge McKeague carefully examined Prather's allegations, Medicare regulations, and the mechanics of the claims process for the services at issue and found no sign that the government would have denied payment based on the late signatures. In response to the majority's finding about the "essence of the bargain," he explained that virtually all regulations are designed to help ensure the government gets what it pays for.

So the timing requirement's supposed antifraud purpose cannot sustain Prather's burden to show materiality. Despite this persuasive dissent, the Sixth Circuit declined to reconsider the case *en banc*, and Brookdale has petitioned the Supreme Court for certiorari.

***U.S. ex rel. Ruckh v. Salus Rehabilitation, LLC et al.*, 304 F. Supp. 3d 1258 (M.D. Fla. Jan. 11, 2018)**

In *Ruckh*, the relator's case centered on what the court considered a "handful of paperwork defects" by the owners and operators of 53 specialized nursing facilities. Because the facilities failed to maintain a care plan and did not keep the most detailed records, relator alleged that the defendants billed Medicare for therapy that was never actually provided. The relator initially obtained an approximately \$350 million jury verdict before the court issued a particularly scathing opinion vacating the judgment and granting defendants' motion for judgment as a matter of law.

The court observed that "[t]he evidence shows not a single threat of non-payment, not a single complaint or demand, and not a single resort to an administrative remedy or other sanction for the same practices." Accordingly, it held that, once the government's knowledge is demonstrated, a relator must submit some proof of affirmative action to deter the practices by the government to prove materiality.

Mere "leniency or tolerance or indifference or perhaps [] resignation" by the government is insufficient. Evidence of how the government "behaved in comparable circumstances" is required to justify a jury verdict, and counterevidence by defendants that the government continued to make payments despite knowledge of the disputed practices is damning to a FCA case. And further, beyond forwarding evidence of government action, a relator must prove "that the defendant knew at the moment the defendant sought payment that non-compliance was material to the government's payment decision."

On May 2, 2018, relator noticed her appeal of the judgment.

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 legally 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

***United States v. Paulus*, 894 F.3d 267 (6th Cir. June 25, 2018)**

Though not an FCA opinion, the Sixth Circuit's ruling in *Paulus* is one the defense bar will likely see cited repeatedly against them in FCA matters involving medical necessity.

The case involved defendant Dr. Paulus's interpretation of angiograms to determine the degree of arterial blockage and whether a stent was necessary. There was testimony that 70 percent blockage is the accepted standard to justify placing a stent without further testing, and 50 percent to 70 percent blockage can justify a stent if supported by further testing. In the government's case, nine doctors testified that the degree of blockage in Dr. Paulus's patients to be less—and some much less—than 50 percent. The government's witnesses, however, also acknowledged that different doctors' interpretation of the same angiogram can vary up to 10-20 percent. And Dr. Paulus provided several studies showing that variability in interpretations can be much higher than that.

Other testimony suggested that Dr. Paulus routinely overestimated the degree of arterial blockage in cardiac patients' angiograms and used that opinion to justify billing the government for unnecessary surgeries.

At the end of the trial, the jury convicted Dr. Paulus. But the district court then set aside the guilty verdict and entered a judgment of acquittal, accepting Paulus's argument that even exaggerated angiogram interpretations are opinions—not facts subject to proof or disproof—and therefore not a basis for proving falsity or fraudulent intent.

The Sixth Circuit disagreed, holding that the degree of blockage “is a fact capable of proof or disproof.” A doctor who misrepresents facts about a patient's medical condition or the physician's subjective assessment of that condition has told a lie and possibly committed fraud. While acknowledging room for good-faith disagreement in medical testing, the Sixth Circuit reaffirmed the government's ability to charge that a physician “saw one thing but willfully recorded another” and the jury's responsibility for weighing the evidence to determine whether it demonstrates a difference of opinion or a lie.

“[O]nce the government's knowledge is demonstrated, a relator must submit some proof of affirmative action to deter the practices by the government to prove materiality.”

***U.S. ex rel. Polukoff v. St. Mark's Hospital*, 895 F.3d 730 (10th Cir. July 9, 2018)**

Dr. Polukoff filed a qui tam action against his colleague Dr. Sorensen and the two hospitals where Dr. Sorensen worked, alleging that Dr. Sorensen performed thousands of medically unnecessary heart surgeries. The district court dismissed the action, holding that it is impossible for medical judgments and conclusions to be false, absent a regulation that clarifies the conditions under which the government will or will not pay.

On appeal, the Tenth Circuit reversed. It found that a medical judgment may be “false or fraudulent,” stating that a doctor's certification of a procedure as “reasonable and necessary” is false under the FCA if the procedure was not “reasonable and necessary” under the government's definition of the phrase. Here, the complaint alleged that Dr. Sorensen performed an unusually large number of the procedures in question, the procedures violated industry and hospital guidelines, other physicians had objected to his practice, and one of the hospital defendants audited 47 cases and found violations of guidelines in many of them. The court found those allegations legally sufficient to claim that Dr. Sorensen performed unnecessary procedures and knowingly submitted false certifications.

The court also found that the complaint adequately alleged express false certification claims against the two hospitals where Dr. Sorensen performed the procedures. Those claims were premised on the hospitals submitting annual cost reports certifying that all services were provided in compliance with “laws and regulations.” Based on allegations that one hospital ignored objections from its medical staff about the practices and the relator notified the other hospital of Dr. Sorensen's suspension, the court found those claims survived as well.

Relators “must satisfy *Escobar*’s two conditions to prove falsity, unless and until our court, en banc, interprets *Escobar* differently.”

2. Fraudulent Inducement

***U.S. ex rel. Marsteller v. Tilton*, 880 F.3d 1302 (11th Cir. Jan. 26, 2018)**

Former employees of MD Helicopters alleged that the company’s CEO, Lynn Tilton, promised a lucrative employment offer to Army Colonel Norbert Vergez, the procurement official responsible for purchasing helicopters. The relators alleged that this improper relationship between MD Helicopter, Tilton, and Vergez amounted to fraud and was sufficient to state a claim under the FCA. In particular, they pointed to Federal Acquisition Regulation (FAR) provision 52.203-13, which requires that contractors timely disclose, in writing, to the Inspector General and contracting officer whenever the “contractor has credible evidence that a principal, employee, agent, or subcontractor of the contractor has committed a violation of federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code or a violation of the civil False Claims Act.”

The district court, ruling pre-*Escobar*, had dismissed the relators’ complaint, ruling that compliance with FAR 52.203-13 was not expressly designated as a condition to payment. On appeal, the Eleventh Circuit reversed and instructed the district court to analyze the allegations in accordance with *Escobar*, which found that the analysis should not turn on whether the government expressly designated a requirement as a condition of payment.

The court further revived the relator’s fraud-in-the-inducement theory—the theory that a claim for payment is “grounded in fraud” even when the fraud was an action prior to the execution of the contract that influenced the government’s decision to enter the contract. Here, the court found that the relator sufficiently alleged that MD Helicopters’ promise before execution that it would comply

with ethics laws was both false when it was made and material to the government’s decision to enter the contract. It also found that the relator sufficiently alleged that MD Helicopter provided incomplete pricing data to the government that induced the government to agree to terms more favorable to MD Helicopter than it would have otherwise.

3. Implied False Certification—The *Escobar* Test

Since the Supreme Court’s opinion in *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.

***U.S. ex rel. Rose v. Stephens Institute*, 909 F.3d 1012 (9th Cir. Nov. 26, 2018)**

Former employees of an art school brought a qui tam suit against the school alleging that it violated the incentive-compensation ban included in its participation agreement with the Department of Education (DOE) under which its students received federal financial aid. Relators alleged that the school offered salary adjustments of up to \$30,000 and expensive trips for certain admissions recruiters who met student recruitment goals. After denying the school’s motion for summary judgment, the district court certified questions for interlocutory appeal.

One of the questions certified for appeal was whether the Supreme Court’s *Escobar* decision overruled the Ninth Circuit’s decision in *Ebeid ex. Rel. U.S. v. Lungwitz*. *Ebeid* states that to establish an implied false certification claim, the relator must show that “(1) the defendant explicitly undertook to comply with a law, rule or regulation that is implicated in submitting a claim for payment and that (2) claims were submitted (3) even though the defendant was not in compliance with that law, rule or regulation.” *Escobar* also addressed implied false certification liability, stating it is viable “at least where two conditions are satisfied”: The claim makes specific representations, and the failure to disclose noncompliance makes those representations “misleading half-truths.”

The Ninth Circuit panel doubted that *Escobar* required them to overrule *Ebeid*, as the Supreme Court did not state that its two conditions were the only way to establish liability under an implied false certification theory, but they were bound by prior Ninth Circuit decisions in *U.S. ex rel. Kelly v. Serco, Inc.* and *U.S. ex rel. Campie v. Gilead Sciences, Inc.* that seem to require *Escobar*’s two conditions. They therefore concluded that relators “must satisfy *Escobar*’s two conditions to prove falsity, unless and until our court, en banc, interprets *Escobar* differently.” The Ninth Circuit then denied a petition for an *en banc* rehearing.

Applying the *Escobar* standard of materiality to the facts, the court found that a reasonable trier of fact could find materiality because the school could not have been paid if it had not certified its compliance with the incentive compensation ban. In addition, the court found that the violations were material because the DOE did not regularly pay claims in full despite such violations. Instead, Government Accountability Office reports showed that the DOE took steps to identify funds provided to schools violating the incentive compensation ban and recouped more than \$59 million in payments between 1998 and 2009.

II. Specific Types of Claims

A. Anti-Kickback Statute Violations

***U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89 (3d Cir. Jan. 19, 2018)**

Accredo Health Group, Inc., a specialty pharmacy that provided services for hemophilia patients, regularly donated to two hemophilia-related charities that then listed Accredo as an “approved vendor” on their websites. In 2010, Accredo informed the charities it would reduce its donation the following year. When the charities initiated a letter-writing campaign to urge Accredo to reconsider, Steve Greenfield, then an executive at Accredo, conducted an analysis and determined that, if Accredo reduced its donation and therefore lost its “approved vendor” status with the charities, it would lose significant market share. Accredo instead increased its donation.

Subsequently, Greenfield filed a qui tam action against Accredo, alleging Accredo violated the FCA by falsely certifying compliance with the AKS because certain referrals arose out of the donation. The district court granted summary judgment to Accredo, holding Greenfield failed to provide evidence suggesting any patients purchased products from Accredo as a result of the charitable donations.

The Third Circuit affirmed but disagreed with the district court’s reasoning. In reviewing the legislative history and intent of both the FCA and AKS, the court concluded Congress intended to reduce false and fraudulent claims, including those stemming from kickback schemes. Accordingly, a relator does not have to show a “kickback directly influenced a patient’s decision to use a particular medical provider.” As such, the court held Greenfield did not have to prove the charity referrals actually caused their members to choose Accredo.

Nonetheless, according to the court, Greenfield had to show *some* link: “For a [FCA] violation, Greenfield must prove that at least one of Accredo’s claims sought reimbursement for medical care that was provided in violation of the [AKS].” Because Greenfield

had not adduced any evidence that at least one of the patients for whom Accredo submitted allegedly false claims was exposed to the kickback scheme, the court affirmed the summary judgment for Accredo.

***Carrel v. AIDS Healthcare Found.*, 898 F.3d 1267 (11th Cir. Aug. 7, 2018)**

Three former managers of the AIDS Healthcare Foundation sued the Foundation under the FCA, alleging that the Foundation offered kickbacks to its employees for giving patients referrals to the Foundation’s own healthcare services, which in turn rendered any claims for federal reimbursement false. The district court dismissed most claims for lack of particularity and later granted summary judgment on the remaining claims based on the AKS employee exception.

On appeal, the Eleventh Circuit affirmed. The AKS’s employee exception provides a safe harbor for “any amount paid by an employer to an employee (who has a bona fide employment relationship with such an employer) for employment in the furnishing of any item or service” (42 U.S.C. § 1320a-7b(b)(3)(B)). The Eleventh Circuit held that the payments that the Foundation made were in exchange for referrals and constituted standalone compensable service under the Ryan White Act. In addition, the court ultimately concluded that the Foundation award of \$100 bonuses to employees for each patient who completed follow-up procedures at the Foundation’s clinics were covered by the employee safe harbor provision.

B. Medicare Advantage

2018 saw a marked increase in the number of FCA litigations against Medicare Advantage plans. Government payment under Medicare Advantage is structured differently than in traditional Medicare Parts A and B circumstances, so the government and relators have had to test out new theories of FCA liability. With Medicare Advantage plans, the government shifts the risk of funding healthcare services onto private plans by paying a capitated (per enrollee) rate to the plan for it to use to provide whatever care its enrollees need. That capitated rate can be adjusted upward based upon the enrollee’s “risk adjustment data,” which reflects several factors, including the individual’s medical diagnoses.

The government and relators had some initial success in 2018 in defeating motions to dismiss with allegations that providing unsupported diagnosis data to the government to increase risk adjustment payments violates the FCA. But they were not successful in maintaining actions based on allegations that risk-adjustment attestations were false certifications or that free, in-home physician examinations caused inflated payments by identifying additional diagnoses.

***U.S. ex rel. Silingo v. WellPoint, Inc.*, 904 F.3d 667 (9th Cir. Sept. 11, 2018)**

A former compliance officer of a vendor company that provides in-home health assessments for Medicare beneficiaries brought a qui tam suit against her former employer and an array of Medicare Advantage plans, alleging that overstated diagnosis codes were used to improperly inflate capitation payments. The relator alleged that the vendor company used unqualified personnel and fabricated diagnoses and that the Medicare Advantage plans then submitted the risk adjustment data containing those diagnoses to the government to fraudulently increase their capitation payments.

The district court dismissed the case twice for failing to satisfy Rule 9(b) pleading standards. The first time, the district court found fault in the relator's "group pleading" against the vendor company and the multiple Medicare Advantage plans. After re-pleading to repeat her averments against the Medicare Advantage plans in separate paragraphs, the district court again dismissed because the allegations "remain undifferentiated."

On appeal, the Ninth Circuit reversed the dismissal, finding that Rule 9(b)'s pleading requirements differ depending on the type of scheme alleged. Where pleading against differently situated defendants, a complaint must identify the role of each defendant in the scheme. But where defendants allegedly each had the exact same role in the scheme, the complaint does not need to distinguish between them to satisfy Rule 9(b). The court analogized its holding to chain and wheel conspiracies, stating "if a fraudulent scheme resembles a wheel conspiracy, then any parallel actions of the 'spokes' can be addressed by collective allegations."

***U.S. ex rel. Poehling v. UnitedHealth Group Inc.*, No. CV 16-08697 (C.D. Cal. Feb. 12, 2018)**

In this intervened qui tam, the government alleged that the defendant Medicare Advantage plan knew that many of its provider-reported diagnosis codes were not supported by the enrollees' medical records and did not make a good-faith effort to identify and delete such invalid codes despite an obligation to do so. As a result of the invalid diagnosis codes, the Medicare Advantage plan received inflated risk adjustment payments.

Though the plan audited the relevant medical records, it allegedly conducted only "one way" reviews, finding and reporting to CMS any additional diagnosis codes but not withdrawing any invalid diagnosis codes identified. It allegedly failed to withdraw "over 100,000 invalid codes of which [it] had actual knowledge." The government alleged both that the submission of diagnosis codes is a claim for risk adjustment payments and that failure to delete invalid diagnosis codes allows the Medicare Advantage plan to retain an overpayment that would otherwise have been returned through

the reconciliation process. The government also alleged several claims based upon the alleged falsity of the annual Risk Adjustment Attestations the defendants signed certifying the validity of its risk adjustment data.

The court dismissed the claims that were based upon the falsity of the Risk Adjustment Attestations because the government had not pleaded that the attestations themselves were material to the payment decision. The court allowed the claim based upon the falsity of the diagnosis data to proceed, stating that the government adequately pled a reverse false claims liability for "knowingly avoid[ing] obligations to repay CMS." The court's materiality analysis was not impacted by the fact that CMS continued to make risk adjustment payments despite general knowledge of the plan's practices. It stated that "The Ninth Circuit since *Escobar* has rejected 'read[ing] too much into' a government agency's continued payment." The court reasoned that because CMS had only general knowledge and not actual knowledge, it could not know how to adjust its payments.

***U.S. ex rel. Derrick v. Roche Diagnostics Corp.*, No. 1:14-cv-04601 (N.D. Ill. June 7, 2018)**

Derrick brought an FCA suit alleging that (1) Roche Diagnostics Corporation and Humana, Inc. engaged in a business scheme in violation of the AKS and (2) Roche retaliated against him for voicing concerns about the legality of the business scheme. The scheme allegedly involved Roche forgiving more than \$30 million of debt owed by Humana in exchange for Humana re-listing Roche's products on Humana's Medicare Advantage formulary. The complaint alleged that Humana's claims to CMS for payment of Roche products that were re-listed on the formulary pursuant to the debt forgiveness deal were false or fraudulent because those Roche products were purchased in violation of the AKS.

Roche and Humana each filed a motion to dismiss the claims, both of which the court denied. The court found that the relator had sufficiently and particularly alleged that Roche and Humana knew that the debt forgiveness in exchange for re-listing on the formulary was likely an illegal kickback and that debt forgiveness is, in fact, remuneration for purposes of the AKS. First, the court found that where a relator lacks facts to identify a specific false or fraudulent CMS claim, it is sufficient that the allegations support an inference that the CMS claim was tainted by fraud. Here, it was alleged that Humana billed CMS monthly for the Roche products that were re-listed on the formulary.

Second, the court noted that willful conduct can be proven circumstantially. The court found that the relator had sufficiently pleaded the intent requirement to violate the AKS, in part, because Humana had planned to hire, but later decided against, actuarial

and legal counsel in negotiating the debt forgiveness deal, and because a Roche supervisor told the relator to discuss the issue with no one else. Finally, the court found that the allegations informed each defendant of the “nature of its alleged participation” in the fraud and that specific conduct does not have to be attributed to each defendant.

U.S. ex rel. Gray v. UnitedHealthcare Insurance Co., No. 15-7137 (N.D. Ill. June 12, 2018)

An enrollee in one of UnitedHealthcare’s Medicare Advantage plans, Gray, the relator, was offered a free in-home physician examination through UnitedHealthcare’s HouseCalls program. When he declined the offer, UnitedHealthcare upped the ante by offering a \$25 gift card. This time he agreed, underwent his examination, and collected the reward. But seeking to collect an even greater bounty, Gray then brought a claim under the FCA.

CMS pays Medicare Advantage organizations capitated rates based on their enrollees’ diagnoses. And generally speaking, more examinations lead to more diagnoses—which, in turn, leads CMS to pay UnitedHealthcare higher rates. These convenient, compensated examinations, Gray alleged, were a fraudulent scheme designed to drive up the rates CMS pays UnitedHealthcare.

The court disagreed. It recognized that CMS has repeatedly and even recently expressed its concern that in-home examinations by Medicare Advantage organizations could cultivate fraud and abuse. But at the same time, CMS has also recognized the benefits patients receive from in-home examinations. Instead of prohibiting them, CMS encouraged Medicare Advantage organizations that offer in-home examinations to develop best practices and committed itself to closely monitoring the data it collects on these in-home examinations.

In allowing UnitedHealthcare’s motion to dismiss, the court held that because CMS is fully aware of the use of in-home examinations to identify new diagnoses—and, in fact, permits them—a program like HouseCalls cannot be considered “material” to whether CMS pays a claim. Essentially, if a government agency’s publication acknowledges its awareness of an ostensibly questionable practice, yet continues to pay claims, that practice cannot be “material” under the FCA.

C. 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.”

UnitedHealthcare Insurance Company v. Azar, 330 F. Supp. 3d 173 (D.D.C. Sept. 7, 2018)

In 2014, CMS published its final rule governing the 60-day Overpayment Rule, which threatens FCA liability for any person who receives an overpayment under the Medicare Advantage program but fails to report and return the funds within 60 days after the overpayment was “identified.”



Fleshing out the meaning of “identified,” the rule provides that an insurer is deemed to have “identified” an overpayment “when it has determined, or should have determined through the exercise of reasonable diligence” that it received an overpayment. “Reasonable diligence,” CMS explained in its commentary to the rule, requires “at a minimum . . . proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments.”

UnitedHealthcare challenged the 60-Day Overpayment Rule, arguing, in part, that the rule was a regulatory overreach that tried to transform the FCA’s knowledge requirement into a negligence standard. The court agreed: “Not being Congress, CMS has no legislative authority to apply more stringent standards to impose FCA consequences through regulation.” In part because the rule improperly expanded the scope of liability under the FCA, the court vacated the rule.

D. Retaliation

***O’Hara v. NIKA Technologies, Inc.*, 979 F.3d 470 (4th Cir. Dec. 22, 2017)**

Relator William O’Hara worked for NIKA Technologies (NIKA), which contracted to provide a federal government agency certain design and cost-estimating services. The same government agency also hired another unrelated company, Northern Taiga Ventures, Inc. (NTVI) to perform other work on the same project. As the project

progressed, O’Hara came to believe NTVI had submitted to the government documents with inaccuracies and misrepresentations. He reported his concern to a manager at the government agency, but the manager disagreed with O’Hara’s assessment and no action was taken. Later, O’Hara was fired by his employer, NIKA, for failing to meet certain project deadlines.

O’Hara sued his former employer, NIKA, under the FCA and the American Recovery and Reinvestment Act (ARRA), alleging that NIKA had fired him in retaliation for reporting the fraud. The district court granted summary judgment in favor of NIKA and held that the FCA “only protects a whistleblower from negative employment action when his employer had reason to know that the whistleblower was contemplating an FCA action against *the employer*.”

On appeal, the Fourth Circuit disagreed with the district court’s reasoning that the FCA’s retaliation provision, § 3730(h), only protects whistleblowing activity “directed at the whistleblower’s employer.” To the contrary, the plain language of § 3730(h) “protects disclosures in furtherance of a viable FCA action against *any person or company*.” As such, protection under the FCA depends “on the type of conduct that the whistleblower discloses—i.e., a violation of the FCA—rather than the whistleblower’s relationship to the subject of his disclosures.”

Nonetheless, Fourth Circuit still ultimately affirmed the district court’s grant of summary judgment in favor of NIKA because O’Hara “did not disclose any conduct that could have led to a viable FCA action.” Specifically, it found that NTVI could not be “liable for defrauding the government by following the government’s explicit directions,” and O’Hara failed to establish that NIKA would not have fired him absent any whistleblowing activity.

***DiFiore v. CSL Behring LLC*, 879 F.3d 71 (3d Cir. Jan. 3, 2018)**

Plaintiff Marie DiFiore worked for CSL Behring from 2008 until she resigned in 2012. While at DSL, DiFiore became concerned about CSL’s marketing of drugs for off-label use and including such off-label use in CSL’s sales forecasts. She reported these concerns to her supervisors.

Over a period of months after her report, DiFiore was subject to several employment actions at work, including receiving warning letters, a negative performance review, and a change in her duties. Shortly after being placed on a performance improvement plan, she resigned in May 2012.

Fiore later filed a FCA lawsuit against CSL, alleging that the various adverse employment actions, including her constructive discharge, were in retaliation for her having reported her concerns about the off-label issues. While the district court granted summary judgment

for CSL on her state-law wrongful discharge claims, it denied summary judgment on the FCA retaliation claim. The case went to trial on that claim. At the trial's conclusion, the court instructed the jury that the adverse-action element of the retaliation claim required "but-for" causation. The jury ruled in favor of CSL.

On appeal, the Third Circuit affirmed. The FCA's retaliation section, § 3730(h), requires that the plaintiff was discriminated against "because of" protected conduct. Neither party disputed that DiFiore had engaged in protected conduct, but they disagreed on whether the "because of" statutory language required "but-for" causation or whether the lower "motivating factor" standard applied.

The Third Circuit reviewed two cases involving different discrimination statutes with similar "because of" statutory language. In both cases, *Gross v. FBL Fin. Servs., Inc.*, 557 U.S. 167 (2009) (age discrimination) and *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 570 U.S. 338 (2013) (Title VII), the courts applied a but-for causation standard. Relying on those and similar cases, the Third Circuit extended the same reasoning to the FCA's retaliation claim, adopted the but-for causation standard, and affirmed.

***Smith v. LHC Group, Inc.*, 727 F. App'x 100 (6th Cir. March 2, 2018)**

Relator Sue Smith brought an FCA suit against her former employer, LHC Group, Inc., alleging that LHC Group constructively discharged her after ignoring her reports that other employees were perpetuating healthcare fraud by seeking and receiving fraudulent reimbursements. The district court held that a constructive-discharge claim requires an employer to act "with the specific intention" (i.e., the subjective intent) of forcing an employee to quit his or her job. Because Smith did not allege LHC's "actions were done with the intent to have Smith quit her job," the district court dismissed Smith's complaint.

The Sixth Circuit reversed and clarified the standard for an employer's intent in a constructive discharge action "is an objective one." It held that "an employee alleging constructive discharge need not prove that his or her employer undertook actions with the subjective intention of forcing the employee to quit." Instead, the intent requirement is met "so long as the employee's resignation was a reasonably foreseeable consequence of the employer's actions."

The court noted that § 3730(h)(1) states that a court should provide "all relief necessary to make that employee... whole" if she is "discriminated against in the terms and conditions of employment." The court concluded that imposing a subjective intent requirement was inconsistent with providing "all relief necessary" as the statute requires.

***Heath v. Indianapolis Fire Dept.*, 889 F.3d 872 (7th Cir. May 9, 2018)**

Quinn Heath applied for a firefighter position with the Indianapolis Fire Department. Around the same time, Heath's father, who was already employed by the same fire department, filed a qui tam suit against the department. The father's suit alleged that the department had made certain false statements to the government to obtain a federal grant.

When Heath was not selected for the fire department's two upcoming academy classes, he joined his father's FCA lawsuit, alleging that the department retaliated against him by not hiring him because of his father's lawsuit. The district court granted summary judgment for the fire department on Heath's retaliation claim, and Heath appealed.

On appeal, the Seventh Circuit concluded that Heath could not show causation because the department's hiring procedures were governed by a local ordinance. Under that ordinance's metrics, Heath did not qualify for automatic selection and was ranked below the candidates whose selection was discretionary. Based on that finding, the Seventh Circuit found that Heath could not establish that retaliation was a motivating factor, much less was the "but-for" cause, of his not being hired. In reaching its decision, the court assumed without deciding that a job applicant was within the definition of "employee" under the FCA.

***Armstrong v. Arcanum Group*, 897 F.3d 1283 (10th Cir. July 27, 2018)**

Relator Mindy Armstrong was employed by The Arcanum Group, Inc., a placement agency that staffed federal government positions. Armstrong was placed with the Real Estate Leasing Services Department of the Bureau of Land Management (BLM). Shortly after working in this group, she complained that her colleagues were falsifying lease-related records. In response, the BLM requested that her employer, Arcanum, remove her from the placement. Arcanum agreed to do so and removed Armstrong from BLM. When Arcanum could not find a suitable replacement position for Armstrong, it terminated her employment.

Armstrong sued Arcanum under the anti-retaliation provisions of the FCA and the National Defense Authorization Act, claiming Arcanum retaliated against her for her complaints at BLM.

The district court granted Arcanum summary judgment, and Armstrong appealed.

On appeal, the Tenth Circuit affirmed, finding that Armstrong did not produce sufficient evidence that her supervisor had knowledge of her complaints before he terminated her. Specifically, the court

noted that there was no evidence that her employer knew about Armstrong's complaints of fraud, finding that the absence of employer knowledge was fatal to a retaliation case. The Tenth Circuit also rejected Armstrong's efforts to build a circumstantial case of employer knowledge, finding no evidence to support her claim that she was retaliated against because of her reporting.

***Potts v. Ctr. for Excellence in Higher Educ., Inc.*, 908 F.3d 610 (10th Cir. Nov. 6, 2018)**

Debbi Potts resigned from CollegeAmerica Denver, Inc. because, according to her, CollegeAmerica engaged in unethical business practices by actively deceiving its accreditor to maintain accreditation. After her resignation, Potts and CollegeAmerica entered a contract whereby Potts agreed not to contact a government or regulatory agency to file a complaint against CollegeAmerica. Nonetheless, Potts later filed a complaint with the Accrediting Commission of Career Schools and Colleges regarding CollegeAmerica's alleged accreditation deception.

CollegeAmerica later sued Potts for breaching the contract, and Potts countersued alleging that CollegeAmerica's claim against her for filing a complaint with the ACCSC violated the FCA's anti-retaliation provision. The district court dismissed Potts's claim, finding that the FCA did not protect acts occurring exclusively after employment had ended.

On appeal, the Tenth Circuit affirmed. The court applied traditional canons of statutory interpretation to find that the FCA's anti-retaliation provisions unambiguously protect only against retaliatory action taken during an employee's employment. Because CollegeAmerica's alleged retaliatory action occurred *after* Potts had resigned, it did not violate the FCA.

III. Bars and Limitations on Actions

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

***U.S. ex rel. Solis v. Millennium Pharmaceuticals, Inc.*, 885 F.3d 623 (9th Cir. Mar. 15, 2018)**

Solis worked as a sales representative for Millennium Pharmaceuticals promoting the sales of a cardiovascular drug. In 2009, she filed a FCA lawsuit alleging various kickbacks and dangerous off-label uses of the drug. The government declined to intervene, and the district court dismissed based on the public-disclosure bar because the information underlying the lawsuit arose from claims filed in earlier federal and state cases. Solis appealed.

On appeal, the Ninth Circuit found that the earlier claims involved the same actors, the same conduct, and the same risk and, consequently, were close enough in kind and degree to have put the government on notice to investigate the alleged fraud before Solis' suit was filed. Despite the prior public disclosures, however, the court vacated the dismissal and remanded for the district court to determine whether or not Solis qualified as an original source based on recent Ninth Circuit case law that modified the original source test and undercut the basis for the district court's decision.

In addition, the court found that claims involving an antibiotic drug were erroneously dismissed by the district court based on the public-disclosure bar. The court affirmed the dismissal of those claims based on failure to satisfy Rule 9(b) and remanded for the district court to decide whether to grant Solis leave to amend the claims.

***U.S. ex rel. Silver v. Omnicare Inc.*, 903 F.3d 78 (3d Cir. Sept. 4, 2018)**

In his FCA lawsuit, relator Marc Silver alleged that PharMerica, a pharmaceutical company that specialized in pharmacy services to long-term care facilities, offered nursing homes unreasonably low, below-market prices for prescription drugs for Medicare Part A patients. The company allegedly made up for the losses by providing the same drugs to Medicare Part D patients, for which it could bill the government at full price.

The district court dismissed the claim based on the public-disclosure bar, finding that Silver had relied on public knowledge to draft his complaint. On appeal, the Third Circuit reversed.

The Third Circuit found that Silver had added additional non-public information that could be used to sufficiently allege a hidden fraud. Specifically, the Third Circuit focused on Silver's references to per diem pricing information—information that was not public in PharMerica's public financial disclosures. The court stated that "Silver's more concrete claim, which set out specific facts suggesting that PharMerica in particular was actually engaged in swapping, relied upon these general disclosures but could not have been derived from them absent Silver's addition of the non-

public per-diem information.” Further, the court broadly restated the principle “that the FCA’s public disclosure bar is not implicated in such a circumstance, where a relator’s non-public information permits an inference of fraud that could not have been supported by the public disclosures alone.”

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. Wood v. Allergan, Inc.*, 899 F.3d 163 (2d Cir. Aug. 9, 2018)**

In August, the Second Circuit found that a violation of the first-to-file bar cannot later be remedied by an amended complaint. When Wood, a former Allergan employee, filed his original complaint in 2010 two similar actions were already pending. Both earlier cases were dismissed for improper service while Wood’s case was still under seal. The district court ruled that the first-to-file rule did not bar Wood’s suit because there were no related cases pending at the time Wood’s third amended complaint was filed. Wood argued on appeal that his complaint, which accused Allergan of providing kickbacks to physicians who prescribed its eye care medications, was both broader and deeper than the two preceding cases. The court disagreed and remanded the case to be dismissed without prejudice, finding that Wood alleged kickback schemes similar to those in the preceding cases and that the first-to-file bar applied to Wood’s detriment.

Notably, the government did not intervene and supported Wood at the district court level but changed its position on appeal and argued that the first-to-file rule dictated dismissal of Wood’s complaint. There is a circuit split on this issue. The Second Circuit focused on the plain language of the FCA and followed the lead of the D.C. Circuit in holding that Wood’s complaint was incurably flawed from the moment it was filed, and that allowing a first-to-file violation to be cured by a later amended complaint is inconsistent with the statutory language. The First Circuit has previously held to the contrary.

C. Statute of Limitations

Under the FCA, an action must be brought within the later of (a) six years after the date the violation is committed, § 3731(b)(1), or (b) three years after the date when facts are known or reasonably should have been known to the United States, § 3731(b)(2).

The Second Circuit held that a violation of the first-to-file bar cannot later be remedied by an amended complaint.

***U.S. ex rel. Hunt v. Cochise Consultancy, Inc.*, 887 F.3d 1081 (11th Cir. Apr. 11, 2018), cert. granted, No. 18-315 (S. Ct. Nov. 16, 2018)**

In *Cochise*, relator Billy Joe Hunt filed a qui tam action more than six years after an alleged fraud occurred, but within three years of when he disclosed the fraud to the government. After the United States declined to intervene in the action, The Parsons Corporation and Cochise Consultancy, Inc. moved to dismiss. The district court concluded that the limitations period in § 3731(b)(2) was inapplicable because the government had declined to intervene or, alternatively, had expired because it began to run when Hunt—not the U.S.—learned of the fraud. Accordingly, the district court dismissed the claim as time barred.

On appeal, the Eleventh Circuit held that § 3731(b)(2)’s three-year discovery rule in the statute of limitations applies even in cases where the United States declines to intervene. This decision is at odds with both the Fourth and Tenth Circuits. Furthermore, the court held that the three-year limitations period in non-intervened cases is triggered by the knowledge of a United States official, not by the relator’s knowledge. This aspect of the opinion is at odds with the Ninth Circuit.

In non-intervened cases, this decision could make FCA claims in the Eleventh Circuit difficult to dispose of on a six-year statute of limitations theory (§ 3731(b)(1)) at the motion to dismiss stage. The 10-year statute of limitations theory (§ 3731(b)(2)) would still work at the motion to dismiss stage, but discovery may be required to prove that a shorter statute of limitations applies. The multiple circuit splits created by this Eleventh Circuit decision caught the attention of the United States Supreme Court and certiorari was granted in November 2018.



D. Government-Action Bar

The government-action bar is less commonly litigated than other limitations on FCA actions. It arises from 31 U.S.C. § 3720(e)(3), which prohibits a person from bringing an action based on allegations or transactions that are the subject of a civil suit or an administrative proceeding in which the government is already a party.

Schagrin v. LDR Industries LLC, No. 14 C 9125 (N.D. Ill. May 23, 2018)

Relator Roger Schagrin was an attorney who was experienced with the steel-pipe industry and international trade. While visiting a Home Depot, Schagrin noticed that LDR pipe was priced unusually low and was imported from China. Suspecting that LDR had unlawfully misclassified some of its imported pipe to avoid certain customs duties, he reported his suspicion to the U.S. Customs and Border Protection Agency. U.S. Customs later determined that LDR had, in fact, misclassified its imported pipe to avoid paying duties and demanded \$6.7 million (later reduced to \$4.85 million) to satisfy those duties.

Largely owing to these penalties, LDR declared bankruptcy in 2014. U.S. Customs filed a proof of claim in the bankruptcy proceedings for the unpaid duties, noting that the findings supporting the claim were the result of penalties imposed by U.S. Customs for incorrectly classifying the imported steel pipe. Schagrin did not file a proof of claim, but shortly after he and his law firm filed a FCA action against LDR based on the same conduct.

In district court, LDR moved to dismiss the complaint, arguing that relator's claims were subject to the FCA's government-action bar, which prevents FCA claims based upon allegations that are the subject of an "administrative civil money penalty proceeding" in which the government is already a party. Among other support, LDR pointed to U.S. Customs' proof of claim that referred to "penalties" assessed.

The district court agreed. In dismissing Schagrin's claims, the court joined several other district courts that found that whether the government has imposed a "penalty" is important to determining whether the government-action bar applies to prevent a subsequent FCA claim. The court reasoned that U.S. Customs' characterization of its proof of claim as a "penalty" was sufficient to find that an "administrative civil money proceeding" had been brought by the government. In addition, the court rejected Schagrin's argument that the government-action bar should not apply to his FCA claims because he was the "original source" of the information that led to the U.S. Customs' action against LDR. The court noted that while the "original source" requirement applied to the public-disclosure bar, the government-action bar requires the government not to bring the claim in a different forum. Given the government had done so in this case, the court found this argument without merit as well.

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. Chase v. HPC Healthcare, Inc., No. 16-16670 (11th Cir. Jan. 24, 2018)

Relator Nancy Chase, a former social worker for LifePath Hospice Inc., accused the company, its parent organization, and other subsidiaries of fraudulently billing Medicare and Medicaid by admitting and recertifying patients who were not eligible for hospice care. After filing a fourth amended complaint, the district court dismissed Chase's lawsuit because the complaint failed to meet the heightened pleading requirements for claims alleging fraud under Rule 9(b).

On appeal, the Eleventh Circuit affirmed the district court's ruling. The court found that although the complaint detailed a scheme,

the “complaint does not include specific examples of the conduct [] describe[d] or allege the submission of any specific fraudulent claim.” More directly, the court noted that Chase failed to identify who made a referral in exchange for a benefit, a single patient that was improperly referred, who provided the bribes, or when those exchanges took place.

The court similarly rejected Chase’s claims for conspiracy and retaliation. The court also held that the district court appropriately denied Chase’s request for leave to amend her complaint again because she had repeated chances to cure the deficiencies but failed to do so.

***Phone Recovery Servs., LLC v. Verizon Washington, D.C., Inc., et al.*, No. 15-CV-1338 (D.C. Cir. Aug. 16, 2018)**

Phone Recovery Services LLC (PRS) brought a qui tam suit on behalf of the District of Columbia against certain telephone companies that provided services in Washington, D.C., including 25 named companies and 15 other unnamed defendants. PRS alleged that the telephone companies failed to pay more than \$29 million in taxes that support and maintain the city’s 911 emergency call system. The trial court dismissed the suit based on the public-disclosure bar, as well as PRS’s failure to satisfy the pleading requirements.

On appeal, the D.C. Circuit found that the suit was not barred by the public-disclosure bar because PRS’s allegations of fraudulent underpayment in taxes were not substantially the same as the allegations of underpayment that had been previously disclosed in the media. The court affirmed, however, the trial court’s conclusion that PRS failed to satisfy the pleading requirements of Super. Ct. Civ. R. 9(b) because the complaint treated all the defendants uniformly and failed to identify with specificity any allegations against a particular defendant.

***U.S. ex rel. Berkowitz v. Automation Aids, Inc.*, No. 17-2562 (7th Cir. July 25, 2018)**

In *Berkowitz*, the relator, a competitor of one of the defendants, claimed that the defendants sold products on the GSA Advantage website that were not compliant with the Trade Agreements Act (TAA). The relator further alleged that the defendants impliedly certified TAA compliance upon submitting invoices to the government. Because the relator was not an insider and did not have inside information, he developed his allegations “by comparing the sales other vendors made on the GSA Advantage online portal with certain product lists he obtained through the normal course of his business that identify the country of origin for various products.” Through his analysis, he concluded that the defendants must have sold non-TAA-compliant end products to the government.

The trend of increased DOJ motions to dismiss has exacerbated a circuit split on the proper standard for a court to apply to these motions.

The Seventh Circuit rejected Berkowitz’s allegations, primarily on Rule 9(b) grounds. In beginning its analysis, the court noted that under Rule 9(b), the relator “must describe the who, what, when, where, and how of the fraud.” Specific to the implied certification context, the Seventh Circuit asserted, with emphasis, “FCA cases based on an implied false certification theory should be effectively addressed through *strict enforcement* of the Act’s materiality and scienter requirements.”

In so holding, the Seventh Circuit affirmed a high bar for particularity and specificity in the implied certification context. This ruling was consistent with the lower court’s finding that “satisfying Rule 9(b) often will be tougher to do in implied certification cases than in cases with an outright affirmative misrepresentation . . . [because] usually it will be easier to set forth the specific details of a fraud scheme that is premised on affirmative lies than it is to sufficiently allege the specifics of a scheme based on material *omissions*.”

B. Government Motions to Dismiss under Section 3730(c)(2)(a)

In the wake of the Granston Memo (see Part IV.A below), DOJ has increased its use of motions to dismiss qui tam complaints under 31 U.S.C. § 3730(c)(2)(a). In November, the DOJ moved to dismiss *U.S. ex rel. Vanderlan v. Jackson HMA, Inc.* (S.D. Miss.) on grounds that the claims “lack merit” and the suit is “hindering administrative settlement negotiations” between OIG and the defendants. In December, the DOJ moved to dismiss 10 kickback-related qui tam complaints filed against various pharmaceutical companies, stating that the relator has no inside knowledge, investigation has not found support for its allegations, and the allegations “conflict with important policy and enforcement prerogatives of the federal government’s healthcare programs” in that the claims would “undermine common industry practices the federal government

has determined are . . . appropriate and beneficial . . .” Also in December, the Solicitor General told the Supreme Court that if the *Gilead Sciences, Inc. v. U.S. ex rel. Campie* case were remanded back to the district court, the government would move to dismiss it both because it would “impinge on agency decisionmaking and discretion” and to avoid burdensome discovery and interference with government operations.

The trend of increased motions to dismiss has exacerbated a circuit split on the standard to be applied to such a motion. The Ninth and Tenth Circuits require the government to state a reason for dismissal that is rationally related to a legitimate government interest, whereas the D.C. Circuit allows the government “an unfettered right to dismiss” a qui tam action. This split was highlighted in 2018 by two district court opinions issued on the same day that reached very different conclusions.

Note: Bradley represents defendants Jackson HMA in U.S. ex rel. Vanderlan v. Jackson HMA, Inc. and Inventiv Health, Inc. in U.S. ex rel. SMSF, LLC v. Biogen, Inc.

U.S. ex rel. Maldonado v. Ball Homes, LLC, No. 5:17-CV-379-DCR (E.D. Ky. June 29, 2018)

In *Maldonado*, the relator alleged that his homebuilder and mortgage lender lied to HUD about whether the property and other new construction builds in Kentucky satisfied FHA mortgage insurance requirements. Faced with a motion to dismiss by the government, the court found that “the plain language of the statute says nothing about the government being required to make any sort of showing in support of its motion to dismiss.”

Repeating the D.C. Circuit’s logic in *Swift*, the court further held that the sole purpose of allowing relators a hearing under the statute is to “give[] the relator a formal opportunity to convince the government not to end the case.” The statutory language entitling a relator to a hearing does not include any “requirement that [relator] be permitted to introduce evidence.” Continuing, the court held that, even if the Sixth Circuit were to adopt the less deferential position taken by the Ninth Circuit, this case would still be subject to dismissal because “the government has a valid interest in reining in weak qui tam actions.”

In sum, the court concluded “that the government has virtually unfettered discretion to dismiss a FCA case, save exceptional circumstances.”

United States v. Acad. Mortg. Corp., No. 16-CV-02120-EMC (N.D. Cal. June 29, 2018)

In contrast to the Eastern District of Kentucky in *Maldonado*, the Northern District of California denied the government’s own motion

to dismiss an FCA lawsuit. Here, the relator alleged that Academy Mortgages defrauded the government by falsely certifying loans for government insurance. The government declined to intervene in the initial complaint. The relator amended its complaint to expand the allegations to nationwide misconduct over a six-year period. Subsequently, the government moved to dismiss under 31 U.S.C. § 3730(c)(2)(A), arguing that the suit would drain its resources. In turn, the relator requested an evidentiary hearing.

The court denied the government’s motion to dismiss, holding that the government did not perform a full investigation of the amended complaint. The court specified a two-part test.

First, the government must identify a valid government purpose and demonstrate a rational relationship between dismissal and that purpose; and, second, the burden shifts to the relator to demonstrate that dismissal is fraudulent, arbitrary and capricious, or illegal. Here, the government offered no evidence that it conducted any further investigation after the complaint was amended.

The court found that the government failed to conduct a full investigation, thus failing both prongs of the test. As a result, the court denied the government’s motion to dismiss and denied the relator’s request for an evidentiary hearing as moot.

C. Government Intervention

U.S. ex rel. Vaughn v. United Biologics LLC, No. 17-20389 (5th Cir. Sept. 7, 2018)

In *Vaughn* the government declined to intervene in the case following five extensions to the intervention deadline. “Tired of litigation without the government’s assistance,” relators consequently moved to dismiss the case with prejudice as to themselves, but without prejudice to the government. Significantly, a separate, but similar qui tam was also pending in the Northern District of Georgia, and, as stated by the court, relators did not want the “decision to quit [to] hamstring the government’s efforts against the defendant elsewhere.”

In affirming the dismissal with prejudice as to relators and without prejudice as to the government, the court discussed the fundamental relationship between the relator and the government in qui tam actions. The court noted that the non-intervening government “remains a distinct entity in the qui tam litigation with protected interests” as evidenced by the government’s ability to request discovery stays and copies of all pleadings and deposition transcripts.

The court also pointed out that relators act based on private interests, and the government, even when it does not intervene, should not be bound by a decision to abandon a case, because it will be left unable to pursue the public’s interests in other actions.

U.S. ex rel. Drennen v. Fresenius Medical Care Holdings, No. 09-10179-GAO (D. Mass. Mar. 30, 2018)

In *Drennen*, the court refused to let the government bring additional FCA claims after intervening following the unsealing of the complaint. After the relator brought FCA claims against Fresenius, the government was granted three extensions by the court so it could determine whether to intervene in the case. The court denied the government's motion for a fourth extension and unsealed the case.

Nearly five years later, the government moved to "partially" intervene only with regard to relator's claims that Fresenius filed false claims with Medicare for medically unnecessary tests. The court granted the government's motion but refused to let the government conduct additional fact discovery. The government later filed a complaint in intervention that added new claims to the relator's complaint. Fresenius moved to strike or dismiss the new claims brought by the government, arguing that the government could not expand the scope of the litigation.

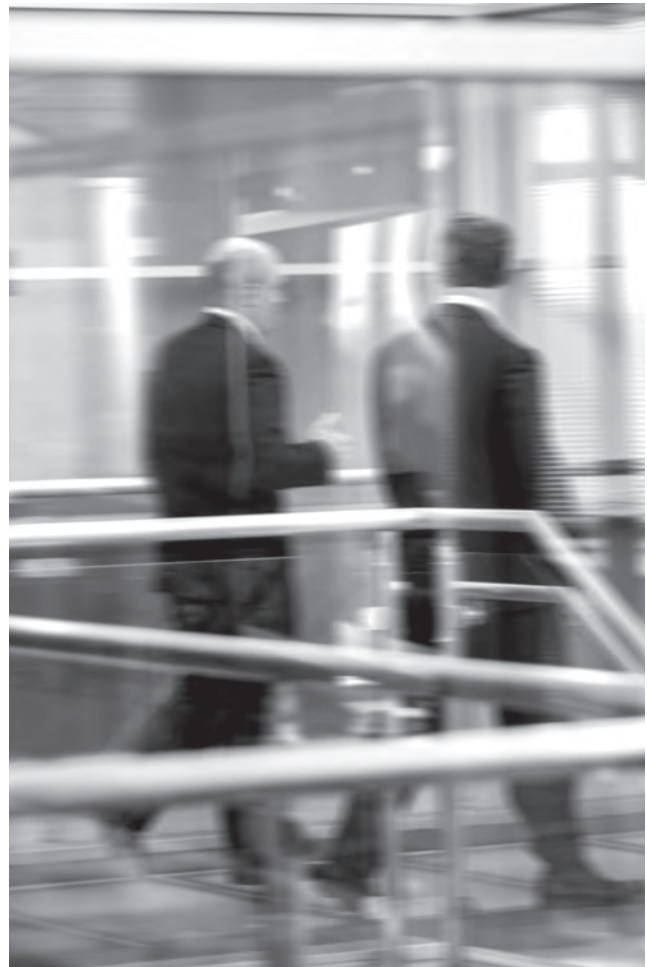
The court noted that the FCA allows the government to intervene under two circumstances: (1) as a matter of right while the complaint remains under seal, and (2) by permission of the court after a showing of good cause if the government originally elected not to intervene. When the government intervenes as a matter of right, it is granted an "editor's privilege" that allows it to change the complaint and add claims if it so chooses. But the court held that, in the second circumstance, when a court permits the government to intervene following a showing of good cause, the presumption is that the government "takes the case as it stands" unless the court allows otherwise. Given that the court refused to allow the government to conduct additional fact discovery, the court reasoned that the permission to intervene was limited to the claims in the unsealed complaint.

Lastly, the court did allow the government to assert FCA violations beyond 2006, the date of the latest allegation in the relator's complaint. Fresenius argued that the relator's allegations in the complaint beyond 2006 were insufficient to meet the heightened standard required under Rule 9(b). The court rejected this argument, reasoning that any allegations of illegal conduct after 2006 present an evidentiary issue to be resolved at trial. As such, the court held that the government could expand its FCA allegations consistent with the discovery already conducted.

D. Relator Alternate-Remedy Intervention

United States v. Couch, 906 F.3d 1223 (11th Cir. Oct. 17, 2018)

Lori Carver, a former employee of a physicians clinic, filed an



FCA lawsuit against the clinic alleging that two of the managing physicians submitted fraudulent claims for medically unnecessary services to the government. The government declined to intervene but continued to investigate the two physicians. Eventually, the government brought criminal charges that partially overlapped with Carver's qui tam action and included forfeiture counts. The criminal case proceeded to trial, and the physicians were convicted. When the government started criminal forfeiture proceedings, Carver moved to intervene under the alternate-remedy provision of the FCA, among other bases. The district court denied Carver's motion to intervene, and Carver appealed.

The Eleventh Circuit first addressed standing. Disagreeing with the Ninth Circuit in *U.S. v. Van Dyck*, 866 F.3d 1130, 1133–34 (9th Cir. 2017), the court concluded that Carver, as a qui tam plaintiff, had standing to assert that the alternate-remedy provision of the FCA gave her a right to intervene in criminal forfeiture proceedings. But the court found that the alternate-remedy provision did not expressly provide a right of intervention in an "alternate proceeding," and here the applicable criminal forfeiture statutes expressly barred third-party intervention. Accordingly, the Eleventh Circuit found the district court properly denied the motion to intervene.

V. DOJ Memos and Policy Announcements

The DOJ's internal policies often begin in the form of memoranda authored by high-ranking DOJ officials and are typically incorporated into the Justice Manual (formerly known as the U.S. Attorney's Manual), the principal internal policy guide for DOJ. In 2018, several such memos issued either directly or indirectly implicated FCA matters.

A. Dismissal of Qui Tam Suits

On January 24, 2018, an internal DOJ memorandum was leaked to the public regarding the factors DOJ will consider in determining whether to seek dismissal of non-intervened qui tam suits. The FCA authorizes the Attorney General to dismiss qui tam actions over a whistleblower's objection, but historically DOJ has rarely done so. This memo—generally referred to as the Granston memo for its author, DOJ Commercial Litigation Branch Director Michael Granston—represented DOJ's first formal articulation of guidance to prosecutors on when such dismissals might be appropriate. The factors include the desire to (1) curb meritless qui tam suits, (2) prevent parasitic or opportunistic qui tam actions that duplicate pre-existing government investigations, (3) prevent interference with agency policies and programs, (4) control litigation brought on behalf of the United States, (5) safeguard classified information and national security interests, (6) preserve government resources, and (7) address egregious procedural errors, such as when relators fail to properly serve the government or when relators breach the FCA's seal requirement.

More information on the Granston memo can be found at [AHLA PG Bulletin, "DOJ Memoranda Signal Tempered Approach to FCA Cases But Are These New Constraints Changing the Tone."](#)

B. Limiting Use of Agency Guidance in Affirmative Civil Enforcement Cases

On January 25, one day after the Granston memo, another significant FCA-related announcement was made. This memo, taking its name from author Rachel Brand, the then-Associate Attorney General, stated that DOJ would no longer use "guidance documents" in civil enforcement cases such as FCA lawsuits. The move was consistent with then-Attorney General Jeff Sessions' and the broader Trump administration's critique of "regulation by guidance." While the Brand memo carved out several exceptions for the appropriate use of informal guidance documents, it nonetheless ushered in a significant change by removing their binding effect. The change has particular resonance in healthcare where, for example, the National and Local Coverage Determinations by Medicare contractors (basically the policy guidance from the private entities that contract with the federal government to collect Medicare payments) were often given the force of law in FCA negotiations.

Further information on the Brand memo is in this alert, ["New DOJ Guidance Portends New Defenses in False Claims Act Cases."](#)

In December 2018, DOJ incorporated guidance on the Brand memo into the Justice Manual. That guidance is set forth in the Justice Manual at Title 1-20.00, titled "Limitation on Use of Guidance Documents in Litigation." The guidance reiterates that "[c]riminal and civil enforcement actions brought by the Department of Justice must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents issued by federal agencies, because guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation." However, the Justice Manual goes on to describe circumstances where DOJ may use reference to agency guidance during litigation, including using a party's compliance or noncompliance with agency guidance as (1) evidence of the party's intent, notice, or knowledge; (2) evidence of whether the party has satisfied, or failed to satisfy, professional or industry standards; and (3) evidence directly relevant to the particular claims at issue in the lawsuit.

C. Avoiding "Piling On"

On May 9, Deputy Attorney General Rod Rosenstein announced a new DOJ policy aimed at encouraging coordination among DOJ and other enforcement agencies and "avoiding unfair duplicative penalties" or "piling on." The policy had four main features:

1. The "federal government's criminal enforcement authority should not be used against a company for purposes unrelated to the investigation and prosecution of potential crime." For example, criminal investigation cannot be used to persuade a company to pay a bigger settlement in a civil case.
2. When resolving a corporate case based on the same conduct, DOJ lawyers from different components should coordinate financial fines, forfeitures, and other penalties to avoid disproportionate punishment.
3. DOJ lawyers should similarly coordinate, where applicable and possible, with other "federal, state, local, or foreign enforcement authorities seeking to resolve a case with a company for the same misconduct."
4. The policy sets forth certain factors that DOJ lawyers may evaluate in determining whether "multiple penalties serve the interest of justice in a particular case." Such factors include "the egregiousness of the wrongdoing; statutory mandates regarding penalties; the risk of delay in finalizing a resolution; and the timeliness of a companies' disclosures and cooperation with the Department."

Additional discussion of Rosenstein’s speech and the new policy can be found in this alert, [“DOJ Announces New Policy about ‘Piling On’ and Discusses the Role of Compliance in Corporate Enforcement.”](#)

D. Corporate Monitorships

On October 11, 2018, DOJ’s Criminal Division Chief Brian Benczkowski announced new guidance relating to corporate monitorships. The Benczkowski memo applies only to DOJ Criminal Division matters (not civil cases or to U.S. Attorneys’ offices), but may indirectly impact FCA cases that involve parallel criminal-civil investigations. The memo retains much of the past guidance on the selection of monitors and elaborates on two existing broad considerations: “(1) the potential benefits that employing a monitor may have for the corporation and the public, and (2) the cost of a monitor and its impact on the operations of a corporation.”

While lacking significant substantive changes in the policy, the memo focuses on the situations in which a monitor would not benefit a company and does not discuss possible affirmative benefits of monitorships. Without stating so directly, the memorandum implies that the cost of monitorships far outweighs the benefit and that monitorships should not be routine.

E. DOJ Compliance Expert

In the same speech announcing the corporate monitorship memo, Benczkowski announced that DOJ was not replacing the in-house DOJ compliance expert who left in 2017. Benczkowski noted that rather than retaining one individual to oversee corporate compliance generally, DOJ planned to hire prosecutors who are, or can be trained to be, compliance experts in specific industries.

F. Yates Revisited

Most readers are acquainted with the original [Yates memorandum](#), the September 2015 memorandum in which then-Deputy Attorney General Sally Yates updated and revised DOJ’s approach toward cooperation credit and individual accountability in corporate investigations.

On November 29, 2018, Rod Rosenstein, the current Deputy Attorney General, announced long-awaited changes to the Yates memo. While the Yates memo remains, it is scaled back in several significant ways.

1. *Disclosure required for cooperation.* A key policy change incorporated in the Yates memo was that cooperation credit (in civil or criminal matters) could be offered only to corporations that provided “all relevant facts” regarding all individuals involved in wrongdoing. While reemphasizing that pursuing individual wrongdoers remained a top DOJ priority, Rosenstein acknowledged the previous policy was inefficient and



unwieldy in the “real world of limited investigative resources.” The revised policy returns the decision of cooperation credit to the discretion of DOJ lawyers. Companies can qualify for credit by identifying individuals who were “substantially involved” in alleged misconduct, and DOJ investigations should not be delayed merely to collect information on less involved individuals.

2. *Civil cases are different.* The more dramatic revisions to the Yates memo involved the treatment of civil cases. Contrary to the Yates memo policy, companies are no longer expected to admit the civil liability of every individual employee to obtain cooperation credit, an approach that Rosenstein characterized as “attractive in theory” but “inefficient and pointless in practice.” The revised policy rejects the all-or-nothing approach in favor of a flexible approach in which DOJ lawyers can give credit based on a spectrum of cooperation.
3. *Releases and ability to pay.* Under the Yates memo, liability releases for individuals were prohibited absent extraordinary circumstances. The revised policy softens that approach to give DOJ lawyers the ability to “negotiate civil releases for individuals who do not warrant additional investigation in corporate civil settlement agreements.” Separately, the revised policy also modifies the calculus regarding whether to pursue an individual civilly. While the Yates memo suggested that an individual’s ability to pay should not factor into that decision, the new policy allows DOJ lawyers to consider financial ability to pay in determining whether to pursue a civil judgment.

WHAT TO WATCH IN 2019

Supreme Court Hears Case on FCA Statute of Limitations – *Cochise Consultancy, Inc. v. U.S. ex rel. Hunt* (No. 18-315)

As noted above, the Supreme Court agreed to hear *Cochise* in which the Sixth Circuit found that a relator in a non-intervened case could still rely on § 3731(b)(2)'s statute of limitation, which requires claims to be brought within three years of when an official of the United States knew or should have known of the underlying facts. That decision was contrary to decisions in the Fourth and Tenth Circuits that found that § 3731(b)(2) did not apply in cases where the government declined to intervene. It also conflicted with a Ninth Circuit decision that held that, in non-intervened cases, the relator was the “official of the United States” for purposes of § 3731(b)(2).

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 experts’ 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 2019.

Bradley represents AseraCare in this matter.

Continued Development of Case Law on Sampling and Extrapolation

The DOJ’s use of sampling and extrapolation to prove liability in medical necessity cases remains a hot topic. The government continues to present extrapolations as leverage in settlement negotiations and attempts to use them in unsealed litigation as proof of falsity to varying degrees of success. Compare *U.S. ex rel. Martin v. Life Care Ctrs. of Am.*, 114 F. Supp. 3d 549 (E.D. Tenn. 2014) (allowing the use of sampling and extrapolation) with *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, No. 3:07-CV-00604-M, 2016 WL 3449833, at *11 (N.D. Tex. June 20, 2016) (sampling and extrapolation “cannot establish liability for fraud in submitting [hospice benefit] claims for ineligible patients”). It remains to be seen what court may be next to address the issue in 2019.

Fate of the Affordable Care Act

In *Texas v. Azar*, No. 4:18-cv-00167 (N.D. Tex. Dec. 14, 2018), the court found the entire Affordable Care Act unconstitutional in a ruling which has been widely criticized and is expected to be appealed. While having other far broader political and legal implications, the ruling also would significantly affect the FCA. If this ruling were to stand, it would reverse the ACA’s amendments relevant to the FCA, including that claims submitted while in violation of the AKS are false for FCA purposes, that overpayments not returned within 60 days are “obligations” for purposes of reverse false claims liability, and the ACA’s revisions to the public-disclosure bar.



Bradley's Government Enforcement and Investigations Practice Group



Birmingham



Brad Robertson
Partner, Birmingham
brobertson@bradley.com
205.521.8188



Jack W. Selden
Partner, Birmingham
jselden@bradley.com
205.521.8472

Tampa



A. Lee Bentley III
Partner, Tampa
lbentley@bradley.com
813.559.5524



Jason P. Mehta
Partner, Tampa
jmehta@bradley.com
813.559.5532

Charlotte



Lyndsay E. Medlin
Associate, Charlotte
lmedlin@bradley.com
704.338.6131

Washington, D.C.

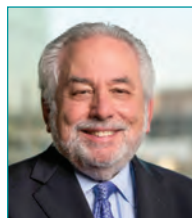


Gregory G. Marshall
Partner, Washington, D.C.
gmarshall@bradley.com
202.719.8207

Nashville



Ty E. Howard
Partner, Nashville
thoward@bradley.com
615.252.2376



Stephen R. Spivack
Partner, Washington, D.C.
sspivack@bradley.com
202.719.8234



Scarlett Singleton Nokes
Counsel, Nashville
snokes@bradley.com
615.252.3556



Erin K. Sullivan
Partner, Washington, D.C.
esullivan@bradley.com
202.719.8208



Tara S. Sarosiek
Associate, Nashville
tsarosiek@bradley.com
615.252.3522



Anna M. Lashley
Associate, Washington, D.C.
alashley@bradley.com
202.719.8273

Bradley

Bradley Arant Boult Cummings LLP