2018 YEAR IN REVIEW – THE FALSE CLAIMS ACT

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Clients and Friends,

The False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (FCA), continued to be a significant focus of government and whistleblower activity in 2018. This Year in Review highlights several key developments, including:

- The recovery by the government of more than $2.8 billion in settlements and judgments in FCA cases in 2018.
- The aftermath of the Supreme Court's landmark decision in *Escobar* and the varying interpretations of "materiality" under the FCA.
- Significant judicial decisions regarding the first-to-file rule, the public disclosure bar, and pleading requirements for FCA cases, among other issues.

In 2018, Haynes and Boone represented healthcare providers, defense contractors, and individuals in FCA investigations and lawsuits. We successfully resolved matters before lawsuits were filed, negotiated favorable settlements, and continued to defend our clients in active litigation. We also advised a number of contractors and healthcare providers regarding FCA compliance and other related issues.

If you have any questions about the issues covered in this year's *Review*, please let us know. We look forward to working with our friends and clients in 2019.

Stacy Brainin, Bill Morrison, Chris Rogers, Nicole Somerville

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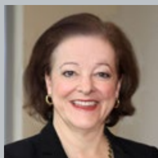

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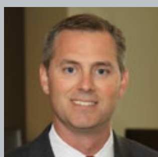

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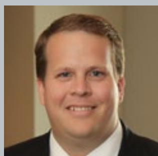

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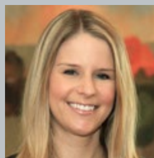

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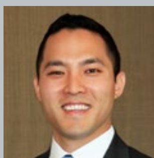

PHIL KIM has extensive experience in healthcare law and focuses his practice on transactional and regulatory healthcare matters for healthcare clients. He represents various types of providers, ranging from healthcare systems, hospitals, ambulatory surgery centers, physician groups (including non-profit health organizations, or NPHOs), home health providers, and other healthcare professionals in mergers and acquisitions, joint ventures, and operational matters. Phil regularly assists clients on various types of healthcare arrangements and provider agreements, and he advises clients on healthcare compliance issues involving liability exposure, the Stark law, anti-kickback statutes, and HIPAA/HITECH privacy issues.

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A. 2018: A LOOK BACK AT THE NUMBERS

On December 21, 2018, the DOJ reported that the United States recovered more than $2.8 billion in settlements and judgments from FCA cases during fiscal year 2018.[1] Although this amount was significantly less than last year's recovery, it continued DOJ's nine-year record of obtaining recoveries in excess of $2 billion. Total recoveries since 1986, the year Congress significantly strengthened the FCA, are now just shy of $60 billion.

DOJ further reported:

- Of the $2.8 billion recovered, $2.5 billion came from the healthcare industry.
- Whistleblowers filed 645 new *qui tam* actions in 2018.
- Of the $2.8 billion recovered, $2.1 billion related to cases filed by private whistleblowers, with whistleblowers receiving over $300 million for their share of the recovery.

Among the cases resolved in 2018, there were several notable settlements and judgments, including:

- A $625 million settlement with AmerisourceBergen Corporation and several subsidiaries to resolve allegations that they improperly repackaged oncology-supportive injectable drugs into pre-filled syringes without following FDA regulations, while also providing kickbacks to providers to purchase drugs through the pre-filled syringe program.
- A $360 million settlement with Actelion Pharmaceuticals US, Inc. to resolve allegations that it illegally used a 501(c)(3) foundation to pay the copays of Medicare patients taking Actelion's pulmonary arterial hypertension drugs to induce those patients to purchase the drugs, in violation of the Anti-Kickback Statute.
- A $270 million settlement with DaVita Medical Holdings LLC to resolve allegations that it provided inaccurate information that caused Medicare Advantage Plans to submit incorrect diagnosis codes to CMS to receive inflated Medicare payments in which DaVita shared.
- A $260 million settlement with Health Management Associates, LLC to resolve allegations that it knowingly billed government health care programs for inpatient services that should have been billed as outpatient or observation services, paid remuneration to physicians in return for patient referrals, and submitted inflated claims for emergency department facility fees.
- A $154 million settlement with three South Korea-based companies—SK Energy Co. Ltd., GS Caltex Corporation, and Hanjin Transportation Co. Ltd.—to resolve claims under the Clayton Act and the FCA that they defrauded the U.S. military by fixing prices and rigging bids for contracts to supply fuel to military bases in South Korea.
- A $149.5 million settlement with Deloitte & Touche to resolve allegations that it knowingly deviated from applicable auditing standards while serving as independent outside auditor of Taylor, Bean & Whitaker Mortgage Corp. (TBW) and therefore failed to detect fraudulent conduct and fraudulent statements submitted by TBW.
- A $65 million settlement with Prime Healthcare Services, related entities and hospitals, and its founder and CEO, Dr. Prem Reddy, to resolve allegations that they knowingly submitted false claims to Medicare by admitting patients who required less costly outpatient care and by falsifying information concerning patient diagnoses, including complications and comorbidities, to increase Medicare reimbursement.

[1] *Release available* ***here***.

- A $5 million settlement with former professional cyclist Lance Armstrong to resolve allegations that he caused the submission of false claims to the U.S. Postal Service for sponsorship payments while actively concealing the team's violations of the sponsorship agreements' anti-doping provisions.

- A jury in the Northern District of Alabama found a mortuary business and its owner violated the FCA by engaging in a kickback scheme with executives of a local organ collection center. The judge trebled the damages found by the jury and imposed additional penalties under the FCA, resulting in a $14.7 million judgment.

B. UPDATE ON ENFORCEMENT POLICIES AND LEGISLATION

Congress and the DOJ were quite active in 2018, implementing several new laws and enforcement policies.

1. Enforcement Update

- **The Granston Memorandum:** Recent years have seen record increases in *qui tam* actions filed under the FCA, but the rate of government intervention in FCA cases has remained relatively static. On January 10, 2018, Michael Granston, Director of DOJ's Civil Fraud Division, issued a memorandum advising U.S. attorneys to consider dismissing meritless FCA suits pursuant to 31 U.S.C. § 3730(c)(2) instead of simply declining intervention (the Granston Memorandum).[2] The Granston Memorandum indicates that the government should more readily exercise its "unfettered" discretion to dismiss certain FCA suits—a tool that it has previously seemed reluctant to use—when dismissal would advance the government's interests, preserve limited resources, and avoid adverse precedent. Towards this end, the memorandum outlines seven non-exhaustive goals for the government to consider in making the dismissal decision:

  1) Curbing meritless *qui tam* actions;
  2) Preventing parasitic or opportunistic *qui tam* actions;
  3) Preventing interference with agency policies and programs;
  4) Controlling litigation brought on behalf of the United States;
  5) Safeguarding classified information and national security interests;
  6) Preserving government resources; and
  7) Addressing egregious procedural errors.

  The DOJ wasted no time acting on this policy, with several notable filings in late 2018. *See, e.g.*, *United States ex rel. Health Choice Grp. v. Bayer Corp.*, No. 5:17-cv-00126 (E.D. Tex.) (DOJ indicated that it would seek dismissal in eleven "essentially cloned" complaints accusing drug makers of violating the Anti-Kickback Statute by engaging in white coat marketing and providing free nurse services and reimbursement support services); *Gilead Scis., Inc. v. United States ex rel. Campie*, No. 17-936 (U.S.) (DOJ indicated it would move to dismiss if case remanded to district court under Ninth Circuit ruling); *United States ex rel. Toomer v. TerraPower, LLC*, 2018 WL 4934070 (D. Idaho Oct. 10, 2018) (district court granted DOJ's motion to dismiss under the Granston Memorandum).

- **The Brand Memorandum:** Also in January 2018, Associate Attorney General Rachel Brand released a memorandum that restricted the use of agency guidance documents in affirmative civil enforcement cases brought by the DOJ (ACE cases), including FCA cases (the Brand Memorandum). The Brand Memorandum defined "guidance documents" as any agency statement of general applicability and future effect that is designed to advise parties about legal rights and obligations. According to the memorandum, "[g]uidance documents cannot create binding requirements that do not already exist by statute or regulation [and] effective immediately for ACE cases, the Department may not use its enforcement authority to effectively convert agency guidance documents into binding rules." The Brand Memorandum was particularly welcomed by the healthcare industry due to the prolific issuance of guidance documents from regulatory agencies like the Centers for Medicare and Medicaid Services (CMS), the Department of Health and Human Services Office of Inspector General (HHS OIG), and the Food and Drug Administration (FDA). The DOJ incorporated these principles into the Justice Manual in December 2018 (formerly known as the United States Attorneys' Manual).[3]

[2] *Release available* ***here***.
[3] *Release available* ***here***.

- **Updated Yates Memorandum:** The DOJ announced an increased focus on individual accountability in corporate investigations in the 2015 Yates Memorandum. In late 2018, the DOJ made important revisions to the policy, including reducing the level of disclosure required by companies under criminal investigation. For example, companies were previously expected to identify all employees involved in the conduct regardless of culpability, but now need only identify individuals who were substantially involved in or responsible for the conduct.[4] In civil cases, the DOJ indicated it would focus on wrongdoing by senior officials, including members of senior management or the board of directors. Despite these changes, DOJ made clear that "pursuing individuals responsible for wrongdoing will be a top priority in every corporate investigation." Indeed, in 2018, the DOJ touted several high-profile FCA settlements involving individual defendants, including Lance Armstrong and the founder and CEO of Prime Healthcare, Dr. Prem Reddy.[5]

2. Legislative Update

- **Tax Cuts and Jobs Act:** In late 2017, Congress enacted sweeping changes to the tax law that significantly impacted the FCA settlement process. *See* 26 U.S.C. §162. Historically, the tax code prohibited deducting as a business expense any fines, penalties, or other amounts paid to the government for the violation of any law. In practice, this meant that FCA defendants could deduct settlement amounts as long as those amounts were not considered punitive. Under the Tax Cuts and Jobs Act, however, Congress clarified that only restitution or amounts paid to come into compliance with law are deductible. The new law further required that restitution amounts be specifically identified in a court order or settlement agreement.

- **Eliminating Kickbacks in Recovery Act of 2018:** Congress also passed comprehensive legislation in 2018 to address the opioid crisis, which included the Eliminating Kickbacks in Recovery Act (EKRA) (to be codified at 18 U.S.C. § 220). The new law prohibits payments intended to induce referrals to recovery homes, clinical treatment facilities, and laboratories. Importantly, the law applies to "any public or private plan or contract, affecting commerce, under which any medical benefit, item or services is provided to any individual." Thus, unlike the Anti-Kickback Statute (AKS), EKRA is an all-payor statute. EKRA contains statutory exceptions that are similar, but not identical, to existing AKS safe harbors. For example, some commission-based payments that may be permissible under the employment safe harbor of the AKS may not fit within the narrower EKRA exception.

- **Inflation Adjustment to FCA Penalties:** As reported in previous *Reviews*, the Department of Commerce issued a final rule that significantly increased FCA penalties in 2016 and required annual increases thereafter. In January 2018, the Department of Commerce announced that FCA penalties in 2018 would range from a minimum of $11,181 to a maximum of $22,363 per violation. *See* 83 Fed. Reg. 706 (Jan. 8, 2018).

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[4] *See* Comments by Deputy Attorney General Rod J. Rosenstein, *available* ***here***.
[5] *See* ***here***.

C. SIGNIFICANT JUDICIAL DECISIONS

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

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

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

Second, the Court held that determining materiality is a "rigorous" and "demanding" fact-based inquiry of whether a noncompliance has a natural tendency to influence, or be capable of influencing, the government's payment decision. *See id.*; *see also United States ex rel. Gelman v. Donovan*, 2017 WL 4280543, at *5 (E.D.N.Y. Sept. 25, 2017) ("[After *Escobar*,] materiality is essentially a matter of common sense rather than technical exegesis of statutes and regulations."). This inquiry may be influenced by non-exclusive factors such as whether the alleged noncompliance goes to the "essence of the bargain," whether the noncompliance is significant (as opposed to "minor or insubstantial"), and whether the government has taken action in response to similar, known violations. *Escobar*, 136 S. Ct. at 2003–04.

Since the Supreme Court issued its opinion in *Escobar*, numerous district and appellate courts have attempted to apply these two key holdings. The following is a summary of some key decisions issued in 2018.

a. Interpretations of *Escobar* Regarding Implied Certification Claims

Escobar held that an implied certification theory of liability is viable *at least* when a defendant (1) submits a claim that makes specific representations about goods or services provided; and (2) fails to disclose noncompliance with a material statutory, regulatory, or contractual requirement, rendering its representations misleading half-truths. But the Supreme Court did not resolve whether these two elements constitute the only way to plead implied certification, or whether they are just one possible way.

In last year's *Review*, we discussed two opinions by the Ninth Circuit that appeared to establish in dicta that the two-element test is mandatory. *See United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325 (9th Cir. 2017); *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890 (9th Cir. 2017). In 2018, the Ninth Circuit addressed this question directly and confirmed its view that the two elements are indeed mandatory. *United States Ex Rel. Rose v. Stephens Inst.*, 909 F.3d 1012, 1018 (9th Cir. 2018).

The Fifth Circuit also indicated that the two-part test is mandatory. In *United States ex rel. Smith v. Wallace*, the court held that a relator failed to allege facts to support an implied false certification claim because he "never identifie[d] any claim that the defendants submitted" or "provide[d] evidence that would support a finding that the claims included 'specific representations' that were 'misleading half-truths' in light of the alleged misstatements in the original applications." 723 F. App'x 254, 256 (5th Cir. 2018).

The Fifth and Ninth Circuits have thus joined the Seventh Circuit—and departed from the Fourth Circuit—in requiring that both of *Escobar's* conditions be met for a valid implied certification claim. *Compare United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447–48 (7th Cir. 2016) *with United States ex rel. Badr v. Triply Canopy, Inc.*, 857 F.3d 174, 178 (4th Cir. 2017). We will continue to monitor for further developments as courts grapple with this issue.

b. Interpretations of *Escobar* Regarding Materiality

i. Essence of the bargain

As discussed above, one factor relevant to materiality is whether the alleged violation goes "to the very essence of the bargain," rather than being "minor or insubstantial." *Escobar*, 136 S. Ct. at 2003 & n.5. Many violations fall into this category. For example, in 2018, courts deemed noncompliance with physician certification timing, medical necessity, medical staff qualifications, and HIPAA regulations to be material for this reason.

In *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, the relator alleged that the defendants submitted claims to Medicare without complying with physician certification timing requirements outlined in 42 C.F.R. § 424.22(a)(2). 892 F.3d 822, 825 (6th Cir. 2018), *petition for cert. filed*, No. 18-699 (U.S. Nov. 28, 2018). The district court dismissed the case because the relator could not "point to a single instance where Medicare denied payment based on violation of § 424.22(a)(2)." But the Sixth Circuit reversed, holding that the timing requirement was an express condition of payment and went to the "essence of the bargain" with the government because it "is a mechanism of fraud prevention, which the government has consistently emphasized in its guidance regarding physician certifications." *See id.* at 834–37.

District courts in Pennsylvania, Massachusetts, and Illinois similarly refused to dismiss claims based on violations of medical regulations that went to the "heart of the bargain" between providers and government-run health care programs. In *United States ex rel. Scalamogna v. Steel Valley Ambulance*, the relator alleged that an ambulance service provider was billing for services that were medically unnecessary, such as transporting patients by ambulance when they could have used a wheelchair van. 2018 WL 3122391, at *2 (W.D. Pa. June 26, 2018). The court held that medical necessity requirements were material because they were a condition of payment under 42 C.F.R. § 410.40 and went to the "heart of the bargain" between Medicare and ambulance service providers. *Id.* at *10. The court explained that "it is difficult to conceive of a more fundamental breach of the bargain than deliberately inflating billing to charge for unnecessary services." *Id.; see also Commonwealth ex rel. Martino-Fleming v. S. Bay Mental Health Ctr., Inc.*, 334 F. Supp. 3d 394, 408 (D. Mass. 2018) (finding allegation that mental health services were provided by unlicensed personnel was material because the hiring of unqualified staff went to the "heart of the bargain" with the state).

In *United States v. America at Home Healthcare & Nursing Services, Ltd.*, the relator alleged that defendants violated the Health Insurance Portability and Accountability Act (HIPAA) by searching confidential medical charts at different facilities to collect the names of patients they could solicit for home health services. 2018 WL 319319, at *6 (N.D. Ill. Jan. 8, 2018). The court held that the relator had sufficiently alleged materiality because unlawfully soliciting patients through HIPAA violations goes "to the very essence of the bargain" between the government and health care providers. *Id.* at *7. Although the court could not turn to any HIPAA-based FCA cases for comparison, the court held that evidence that "a home health agency has pilfered protected health data to solicit patients has a good probability of affecting a payment decision." *Id.*

In contrast to the above cases, district courts may dismiss where the alleged regulatory violation is deemed minor or insubstantial. For example, in *United States ex rel. Cressman v. Solid Waste Services, Inc.*, the relator alleged that the defendant, a company that performed waste pickup services for federal agencies, did not disclose its improper discharge of waste at its solid waste transfer station. 2018 WL 1693349, at *2 (E.D. Pa. Apr. 6, 2018). But the court held that the "essence of the bargain" between defendant and the federal agencies was that defendant would collect, transport, and dispose of waste. *Id.* at *7. Since defendant undoubtedly performed those services, and none of the agencies' waste ever went to the transfer station where the violation occurred, the violation was not material.

ii. Continued payment

Escobar also established that materiality may turn on whether or not the government would pay the claim if it knew of the claimant's violation. The Court explained that non-materiality may be shown by, for example,

evidence that "the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated." *Escobar*, 136 S. Ct. at 2003–04; *see also United States ex rel. Berkowitz v. Automation Aids, Inc.*, 896 F.3d 834, 842–43 (7th Cir. 2018) ("[T]he fact that the government has allegedly paid millions of dollars for the non-compliant products suggests that [the relator] cannot satisfy the materiality prong of the implied certification theory.").

In *United States ex rel. Berg v. Honeywell International, Inc.*, the relator alleged that the defendant knowingly falsified energy cost baseline calculations to meet requirements for a U.S. Army contract to install energy-efficient lighting systems at bases in Alaska. 740 F. App'x 535, 537 (9th Cir. 2018). The Ninth Circuit affirmed summary judgment in favor of the defendant. Though the Army learned of the relators' allegations in 2002, it nonetheless paid defendant's claims from 2003 through 2008. *Id.* at 538. Thus, the government's continued payment of the claims was evidence that the alleged falsification was not material.

Similarly, in *United States ex rel. Kolchinsky v. Moody's Corp.*, the relator alleged that the defendant artificially inflated credit ratings for residential mortgage-backed securities and collateralized debt obligations, which, in turn, tricked the government into purchasing inaccurate credit-rating services. 2018 WL 1322183, at *1 (S.D.N.Y. Mar. 13, 2018). But the court held that the relator had not shown materiality, since the government "continued to pay Moody's for its credit-ratings products each year" despite being aware of the allegations, and, in fact, "also entered into new service contracts." *See id.* at *4–5.

Further, in *United States ex rel. Patel v. Catholic Health Initiatives*, the relators alleged that a hospital network had violated the FCA by misrepresenting the ownership structure of the network after it bought out relators and other physician-investors. 312 F. Supp. 3d 584, 588 (S.D. Tex. 2018). The district court dismissed the case with prejudice because "[n]othing in Relators' filings suggest[ed] that the government would stop the flow of funds to this hospital if it knew the truth of its ownership." *Id.* at 605. The relators were required to allege that the government would not continue to reimburse the hospital; instead, the relators' dispute was "entirely and only about which business entity [wa]s the proper recipient of those reimbursements." *Id.*

In contrast, one court held that the relator satisfied the materiality standard by alleging fraud that would necessarily impact the government's payment of claims. In *United States ex rel. Luke v. HealthSouth Corp.*, the relator alleged that defendants intentionally misrepresented patients' disability ratings to report lower "functional independence measure" (FIM) scores to the government. 2018 WL 3186941, at *1 (D. Nev. June 28, 2018). The government used those FIM scores to determine facilities' reimbursements; "the lower the FIM, the higher the reimbursement payment." *Id.* at *6. Though there were no allegations of the government's payment activity after learning of the alleged fraud, the court held that the relator had plausibly alleged materiality because the "alleged manipulation of the criteria *by which payment is determined*" necessarily implicated the government's payment of the defendants' claims. *See id.* (emphasis added).

iii. Conclusory allegations

A conclusory statement that the government would not have paid a claim or entered into an agreement with the defendant had it been aware of the alleged false statement or fraudulent conduct is insufficient for materiality. *See, e.g.*, *United States ex rel. Pelullo v. Am. Int'l Group, Inc.*, 2018 WL 6179013, at *1 (2d Cir. Nov. 27, 2018) (explaining that "wildly speculative contentions" of materiality do not state an FCA claim).

Several district courts dismissed *qui tam* cases in 2018 on this basis. For example, in *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, the district court dismissed claims that the insurer-defendant had falsely attested to the validity of diagnostic data related to the health status of patients enrolled in Medicare Advantage plans. 2018 WL 1363487, at *9–10 (C.D. Cal. Feb. 12, 2018) (note that allegations related to exaggerated patient diagnoses and retention of overpayments survived the motion to dismiss). While the complaint discussed the materiality of the diagnostic data itself, "the key allegation that the *attestations* have a direct impact on CMS' risk adjustment payments [wa]s missing." *Id.* at *9 (emphasis added).

In *United States ex rel. Daugherty v. Tiversa Holding Corp.*, the relator alleged that the defendant made false representations to obtain grant payments from the Department of Homeland Security. 2018 WL 5045336, at *5 (S.D.N.Y. Oct. 17, 2018). But the court dismissed the complaint because it had cited only general government policies about the importance of complying with grant conditions to establish materiality. *Id.* at *7. "Under *Escobar*, this is insufficient." *Id.*; *see also United States ex rel. Potter v. CASA de Maryland*, 2018 WL 1183659, at *1 (D. Md. Mar. 6, 2018) (conclusory allegations that the defendants "would not have received federal funds if the government knew about the I-9 deficiencies" were not enough).

Finally, in *United States ex rel. Kietzman v. Bethany Circle of King's Daughters of Madison, Indiana, Inc.*, the relator alleged that the hospital-defendant performed and billed for unnecessary radiological scans, gave urologists kickbacks in the form of purchasing and billing Medicaid for fiduciary markers that should have been paid for by the urologists themselves, and violated various CMS documentation and supervision requirements. 305 F. Supp. 3d 964, 975 (S.D. Ind. 2018). But the complaint failed to satisfy *Escobar*'s materiality standard because it did "not contain a single nonconclusory allegation of materiality." *Id.* at 977. Specifically, "[n]o facts [we]re alleged as to what types of claims the government usually did or did not pay, nor as to what the government's compliance priorities were, nor as to the degree of severity of the Hospital's alleged breaches of regulation." *Id.*

2. Pleading with particularity

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

There is no dispute Rule 9(b) applies in FCA cases. But as we have discussed in previous *Reviews*, circuit courts are split on how exactly that standard applies and, in particular, whether the plaintiff must plead specific representative false claims to survive a motion to dismiss. Some have questioned whether this alleged split is illusory, and in 2018, the Supreme Court denied a handful of petitions seeking to resolve the question. In any event, circuit courts continue to express at least facially different tests that could affect the outcome of a given case.

a. The Supreme Court declines review in several cases requesting clarification of the Rule 9(b) standard in FCA cases.

For the last several years, litigants have often asked the Supreme Court to clarify how Rule 9(b) applies in FCA cases. The Supreme Court has thus far declined to enter the fray, and 2018 was no different. The Court denied at least three petitions in the last year asking it to resolve this alleged circuit split. *United States ex rel. Chase v. Chapters Health Sys., Inc.*, No. 17-1477 (cert. denied Oct. 1, 2018); *United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, No. 17-1300 (cert. denied May 29, 2018); *Medical Device Bus. Servs., Inc., f/k/a DePuy Orthopaedics, Inc. v. United States ex rel. Nargol*, No. 17-1108 (cert. denied Apr. 16, 2018).

The responses in opposition to these petitions struck a similar tone—they claimed there is no circuit split and thus nothing to clarify. In *Chase*, for example, the petitioners had argued that the Fourth, Sixth, Eighth, and Eleventh Circuits impose a "rigid" view of Rule 9(b)'s particularity requirement—requiring representative samples of the alleged false claims—while the First, Third, Fifth, Seventh, Ninth, Tenth, and D.C. Circuits have allowed for more flexibility and have not always required representative samples. Petition for a Writ of Certiorari, No. 17, 1477, at 13, 15 (Apr. 24, 2018). The respondent claimed this was overstated because "[n]o circuit currently applies a *per se* rule mandating False Claims Act relators to plead a representative claim in all circumstances" and "*every circuit* to address the issue now recognizes that a False Claims Act relator may satisfy Rule 9(b) without pleading the contents of a specific bill for reimbursement, provided that certain other conditions are met." Brief in Opposition, No. 17-1477, at 11, 15 (Aug. 13, 2018).

The Court declined to resolve that dispute in *Chase* and, per its usual practice, gave no explanation. The Court has expressed at least some level of interest in this

issue, as it has twice asked for the views of the Solicitor General on whether to address the split. The Court, however, has consistently decided not to get involved.

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

Without Supreme Court intervention in 2018, circuit courts were left to apply their own 9(b) precedents in a variety of factual circumstances—and litigants were left to decide the differences, if any, between these approaches.

The Ninth Circuit in *United States ex rel. Silingo v. Wellpoint, Inc.*, held that the complaint provided adequate detail of the submission of false claims without a representative example. 904 F.3d 667, 678–79 (9th Cir. 2018). Under the Ninth Circuit's precedents, a relator need only "provide 'reliable indicia that lead to a strong inference that claims were actually submitted'" and need not "identify representative examples of actual false claims, though that is one way to satisfy the heightened pleading requirement." *Id.* Thus, even though it appeared that the relators had not pled any details about the submission of false claims, the court found "ample circumstantial evidence from which to infer that" false claims had been submitted. *Id.* at 679.

Contrast that with two opinions from the Eleventh Circuit, which relied on a similarly-phrased standard to different effect. In *United States ex rel. Chase v. HPC Healthcare* (discussed above), the Eleventh Circuit stated that the "key inquiry is whether the complaint includes 'some indicia of reliability' to support the allegation that an actual false claim was submitted." 723 F. App'x 783, 789 (11th Cir. 2018). However, unlike the Ninth Circuit, the court emphasized that submission must not be "inferred from the circumstances" and requires proof of specific billing information or direct knowledge of the submission of false claims. *Id.* The court affirmed the dismissal of the relator's complaint because it contained neither. *Id.* at 790.

The Eleventh Circuit again rejected circumstantial allegations of false claims in *Carrel v. AIDS Healthcare Foundation, Inc.*, noting that "[a]lthough the relators allege a mosaic of circumstances that are perhaps consistent with their accusations that [defendant] made false claims," the complaint lacked "more exact allegations that these factors converged into actual false claims." 898 F.3d 1267, 1277, 1278 (11th Cir. 2018). And this even though the relators had apparently made specific allegations about a few representative claims; the court held that those claims could not help relators "because they involved no fraud." *Id.* at 1277. In other words, the court held that perfectly lawful conduct could not be the basis for the relator's allegations of a fraudulent scheme.

The Sixth Circuit reached a similar conclusion in *United States ex rel. Roycroft v. Geo Group, Inc.*, finding that the relator had alleged the presentment of at least one representative claim—as required by the court's precedents—but that those allegations failed "to identify what is false in the representative claims, so as to connect the claims to the broader scheme." 722 F. App'x 404, 407 (6th Cir. 2018). The Sixth Circuit further discussed its view of the 9(b) standard in *United States ex rel. Crockett v. Complete Fitness Rehabilitation, Inc.* 721 F. App'x 451, 457–58 (6th Cir. 2018). The court stated a general rule that the "failure to identify claims that were actually submitted to the government subjects an FCA fraud claim to dismissal," but also acknowledged a narrow exception "for billing employees who have detailed personal knowledge of the submitting entity's billing practices." *Id.* at 458. The Sixth Circuit nevertheless found that the relator could not invoke that exception because she had no such knowledge. *Id.*

Finally, in *United States ex rel. Berkowitz v. Automation Aids, Inc.*, the Seventh Circuit noted that, under its precedents, the required particularity under Rule 9(b) "may depend on the facts of a given case." 896 F.3d 834, 839 (7th Cir. 2018). A relator need only "use some means of injecting precision and some measure of substantiation into their allegations of fraud." *Id.* at 840. Despite this flexibility, the court in *Berkowitz* affirmed the dismissal of a complaint that did not include "any specific allegations regarding the particularities of the fraud scheme." *Id.* at 842. The relator requested a relaxed standard based on his lack of access to substantiating information, but the court held that a relator must nevertheless provide some specificity and substantiation to survive a motion to dismiss. *Id.* at 841.

3. Falsity

As the name implies, the FCA only imposes liability for "false claims"—that is, for presenting a false or fraudulent claim or making a false record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(A)-(B). The terms "false" and "fraudulent" are not defined in the statute, and the Tenth Circuit issued a significant ruling on falsity in the medical necessity context in 2018.

In *United States ex rel. Polukoff v. St. Mark's Hospital*, the relator alleged that the defendant cardiologists made false representations to the government that certain cardiac procedures were medically reasonable and necessary. 895 F.3d 730 (10th Cir. 2018). In holding that the complaint did not allege falsity, the district court in Utah explained that "[o]pinions, medical judgments, and conclusions about which reasonable minds may differ cannot be false for purposes of an FCA claim." *United States ex rel. Polukoff v. St. Mark's Hosp.*, 2017 WL 237615, at *10 (D. Utah Jan. 19, 2017). The Tenth Circuit reversed, holding that it is possible for medical judgment to be false or fraudulent under the FCA and explaining "that a doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase." 895 F.3d at 743. The Tenth Circuit's decision followed on the heels of a criminal healthcare fraud case, *United States v. Paulus*, in which the Sixth Circuit reached a similar conclusion. 894 F.3d 267, 275 (6th Cir. 2018) ("[t]he degree of stenosis *is* a fact capable of proof or disproof," and thus exaggerated conclusions about angiograms can form the basis for falsity).

4. Reverse False Claims

A defendant may also be liable under the FCA for a "reverse false claim" if it makes or uses a false record or statement for the purpose of avoiding or decreasing an "obligation" owed to the United States. *See* 31 U.S.C. §3729(a)(1)(G). Several cases addressed reverse false claims liability in 2018, but one in particular had a significant impact on the potential for reverse false claims liability in connection with the Medicare Advantage Program.

Under the Affordable Care Act (ACA), "[a]n overpayment must be reported and returned" within "60 days after the date on which the overpayment was identified," and failure to do so may result in FCA liability. 42 U.S.C. § 132a-7k(d). In 2014, CMS issued a Final Rule which stated that a Medicare Advantage organization has "identified" an overpayment "when it has determined, or should have determined through the exercise of reasonable diligence, that it received an overpayment." 42 C.F.R. § 422.326(c). Thus, under the CMS rule, failure to act with reasonable diligence could result in FCA liability.

As we have reported in previous *Reviews*, the DOJ intervened in several FCA actions involving Medicare Advantage organizations in recent years. *See, e.g.*, *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, No. 2:16-cv-08697 (C.D. Cal.); *United States ex rel. Swoben v. UnitedHealthcare Ins. Co.*, No. 2:09-cv-05013 (C.D. Cal.). Yet in 2018, UnitedHealthcare Insurance Co. ("United") went on the offensive and filed a lawsuit against the federal government, arguing that the CMS overpayment rule impermissibly expanded the scope of liability under the FCA. *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173 (D.D.C. Sept. 7, 2018). United argued that the FCA imposes liability for false claims that are submitted "knowingly," which is defined as (i) actual knowledge of the information, (ii) deliberate ignorance of the truth or falsity of the information, or (iii) acting in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1). In contrast, the CMS overpayment rule could subject Medicare Advantage plans to potential FCA liability based on merely negligent inaction (e.g., failing to proactively search for and find overpayments). The district court agreed, adding that Congress had no intention of turning the FCA, a statute enacted to combat fraud, into a vehicle for punishing honest mistakes or incorrect claims submitted through mere negligence. 330 F. Supp. 3d at 191. Because the court concluded that the definition of "identified" in the CMS overpayment rule was inconsistent with the knowledge requirement in the FCA, the court vacated the CMS overpayment rule.[6]

[6] While this section focuses on the FCA issue, the court's decision was also based on two other findings: (1) the overpayment rule violated the statutory mandate of actuarial equivalence between CMS payments for coverage under traditional Medicare and Medicare Advantage, and (2) the overpayment rule's definition of "identified" was finalized without adequate notice as required by the Administrative Procedure Act. 330 F. Supp. 3d at 184–89, 191–92.

Just weeks after the district court's ruling, the DOJ intervened in yet another Medicare Advantage FCA action. *United States ex rel. Ormsby v. Sutter Health et al.*, No. 15-cv-01062 (N.D. Cal.). There, as in the UnitedHealthcare cases cited above, the relator alleged that Sutter Health knowingly submitted inaccurate risk adjustment data and knowingly retained overpayments it received based on that inaccurate or false data. Thus, despite the D.C. ruling, it appears the DOJ will continue to focus on Medicare Advantage organizations and reverse false claims liability in 2019.

5. Scienter

The FCA requires a plaintiff to show that the defendant had the requisite scienter—i.e., that the defendant "knowingly" submitted a false or fraudulent claim. 31 U.S.C. § 3729(a)(1). To act "knowingly," a defendant must have acted with "actual knowledge of the information" or in "deliberate ignorance" or "reckless disregard" of the "truth or falsity of the information." 31 U.S.C. § 3729(b)(1). While the FCA does not require plaintiffs to show a specific intent to defraud, it does require more than a showing of negligence. *See United States v. Wagoner*, 2018 WL 4539819, at *6 (N.D. Ind. Sept. 20, 2018) ("Innocent mistakes or negligence are not actionable.") (citation omitted).

a. Actual knowledge

Generally, to show actual knowledge, a "Plaintiff must allege that Defendant knew its statements were false when made, meaning Defendant knew the statements were 'lie[s].'" *United States ex rel. Durkin v. Cty. of San Diego*, 2018 WL 3361148, at *5, *7 (S.D. Cal. July 10, 2018) (citing *Wang ex rel. United States v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992)). In 2018, several courts found that actual knowledge may be shown circumstantially by alleging that the defendant's actions were part of a pattern of similar actions. *E.g.*, *United States ex rel. Kelly v. Select Specialty Hosp.-Wilmington, Inc.*, 2018 WL 1568874, at *7 (D. Del. Mar. 30, 2018). In *Kelly*, the plaintiff survived a motion to dismiss because she alleged that one of the defendants regularly forged signatures on claims to the government, which suggested that the allegedly fraudulent claims were submitted purposefully and with actual knowledge. *See id.* Similarly, a plaintiff sufficiently pleaded scienter by alleging an overarching scheme, including that the defendant "engaged in improper and unlawful marketing strategies. . . marketed [products] with defective and inadequate warnings to downplay the risks, and intentionally misrepresented . . . facts . . . in connection with its communications to the public, government representatives and to physicians." *In re Baycol Prods. Litig.*, 2018 WL 5017923, at *2 (D. Minn. Oct. 16, 2018).

b. Deliberate ignorance and reckless disregard

Courts in 2018 found that deliberate ignorance or reckless disregard may be alleged through evidence of the defendant's disregard of its compliance programs or complaints from employees. For example, the Sixth Circuit held that a relator sufficiently pleaded scienter where it provided factual allegations showing that the defendants "deliberately ignored multiple employees' concerns about their compliance with relevant regulations, and instead pressured their employees only cursorily to review claims for compliance problems so that they could be quickly submitted for reimbursement." *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 838 (6th Cir. 2018); *see also, e.g.*, *United States ex rel. Schmuckley v. Rite Aid Corp.*, 2018 WL 4214887, at *4 (E.D. Cal. Sept. 5, 2018) (finding scienter in the form of reckless disregard where defendant "delegat[ed] . . . compliance to its employees then fail[ed] to conduct even 'a limited inquiry' to ensure compliance"); *United States ex rel. Bawduniak v. Biogen Idec Inc.*, 2018 WL 1996829, at *6 (D. Mass. Apr. 27, 2018) ("Defendant's Compliance Department repeatedly expressed concern over Defendant's speaking and consulting programs, and . . . those concerns were communicated but ignored.").

c. Mere mistakes are not actionable

On the other hand, courts have dismissed FCA actions where the facts support at most that the defendant made mistakes or acted negligently. *E.g.*, *United States ex rel. Berkowitz v. Automation Aids, Inc.*, 896 F.3d 834, 842 (7th Cir. 2018). In *Berkowitz*, the Seventh Circuit explained a relator must plead facts "that would lead a reasonable person to realize that [the defendants were] causing the submission of a false claim." *Id.*

d. Conclusory allegations of scienter are not enough

The *Berkowitz* court also noted that though a relator may face difficulty in alleging with accuracy the details of a competitor's operations, this "does not relieve [the relator] of his obligation to adequately plead all of the elements of an FCA claim or to fully investigate his claim before filing a complaint." *Id.* at 843. Other cases have held similarly that conclusory allegations of scienter are insufficient to state an FCA claim. *See United States ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C.*, 319 F. Supp. 3d 747, 750 (S.D.N.Y. 2018) (holding relator's allegations of intent were "based on little more than conjecture"); *United States ex rel. Durkin v. Cty. of San Diego*, 300 F. Supp. 3d 1107, 1128–30 (S.D. Cal. 2018) (holding scienter allegations failed for want of specificity); *United States ex rel. Folliard v. Comstor Corp.*, 308 F. Supp. 3d 56, 89 (D.D.C. 2018) ("Merely alleging a time period, the volume of items sold and total sales value involved in the underlying alleged fraud scheme . . . is not enough to show scienter."), *reconsideration denied*, 2018 WL 5777085 (D.D.C. Nov. 2, 2018).

6. Statute of Limitations

An FCA action must be brought: (1) within six years of the alleged violation or (2) within three years after the government has knowledge of "facts material to the right of action," but no later than ten years after the alleged violation was committed. 31 U.S.C. § 3731(b). The question of when a claim should receive the benefit of the latter extended limitations period created a three-way circuit split in 2018.

Whether the government's "knowledge" of the disputed violation can trigger an extension to the limitations period in some circuits depends on whether the government has chosen to intervene in the case. For example, the Fourth Circuit has held that it "would be problematic" to read the text of § 3731(b) as allowing the government's knowledge of a violation to affect the limitations period in non-intervened FCA cases. *United States ex rel. Sanders v. N. Am. Bus Indus., Inc.*, 546 F.3d 288, 293 (4th Cir. 2008). The *Sanders* court reasoned that such an understanding of the statute would create "the bizarre scenario in which the limitations period in a relator's action depends on the knowledge of a nonparty to the action." *Id.* The Tenth Circuit has held similarly, explaining that holding otherwise "would result in evisceration of the six-year statute of limitations in § 3731(b)(1) in the vast majority of cases." *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 726 (10th Cir. 2006) ("Surely, Congress could not have intended to base a statute of limitations on the knowledge of a non-party.").

The Third and Ninth Circuits, on the other hand, do allow for such an extension in non-intervened cases. *See United States ex rel. Malloy v. Telephonics Corp.*, 68 F. App'x 270 (3d Cir. 2003); *United States ex rel. Hyatt v. Northrop Corp.*, 91 F.3d 1211 (9th Cir. 1996). But, those circuits hold that the limitations period begins to run when the relator—not the government—knows of the facts material to the right of action.

This year, the Eleventh Circuit took an even broader view in *United States ex rel. Hunt v. Cochise Consultancy, Inc.* 887 F.3d 1081, 1092 (11th Cir. 2018). There, the relator filed a *qui tam* action more than six years after the alleged FCA violation, but within three years of disclosing the alleged conduct to the relevant government authority. *Id.* at 1083. The Eleventh Circuit held that the extension applied in the declined case because the limitations "period begins to run when the relevant federal government official learns of the facts giving rise to the claim." *Id.* The court in Hunt further reasoned that the Fourth and Tenth Circuits "failed to consider the unique role that the United States plays even in a non-intervened *qui tam* case." *Id.* at 1092. Specifically, the court found it persuasive that the government receives most of the recovery in an FCA case and retains the power to stay discovery, to veto a relator's voluntary dismissal of the action, to seek to intervene at any time upon a showing of good cause, and to request pleadings and deposition transcripts. *Id.* at 1091–92. Given this level of involvement in non-intervened cases, the *Hunt* court held that it could not say "that Congress, by specifying that § 3731(b)(2)'s limitations period is triggered by the knowledge of a United States official, necessarily intended that this limitations period be available only in § 3730 civil actions where the United States is a party and not in non-intervened *qui tam* actions." *Id.* at 1092. In late 2018, the Supreme Court decided to take up the circuit split and granted certiorari in the Eleventh Circuit case. 2018 WL 4385694 (U.S. Nov. 16, 2018).

7. Public Disclosure and Original Source

The public disclosure bar prohibits *qui tam* suits based on publicly disclosed allegations of fraud, unless the relator has sufficient knowledge of the fraud to qualify as an "original source." 31 U.S.C. § 3730(e)(4). This defense is continually a source of litigation, as courts attempt to strike the congressionally intended balance between discouraging parasitic lawsuits and properly incentivizing true whistleblowers. In 2018, the Third and Ninth Circuits addressed the public disclosure bar and the original source exception in several cases. These significant decisions are summarized below.

a. When is the public disclosure bar triggered?

The public disclosure bar provides that a "court shall dismiss an action or claim under this section…*if substantially the same allegations or transactions* as alleged in the action or claim were publicly disclosed…" 31 U.S.C. § 3730(e)(4)(A) (emphasis added).

This year, the Third Circuit reversed a district court's dismissal of a case under the public disclosure bar, holding that the bar was not triggered where the non-public information on which the relator relied gave rise to an inference of fraud that could not have been supported by the public disclosures alone. *United States ex rel. Silver v. Omnicare, Inc.*, 903 F.3d 78 (3d Cir. 2018). In doing so, the court explained the difference between an "allegation" of fraud (which is a specific allegation of wrongdoing) and a "transaction" that raises an inference of fraud (which consists of both the allegedly misrepresented facts and the allegedly true state of affairs). *Id.* at 83. The Third Circuit applies a formula to determine whether a fraudulent "transaction" raising an inference of fraud has been publicly disclosed: the disclosure must include "'both a misrepresented [X] and a true [Y] state of facts.'" *Id.* at 84 (quoting *United States ex rel. Atkinson v. PA. Shipbuilding Co.*, 473 F.3d 506, 519 (3d Cir. 2007)). Here, financial information and information about the concept of the alleged scheme had been publicly disclosed, but the court found that the relator alleged specific facts suggesting that the defendant in particular was *actually engaged in* the fraudulent scheme. *Id.* at 86. Those non-public facts gave rise to "an inference of fraud that could not have been supported by the public disclosures alone." *Id.* The court clarified that "the FCA's public disclosure bar is not triggered when a relator relies upon non-public information to make sense of publicly available information, where the public information—standing alone—could not have reasonably or plausibly supported an inference that the fraud was in fact occurring." *Id.* at 89.

In contrast, the Ninth Circuit upheld two dismissals under the public disclosure bar, holding that several publicly-available sources, taken together, disclosed "substantially the same allegations or transactions" as the relators alleged in their complaints. *United States ex rel. Yagman v. Mitchell*, 711 F. App'x 422 (9th Cir. 2018); *United States ex rel. Hong v. Newport Sensors, Inc.*, 728 F. App'x 660 (9th Cir. 2018).

In *Yagman*, the public disclosures were made in declassified portions of a Senate Report and various news articles, all of which the relator incorporated by reference into the complaint. 711 F. App'x at 423. The district court dismissed the claims under the public disclosure bar and the Ninth Circuit affirmed, focusing on the fact that the relator's complaint merely incorporated facts from the publicly-available sources by reference and provided no additional details. The court found there was "more than enough in the publicly available materials to raise an inference of exactly the type of fraud that Yagman alleged," and therefore the suit was barred by the public disclosure bar. *See id.*

A few weeks later in *Hong*, the Ninth Circuit again upheld a district court's dismissal under the public disclosure bar. 728 F. App'x at 662. The relator alleged that the defendant entered into contracts with several federal agencies by falsely certifying that it employed the principal investigator when in fact the investigator was a full-time professor for UC Irvine. The public disclosures at issue were various publicly-available databases and a UC Irvine faculty profile that included relevant details of the government contracts and identified the principal investigator. *See id.* at 662. The Ninth Circuit upheld the district court's dismissal under the public disclosure bar, stating that the relator's claim was "based upon" the allegedly fraudulent "transaction" disclosed in the publicly-available documents. *Id.* The Ninth Circuit

rejected the relator's argument that he introduced undisclosed information that the principal investigator "knowingly" submitted the allegedly fraudulent application, holding instead that the investigator's state of mind was already publicly evident from her certification of compliance. *Id.*

b. Who is an original source?

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

In 2018, the Third Circuit revived a suit that had been dismissed under the public disclosure bar, holding that the original source exception *could* apply. *United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh*, 728 F. App'x 101 (3d Cir. 2018). The court held that the district court improperly dismissed relators' claims where the relators asserted that they had "independent material knowledge" of the false claims and "directly observed" the false certifications. *Id.* at *104–05. Because relators "repeatedly pleaded that they directly observed" the false certifications and had "independent knowledge" of the fraud, the Third Circuit held that dismissal at this stage was improper. *Id.* Rather than throw the case out on a motion to dismiss, the Third Circuit explained that the district court should have given the parties an "opportunity to develop the facts in discovery" as to relators' "claim that they did not rely on public disclosures" when they brought the case. *Id.* at *105. On that basis, the court reversed and remanded so that the district court could reconsider whether the public disclosure bar precluded the action.

The Ninth Circuit also clarified the elements of the original source exception in *United States ex rel. Solis v. Millennium Pharmaceuticals, Inc.* 885 F.3d 623 (9th Cir. 2018). There, the district court followed a three-part test to determine whether the relator was an original source: "(1) he must have 'direct and independent knowledge' of the information on which his allegations are based; (2) he must have 'voluntarily provided the information to the Government before filing' his FCA action; and (3) he 'must have had a hand in the public disclosure of allegations that are a part of [his] suit.'" *Id.* at 627–28 (quoting *Wang ex rel. United States v. FMC Corp.*, 975 F.2d 1412, 1417–18 (9th Cir. 1992)). The district court held that the relator was not an original source because he did not have a hand in the public disclosure of the allegations. *Id.* at 628. However, the Ninth Circuit found that intervening caselaw made the third element inapplicable. *Id.* As to the claims that the district court had dismissed under the public disclosure bar, the Ninth Circuit vacated the dismissal and remanded for the district court to determine whether the relator qualified for the original source exception under the first two elements of the test. *Id.* at 629.

8. First-to-File Rule

The FCA's first-to-file rule provides that "no person other than the government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5).

In 2018, the Supreme Court declined to review the Tenth Circuit's dismissal of a relator's claim based on a broad interpretation of "intervention" under the first-to-file rule. *See United States ex rel. Little v. Triumph Gear Sys., Inc.*, 870 F.3d 1242 (10th Cir. 2017), *cert. denied*, 2018 WL 534815 (U.S. Mar. 19, 2018). Initially, a named relator filed a sealed complaint in the district court claiming that defendant Triumph violated the FCA. *Id.* at 1245. The complaint also named three "John Doe" relators. *Id.* An amended complaint was later filed in the same action, this time by two new named relators who claimed to be two of the original "Doe" relators. *Id.* The amended complaint did not mention the original named relator. *Id.* Triumph filed a motion to dismiss, arguing that the amended complaint should be dismissed because the two new relators impermissibly intervened in the action. The district court concluded that the two new relators entered the action pursuant to a Rule 15 amendment and the first-to-file rule therefore did not apply. *Id.* at 1246.

The Tenth Circuit reversed, clarifying that the right to amend the complaint under Rule 15 belongs only to *parties*—not *non-parties*. The two new relators, as *non-parties*, had no right to amend the complaint under

Rule 15. *Id.* at 1248. The court further held that, even assuming the two new relators were the original two John Doe relators, that fact would not protect their claims from the first-to-file rule because they had not received the court's permission to proceed anonymously. *Id.* at 1249–50. Therefore, they were not considered "parties" to the case. *Id.* The relators sought Supreme Court review, but the Court denied certiorari.

As discussed in previous *Reviews*, courts differ on whether a first-to-file defect can be cured by a party's amendment or whether an action needs to be re-filed after a first-filed suit is dismissed. *See, e.g.*, *United States ex rel. Shea v. Cellco P'ship*, 863 F.3d 923, 930 (D.C. Cir. 2017); *United States ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1, 6 (1st Cir. 2015). This year, the Second Circuit joined the Fourth and D.C. Circuits in holding that amendment is insufficient to cure such a defect. *United States ex rel. Wood v. Allergan*, 899 F.3d 163 (2d Cir. 2018). There, the complaint at issue was filed by Wood against his former employer, Allergan. At the time Wood filed his complaint, two other actions alleging similar FCA violations were already pending. *Id.* at 167. While Wood's complaint was still under seal, the two similar actions were dismissed for failure to properly serve Allergan. *Id.* at 168. Following the dismissals, the government declined to intervene as to Wood's complaint and his complaint was unsealed. *Id.* Wood then filed an amended complaint. *Id.* At the time Wood filed his amended complaint, no other related actions were pending. *See id.*

Allergan argued that Wood's complaint should be dismissed because it violated the first-to-file rule, but the district court disagreed. *Id.* The district court held that Wood's complaint could proceed because there were no pending related actions when his complaint was amended. *Id.* Because the issue was one of first impression for the Second Circuit, the district court granted leave for Allergan to file an interlocutory appeal. *Id.* at 168.

The Second Circuit reversed, holding that the first-to-file rule violation could not be cured by the amended complaint. *See id.* at 175. The court looked to the statutory scheme and held that allowing the amended complaint to proceed would be inconsistent with the plain language of the statute. *Id.* at 171–72. The court focused on the word "bring," and concluded that the first-to-file rule clearly states that an action cannot be *brought* while a first-filed action is pending. *Id.* at 172. Because related actions were already pending at the time, Wood violated the first-to-file rule when he *brought* his original complaint. *Id.* The court reasoned that amending a complaint is not "bringing" a new action—it is only bringing a new complaint in an already pending action. *Id.*

9. Anti-Kickback Statute

Violations of the Anti-Kickback Statute (AKS) often serve as the basis for liability under the FCA. The AKS prohibits knowingly and willfully offering, paying, soliciting, or receiving any remuneration (including any kickback, bribe, or rebate) to induce or reward referrals for items or services reimbursable under a federal healthcare program. 42 U.S.C. § 1320a-7b(b).

In January 2018, the Third Circuit joined other circuits by holding that for a relator to prevail on summary judgment, they must provide evidence of at least one false claim linked to the alleged kickback scheme. *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89 (3d Cir. 2018). In *Greenfield*, the relator alleged the defendant, a specialty pharmacy providing services for patients diagnosed with hemophilia, paid kickbacks in the form of donations to two hemophilia-related charities and afterwards submitted claims to the government certifying compliance with the AKS, thereby violating the FCA. The district court granted summary judgment for the defendant after the relator failed to provide evidence that at least one of the 24 federal claims for reimbursement was linked to the alleged charity donation kickback scheme. The Third Circuit affirmed, holding the relator "must point to at least one claim that covered a patient who was recommended or referred to [defendant] by [one of the charities]." *Id.* at 99. The Third Circuit also rejected the relator's assertion that the taint of kickbacks rendered every claim as false. Again, focusing on the necessity of a link, the court maintained a "kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient." *Id.* at 100.[7]

[7] The Third Circuit, however, rejected the district court's holding that the phrase "resulting from" in the AKS requires "but for" causation. Instead, the Third Circuit adopted the rule that the relator must only prove one of the claims sought reimbursement for services provided in violation of the AKS. 880 F.3d at 96–98.

Another important decision at the summary judgement stage came out of the Northern District of Illinois. *United States v. Novak*, 2018 WL 4205540 (N.D. Ill. Sept. 4, 2018). Edward Novak, the former CEO of Sacred Heart Hospital, was convicted of violating the AKS for paying kickbacks to physicians in exchange for the referral of Medicare and Medicaid patients to Sacred Heart. Subsequently, the government filed an FCA action against Novak related to the same kickback scheme seeking treble damages. In its motion for summary judgement, the government contended collateral estoppel barred the defendant from contesting liability for the FCA claim. Essentially, the government argued, because the defendant was guilty of violating the AKS, he could not deny liability for the FCA claim arising out of the same conduct. The district court disagreed, holding that FCA and AKS convictions require different elements of proof. Because "the elements that the jury had to find [for the AKS conviction] did not include false statement or fraud," summary judgment was denied. *Id.* at *2.

Finally, the Eleventh Circuit explored the scope of the statutory employee safe harbor, one of the many exemptions found in the AKS that protects legitimate business behavior. *Carrel v. AIDS Healthcare Found.*, Inc., 898 F.3d 1267 (11th Cir. 2018). The employee safe harbor applies to "any amount paid by an employer to an employee . . . for employment in the provision of covered items or services." 42 U.S.C. § 1320a-7b(b)(3)(B). In *Carrel*, the relators, former employees of AIDS Healthcare Foundation, Inc. ("AHF"), alleged that AHF provided kickbacks in the form of financial incentives paid to employees for referring HIV-positive patients to other healthcare services provided by the defendant. 898 F.3d at 1269. The district court dismissed most of the claims for lack of particularity because the relators relied on general allegations of the scheme. For the two remaining claims, the district court granted summary judgment because although the remaining claims specifically cited representative false claims where employees were paid money for referrals, the court held these claims fell under the employee safe harbor. The Eleventh Circuit affirmed, holding that AHF was entitled to pay bonuses to employees for referrals to AHF services. Relying on the plain text of the statute, the court found "the employee exemption plainly covers the payments." *Id.* at 1274. The employee safe harbor is meant to be broad since, as the court pointed out, it "covers 'any amount paid by an employer to an employee' without specifying the terms, method, or frequency of payment." *Id.*

10. Retaliation Against Whistleblowers

To protect whistleblowers, the FCA has an anti-retaliation provision that imposes liability on an employer if an employee is "discriminated against in the terms and conditions of employment because of lawful acts done by the employee . . . in furtherance of . . . efforts to stop one or more violations of [the FCA]." 31 U.S.C. § 3730(h)(1). To maintain a retaliation action, an employee must prove that (1) she engaged in a protected activity; (2) her employer knew about these acts; and (3) she suffered adverse action because of these acts.

a. Protected activity

As discussed in prior *Reviews*, courts have continued to grapple with defining the circumstances that constitute "protected activity" sufficient to trigger the FCA's anti-retaliation provision. One court explained that a clear example of "protected activity" would be "going directly to the president of a company to complain of fraudulent claims." *Uehling v. Millennium Labs., Inc.*, 2018 WL 2149312, at *3 (S.D. Cal. May 10, 2018). But while conversations with employers that raise specific objections to fraud are likely sufficient, voicing only general complaints or concerns likely is not. *See United States ex rel. Branscome v. Blue Ridge Home Health Servs., Inc.*, 2018 WL 1309734, at *5–6 (W.D. Va. Mar. 13, 2018). The relator in *Branscome* expressed general dissatisfaction with a physical therapist's care, but the court held that this did not constitute "protected activity" as there was no specific reporting of fraud or billing concerns. *Id.* at *6.

In addition, to satisfy the first element, a relator need not prove an underlying FCA violation. Rather, courts have held that a relator's good faith belief may be sufficient. For example, in *United States ex rel. Kietzman v. Bethany Circle of King's Daughters of Madison, Indiana, Inc.*, the district court explained that the key question is whether "(1) the employee in good

faith believes, and (2) a reasonable employee in the same or similar circumstances might believe, that the employer is committing fraud against the government." 305 F. Supp. 3d 964, 981 (S.D. Ind. 2018) (quoting *Fanslow v. Chi. Mfg. Ctr., Inc.*, 384 F.3d 469, 480 (7th Cir. 2004)).

Similarly, the Sixth Circuit upheld a retaliation claim based on a relator's reasonable belief that fraud occurred even where the relator had not sufficiently pleaded a specific FCA violation. *United States ex rel. Crockett v. Complete Fitness Rehab., Inc.*, 721 F. App'x 451 (6th Cir. 2018). In *Crockett*, an occupational therapist was fired for resisting her employer's instructions to engage in billing practices the therapist believed violated the FCA. *Id.* at 455. The therapist never alleged specific instances of false claims, which, in the employer's eyes, required dismissal of the therapist's retaliation claims. *Id.* at 460. However, the Sixth Circuit noted that whistleblowers are not required to prove that the employer actually engaged in fraud. *Id.* at 461. Instead, an employee must show only that "her allegations of fraud grew out of a reasonable belief in such fraud." *Id.*

b. Employer's knowledge

The second element of an FCA retaliation claim requires that the employer know of the whistleblower's protected activity. The Tenth Circuit affirmed summary judgment for an employer where there was no evidence that the employer had actual knowledge of an employee's complaints of falsification of records. *Armstrong v. The Arcanum Grp., Inc.*, 897 F.3d 1283, 1288–89 (10th Cir. 2018). In *Armstrong*, the relator had allegedly told a fellow employee and a team leader about her concerns that records were being falsified, but there were no allegations that the relator's supervisor—the individual responsible for terminating the relator—knew about her concerns. *Id.* The Tenth Circuit explained that a jury could not infer that employees other than the relator must have told the supervisor about relator's concerns, as such an inference would be "improper speculation." *Id.* at 1288. Nor could the supervisor be deemed constructively knowledgeable based on principles of agency law. *Id.* at 1289–91.

The issue of actual notice also comes into play where an employee's alleged protected activity falls within his or her regular responsibilities. In such cases, some courts have held that an employee must "overcome the presumption that [she is] merely acting in accordance with [her] employment obligations to show that the employer was put on notice." *E.g.*, *Singletary v. Howard Univ.*, 2018 WL 4623569, at *3 (D.D.C. Sept. 26, 2018); *United States ex rel. Hutchins v. DynCorp Int'l, Inc.*, 2018 WL 4674577, at *21 (D.D.C. Sept. 28, 2018).

In *Singletary*, the relator's standard role as employee was to "'bring the institution into compliance' with applicable federal regulations." 2018 WL 4623569, at *3. Thus, to satisfy the "protected activity" and knowledge elements, she needed to differentiate the complaints underlying her retaliation claim from her regular responsibilities. But the district court dismissed her claim as she had only provided "sparse allegations—without further detail of who she informed or what she said." *Id.*

Similarly, in *Hutchins*, the relator's day-to-day job was to "review[] [the defendant]'s compliance with regulatory and contractual requirements." 2018 WL 4674577, at *21. As in *Singletary*, the district court dismissed the relator's retaliation claim where "he did not describe the[] activities as fraudulent when he reported them to his superiors," "he did not step outside the usual chain of command to express his concerns, and he did not inform the [defendant] of the alleged fraud until after he had been terminated." *Id.*

On the other hand, one district court explicitly rejected this heightened notice burden. *Malanga v. New York Univ.*, 2018 WL 333831 (S.D.N.Y. Jan. 9, 2018). In *Malanga,* the relator was a "fraud alert" employee—that is, an employee whose job responsibilities include detecting fraud. *Id.* at *1. The district court held that "a fraud-alert employee does not have to offer any more evidence of notice than a non-fraud alert employee" as the court did not want to "impose a hardship on a class of plaintiffs who were subject to retaliation simply because they were doing their job." *Id.* at *2.

c. Causation

With respect to the third element, the Third Circuit clarified that the phrase "because of" in § 3730(h) requires that the retaliation would not have occurred "but for" the employee's protected activity. *DiFiore v. CSL Behring, LLC*, 879 F.3d 71, 76 (3d Cir. 2018). In *DiFiore*, a former employee argued that she should only have to prove that her protected activity was a "motivating factor" in the adverse actions taken by her former employer. 879 F.3d at 76. In upholding the higher standard of causation, the Third Circuit leaned on the Supreme Court's analysis of identical language in federal age discrimination and civil rights statutes, as well as traditional tort causation principles. *Id.* at 77. Other courts have considered the causation standard, but some have sidestepped a final determination, possibly setting up a future Supreme Court decision regarding the meaning of the statutory phrase "because of." *See, e.g.*, *Heath v. Indianapolis Fire Dep't*, 889 F.3d 872, 874 (7th Cir. 2018).

Courts in 2018 have also dealt with disputes about whether an employer's actions constituted an "adverse action," with many decisions turning on whether the actions against the employee were "materially adverse"—that is, actions that "might have dissuaded a reasonable worker from [engaging in protected activity]." *E.g.*, *United States ex rel. Herman v. Coloplast Corp.*, 295 F. Supp. 3d 37, 42 (D. Mass. 2018). Placing an employee on leave and filing meritless counterclaims against that employee are materially adverse actions that might reasonably deter employees from engaging in protected activity. *Id.* at 43–45. Conversely, reassigning an employee's job duties might not be a materially adverse action under the circumstances. *Id.* at 44.

Relatedly, the Sixth Circuit appeared to eliminate the requirement in § 3730(h)(1) that an employer have a "retaliatory motive" to satisfy the third element of a retaliation claim. *Smith v. LHC Grp., Inc.*, 727 F. App'x 100, 106 (6th Cir. 2018). In *Smith*, an employee discovered allegedly fraudulent billing practices and reported this discovery to management. *Id.* at 103. Management failed to change the practices and the employee resigned, deciding that her continued employment would make her a party to an illegal scheme. *Id.* The Sixth Circuit reversed dismissal of the retaliation claim, explaining that the FCA's retaliation provision does not require the relator to prove that her employer had a specific subjective intent of forcing her to quit, but rather contemplates a "more general intent that takes into account all of the circumstances in addition to the employer's 'specific intention.'" *Id.* at 102, 110.

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