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False Claims Act
2020 Year in Review

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CONTENTS

WITH ONLY TWO FCA SETTLEMENTS EXCEEDING **$100 MILLION** IN 2020, DOJ'S **$2.2 BILLION IN TOTAL 2020 RECOVERIES** PALES IN COMPARISON TO PAST YEARS.

INTRODUCTION

This year saw substantial activity in FCA settlements and litigated court cases. Although no single case or development dominated the discourse this year, several important court decisions were issued, including two that may warrant Supreme Court attention in 2021. Multiple settlements demonstrated that notwithstanding the investigatory challenges presented by the global pandemic, DOJ and other authorities continue their focus on FCA enforcement.

The year saw significant cases showcasing the government's enforcement priorities. Enforcement of the Anti-Kickback Statute (AKS) through FCA actions clearly remains an area of focus for DOJ and a significant risk for many companies. The two largest FCA settlements of the year were based on alleged AKS violations. In January, DOJ announced a criminal and civil global resolution with a health information developer accused of soliciting and receiving kickbacks from drug manufacturers in exchange for manipulating its electronic health record program to increase prescriptions for the manufacturers' opioid drugs. The company agreed to pay $118.6 million to settle FCA liability. In July, DOJ announced the largest FCA settlement of the year — $642 million — against a pharmaceutical company for allegedly funneling physician kickbacks through its speakers program and improperly paying patient copayments thru charitable foundations. DOJ also filed suit against two pharmaceutical manufacturers alleging they conspired with purportedly independent foundations to illegally subsidize Medicare copayments for the drug Copaxone in violation of the AKS.

DOJ also announced settlements with several nursing home companies in 2020. These settlements included allegations of "upcoding" therapy RUG scores or providing unnecessary rehabilitation services to inflate RUG scores. Such matters included settlements of $15.4 million and $9.5 million in February, $10 million and $4 million in April, and $16.7 million in July. Also in the category of therapy RUG-related settlements, the 11th Circuit partially reinstated a jury verdict against a rehabilitation company that could result in over $260 million in liability.

DOJ continued its pursuit of Medicare Advantage plans this year by filing suit against Anthem, Inc. in April 2020, alleging the company engaged in retroactive chart reviews to add diagnosis codes that would increase plan payments, but intentionally failed to delete inaccurate diagnosis codes that led to unjustifiably high payments under the plan. Ominously foreshadowing the amount of damages at stake in such cases, DOJ alleged that the inaccurate codes generated $100 million or more per year in excess revenues for the company. This case is especially significant because it appears to be a DOJ-generated case as opposed to a whistleblower complaint, demonstrating that DOJ is actively investigating and pursuing such cases on its own initiative.

As demonstrated in the summaries below, the courts were also active in 2020, with important appellate decisions in the areas of medical necessity, government authority to dismiss, binding authority of sub-regulatory guidance, and materiality. Two appellate courts addressed the *AseraCare* question of whether competing expert medical opinions can serve as evidence of falsity in cases based on whether a service was medically necessary. These cases prompted petitions for a *writ of certiorari*, potentially setting up a Supreme Court showdown later this year. Appellate courts brought further clarification to the government's dismissal authority under 31 U.S.C § 3730(c)(2)(A), suggesting in the process that the timing of the government's attempt to dismiss a case over relator's objection can be critical to the standard applied.

By the numbers, the 2020 enforcement environment appears as busy if not as fruitful as in years past. Although the total amount of FCA recoveries in 2020 was the lowest since 2008, the number of newly received referrals, investigations, and *qui tam* actions increased from 2018 and 2019. Notably there was a significant spike in new non-*qui tam* investigations. The relatively lower recovery, therefore, doesn't stem from lack of enforcement activity but from fewer blockbuster settlements. With only two FCA settlements exceeding $100 million in 2020, DOJ's $2.2 billion in total 2020 recoveries pales in comparison to past years.

Once again, healthcare led the way from an industry perspective, accounting for $1.8 billion — over 81% of the $2.2 billion total recovered. Government contractors involved in various types of procurement represented a significant portion of the remaining recoveries. The *qui tam* provisions of the FCA, which allow whistleblowers to initiate cases on behalf of the government against alleged violators, remain the most common vehicle for FCA claims. Whistleblowers filed 672 cases in FY2020, and their recoveries accounted for over $1.6 billion of the total.

The DOJ also emphasized its continued efforts to hold individuals accountable under the FCA, citing several notable multimillion-dollar settlements with doctors and government contractor owners in its announcement of 2020 FCA results. DOJ's continued pursuit of individual accountability represents a key risk for doctors and other healthcare providers, as well as industry executives doing business with the government.

As we continue to watch for new trends in 2021, we review the key decisions and policy developments from 2020.

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. While less discussed, the FCA also requires a showing of proximate causation between the defendant's action and the damages incurred.

A. 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 an express certification but rather that the act of submitting a claim for reimbursement itself implies compliance with some provision that is a precondition to payment.

U.S. ex rel. Druding v. Care Alternatives, 952 F.3d 89 (3rd Cir. March 4, 2020)

In this hospice eligibility case, the Third Circuit staked out a position opposed to the 11th Circuit's holding in the 2019 *AseraCare* case covered in our 2019 FCA Year in Review. Specifically, the Third Circuit held that a physician's medical judgment with respect to a patient's hospice eligibility could be subjectively false and can be the subject of a battle of the experts to establish falsity.

For Medicare and Medicaid patients to receive federal hospice benefits, a physician must certify that the patient has a terminally ill prognosis with a life expectancy of six months or fewer. Victoria Druding and other relators were former employees of Care Alternatives, a hospice service provider in New Jersey.

In their complaint, the relators alleged that Care Alternatives fraudulently submitted Medicare and Medicaid claims for ineligible hospice patients.

After the government declined to intervene, relators proceeded in the litigation. During discovery, the parties offered competing medical-expert testimony regarding the patient's hospice eligibility. Relying on the reasoning in *United States v. AseraCare, Inc.,* 176 F. Supp. 3d 1282 (N.D. Ala. 2016), the district court found that a mere difference of opinion between experts about the prognosis was insufficient to show falsity. As a result, it granted summary judgment for Care Alternatives.

The Third Circuit reversed, specifically "reject[ing] the District Court's objective-falsehood requirement for FCA falsity" that the lower court had adopted from *AseraCare*.

The Third Circuit explained that the district court improperly conflated the falsity and scienter elements of the FCA. In particular, the court found that objectivity of a medical opinion is relevant to proving scienter, not falsity, and that the district court inappropriately conflated both by requiring the relators to provide "evidence that the physician knowingly made false determinations" to prove falsity. Additionally, the Third Circuit found that a medical expert's opinion can be evidence of non-compliance with regulations and that non-compliance with regulations can give rise to legal falsity and FCA liability — regardless of the claim's factual correctness. In doing so, it departed with the 11th Circuit's opinion in *AseraCare* — issued shortly before oral argument in this case — which limited the falsity inquiry to "the accuracy of the physician's clinical judgment regarding terminality." The Third Circuit found this formulation inappropriately limited falsity to "factual falsity" and, contrary to the 11th Circuit's view, that subjective medical opinions can be "false" under the FCA.

Winter ex rel. U.S. v. Gardens Regional Hosp. & Med. Ctr., 953 F.3d 1108 (9th Cir. March 23, 2020)

The Ninth Circuit also weighed in on the question of objective falsity in a medical necessity case. Jane Winter, a registered nurse, alleged that Gardens Regional Hospital and other providers submitted medically unnecessary inpatient claims to Medicare. The District Court for the Central District of California held that "subjective medical opinions… cannot be proved objectively false" and that Winter therefore failed to state a claim under the FCA.

The Ninth Circuit reversed, finding that the FCA does not require proof of "objective falsity." The court held that a doctor's clinical judgement could be false under the FCA if the clinical judgment "implies the existence of facts that do not exist, or if it is not honestly held." In this case, the Ninth Circuit held that Winter alleged "more than just a reasonable difference of opinion" when she presented statistical data on 65 claims that were medically unnecessary under Garden Regional Hospital's own admission criteria.

In holding that a false certification of medical necessity can give rise to FCA liability, the Ninth Circuit joins similar holdings in the Fifth, 10th, and Third Circuits. In joining those courts, the Ninth Circuit distinguished *United States v. AseraCare* in the 11th Circuit.

U.S. ex rel. Vatan v. QTC Medical Services, Inc., 812 F. App'x 485 (9th Cir. July 10, 2020)

QTC Medical Services, Inc. contracted with the Department of Veterans Affairs to review certain VA files. Relator David Vatan later alleged that QTC submitted false claims related to that work because (1) it falsely certified that it reviewed entire claims folders when it had not and (2) had generally conducted a deficient review under the terms of its contract with the VA.

The District Court for the Central District of California granted summary judgment for QTC, finding that the false-certification claim failed. Specifically, the district court held that QTC's answering "yes" to a certification question without first reviewing the entire file was not objectively false under the FCA when there is no requirement to review each page before answering. Vatan appealed.

On appeal, the Ninth Circuit affirmed. In a brief opinion, the Ninth Circuit held that Vatan could not establish a "false statement or fraudulent course of conduct" as required for liability under the FCA. The court found no issue with QTC's training guide, which instructed analysts to use the "process of elimination" to review the entire claims file. Such a process, the court held, was not inconsistent with answering "yes" and was not an example of an objective falsehood for FCA purposes. Further, the court held that Vatan's general allegation that QTC's performance was deficient was unactionable for FCA purposes as it was "untethered to any specific false representation."

B. Materiality

U.S. ex rel. Janssen v. Lawrence Memorial Hospital, 949 F.3d 533 (10th Cir. Feb. 7, 2020)

Relator Stacey Janssen brought an FCA complaint against Lawrence Memorial Hospital (LMH) alleging that LMH engaged in two separate schemes in violation of the FCA: First, Janssen contended that LMH falsified patient arrival times to increase Medicare reimbursement under certain pay-for-reporting and pay-for-performance programs, and, second, Janssen contended that LMH falsely certified compliance with education requirements of the Deficit Reduction Act (DRA) to receive Medicare reimbursements to which it was not entitled. The government declined to intervene. The district court granted summary judgment in favor of LMH on the FCA's materiality requirement, and Janssen appealed.

On appeal, the 10th Circuit affirmed the district court's decision, finding that false statements about patient arrival times and compliance with the DRA were not material to the government's decision to pay Medicare claims. In analyzing the materiality requirement, the 10th Circuit, relying on the Supreme Court's decision in *Universal Health Services, Inc. v. U.S. ex rel. Escobar,* 136 S. Ct. 1989 (2016), rejected relator's argument that materiality should be based on either an objective or subjective analysis that does not focus on the actions of the specific recipient of the information at issue in the case. Instead, the court found *Escobar* requires a "holistic" inquiry into "the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." The court focused on three central factors in this inquiry that were noted in *Escobar*: 1) whether the government consistently refuses to pay similar claims based on non-compliance with the provision at issue, or pays such claims despite knowledge of non-compliance; 2) whether non-compliance goes to the "very essence of the bargain;" and 3) whether the government specifically identified the provision as a condition of payment. Because the 10th Circuit agreed that the alleged violations were not likely to affect the decision of the government, it affirmed the district court's decision.

The court's analysis reinforces *Escobar's* materiality analysis as a heavily fact-specific analysis focused on the government's past reaction to non-compliance with the provisions at issue.

Barnes ex rel. U.S. v. Clark County, 800 F. App'x 582 (9th Cir. Apr. 10, 2020)

Relator Cheryl Nolte Barnes alleged that municipal defendants made false statements to the Federal Aviation Administration (FAA) in grant and Passenger Facility Charge applications. The Ninth Circuit affirmed dismissal of Barnes' complaint, because, in support of the FCA's materiality element, Barnes cited "a long

list of statutes, regulations, and policies" but failed to plausibly allege that the FAA "placed significant weight" on the defendants' certification of compliance with particular statutory provisions when approving each application for funds.

In addition the court noted that, even if the defendants had historically violated ordinances when acquiring title to the airspace, thereby making the broad-reaching certifications theoretically false, such "past noncompliance could not have been material to the FAA's decision to approve the County's subsequent applications—none of which appears to involve projects implicating Ordinance 1599." Specifically, the court held that the scope of certifications should be limited to compliance with the relevant statutory provisions as the law related to each specific application for funds — whether the defendants "had complied with the provisions in every prior application for federal funding" could not plausibly be material.

U.S. ex rel. Porter v. Magnolia Health Plan, Inc., 810 F. App'x 237 (5th Cir. Apr. 15, 2020)

Relator Gwendolyn Porter, a registered nurse, alleged that her former employer, a contractor for the Mississippi Division of Medicaid, violated the FCA by using professional nurses for tasks that purportedly required the expertise of registered nurses. Affirming the district court's dismissal of Porter's complaint for lack of materiality and finding further amendment futile, the Fifth Circuit emphasized *Escobar's* mandate that the FCA is not "an all-purpose antifraud statute."

Although the contracts between the defendant and Medicaid required compliance with all applicable federal and state law and the policies, rules, and regulations of the Mississippi Division of Medicaid, the court found such "boilerplate language" insufficient to demonstrate that the staffing of care and case management positions was material to payment where the contracts did not specifically address the qualifications of those positions. Further, the Fifth Circuit noted, as particularly indicative of Porter's inability to ever plead materiality, the fact that the Mississippi Division of Medicaid took no action after Porter informed it of the defendant's alleged illegal staffing, choosing instead to continue paying and renewing its contract with the defendant even after the lawsuit was unsealed.

Porter has appealed the court's dismissal.

U.S. ex rel. Ruckh v. Salus Rehabilitation, 963 F.2d 1089 (11th Cir. June 25, 2020)

In *Ruckh*, the 11th Circuit largely reinstated a jury verdict that, once damages were trebled and penalties applied, reached a nearly $350 million judgment against two skilled nursing facilities and affiliated management companies. Previously, the district court had set aside the verdict, characterizing the evidence as a "handful of paperwork defects."

On appeal, the 11th Circuit first addressed whether a litigation financing agreement that Ruckh, the relator, had entered deprived her of standing. The court held that she maintained sufficient interest to pursue the appeal because the FCA does not explicitly prohibit such agreements; she sold only a small 4% interest in her share of the judgment; and she retained, under the agreement, sole authority to control the litigation.

Turning to materiality, the 11th Circuit held that evidence of the facilities' submission of false claims to Medicare through upcoding and ramping (driving up reimbursement by timing spikes in treatment to coincide with certain assessment periods) satisfied the *Escobar* materiality standard. These violations were material, the court held, because they affected the amount of payment the facilities received. In contrast, the facilities' absence of comprehensive care plans for Medicaid claims failed to satisfy the materiality standard. Not only was there no evidence that Medicaid declined payments for these types of violations, there was also evidence that, despite the facilities' self-reporting these violations, Medicaid continued to pay the claims. Ultimately, of the original $115 million in damages, the court reinstated the jury's verdict on $85 million in Medicare claims, with instructions to treble and apply statutory penalties to these damages.

On August 27, 2020, the 11th Circuit declined to reconsider the case *en banc*.

United States v. Strock, 982 F.3d 51 (2d Cir. Dec. 3, 2020)

In the Second Circuit, the federal government successfully reversed a district court dismissal of their action. The United States had brought an action under the FCA and federal common law against defendants Lee Strock, Cynthia Ann Golde, Strock Contracting, Inc., and Kenneth Carter alleging that the defendants had fraudulently set up a company (VECO), putatively owned by a service-disabled veteran, in order to apply for and receive valuable federal contracts reserved for small businesses owned by service-disabled veterans. According to the government, these contracts were then funneled to Strock Contracting, Inc., contracts that it otherwise would not have qualified for. The district court granted defendants' motion to dismiss, holding among other reasons that the government had failed to adequately plead materiality because they did not allege that the misrepresentation was material to the government's decision to pay VECO.

On appeal, the Second Circuit held that the government had adequately pled materiality, holding that the materiality standard

established by *Universal Health Services, Inc. v. United States ex rel. Escobar* (136 S. Ct. 1989) provided for an expansive understanding of "payment decision" that includes both the initial contract award decision and the ultimate payment on that contract. Rejecting the defendant's argument that the ultimate payment alone was dispositive, the court held that both pieces of the payment decision could be evidence of materiality, either independently or together. Here, the court held that the government had adequately pled that VECO's misrepresentation was material to the government's decision to award the contract, as the government had expressly stated that being a service-disabled veteran-owned small business was a condition of eligibility, and by illustrating the steps and efforts taken by the government to ensure that the applicant was owned by a service-disabled veteran prior to awarding the contracts.

On remand, the court directed the district court to reconsider the claims in light of this broader definition of "payment decision," further indicating that *Escobar's* standard is to be interpreted under an expansive lens.

U.S. ex rel. Gardner v. Vanda Pharmaceuticals, Inc., No. 17-cv-00464, 2020 WL 2542121, (D.D.C. May 19, 2020)

Relator Richard Gardner filed suit under the FCA against Vanda Pharmaceuticals, Inc., alleging that Vanda submitted numerous false claims to both Medicare and Medicaid by promoting and marketing two of its drugs, Fanapt and Hetlioz, for off-label uses. The government declined to intervene, and Vanda filed a motion to dismiss.

Applying *Escobar's* materiality standards in the misbranding context, the court found that relators' allegations "do not give rise to a plausible inference that the off-label prescription of Fanapt and Hetlioz was material to the government payment decisions under either the Medicare or Medicaid programs." The court acknowledged that Medicare Part D's statutory language limited a "covered Part D drug" to those used "for a medically accepted indication," which required FDA approval or inclusion in a statutorily recognized drug compendium. Nonetheless, the court stated that, even if on-label use were a condition of payment under the Medicare program, Gardner failed to plead sufficient facts to establish materiality, such as whether the government had actual knowledge that the use was off-label and whether the government regularly pays these types of claims despite knowledge of off-label use. The conclusory pleading that government payors would not have covered the prescriptions if they had known about the off-label uses was not sufficient.

[T]he facilities' absence of comprehensive care plans for Medicaid claims failed to satisfy the materiality standard. Not only was there no evidence that Medicaid declined payments for these types of violations, there was also evidence that, despite the facilities' self-reporting these violations, Medicaid continued to pay the claims.

U.S. ex rel. Goodman v. Arriva Medical, LLC, 471 F. Supp. 3d 830 (M.D. Tenn. July 8, 2020)

Arriva Medical, LLC was a diabetic-testing supply company. Relator Gregory Goodman filed a *qui tam* complaint alleging various theories of liability under the FCA. After the government intervened, it filed a new complaint alleging that Arriva submitted false claims by (1) waiving its customers' Medicare copayment and deductible obligations in violation of the Anti-Kickback Statute (AKS), (2) billing Medicare for supplies provided to deceased customers, and (3) billing for glucose meters in violation of Medicare's so-called five-year rule. The parties disputed whether Arriva could discover evidence of the government's treatment of other suppliers engaged in conduct similar to that alleged in the complaint. Arriva argued that the requested discovery was relevant to whether its alleged conduct was material to the government's decision to pay, a requirement for FCA liability.

In resolving a motion to compel, the district court denied Arriva's request for evidence of the government's treatment of other suppliers alleged to have waived copayments and deductibles in violation of the AKS because materiality is statutorily established for AKS-based FCA claims. The court also rejected Arriva's request for discovery related to the government's treatment of suppliers that billed for deceased customers because these claims were facially false and, as such, were necessarily material to the government's decision to pay.

In contrast, the court permitted discovery of the government's prior tolerance for violations of the five-year rule. The court first observed that the five-year rule fit "fairly neatly into the *Escobar* mold." In permitting the discovery on this claim, the court rejected the government's argument that the materiality of the five-year rule violation was undisputed. Even though Arriva knew Medicare frequently denied its claims filed in violation of the rule, Medicare was not necessarily giving other suppliers the same treatment. The court explained that "[i]t would significantly undermine the holding of *Escobar* if the government could manufacture an illusion of indisputable materiality simply by being extra strict ahead of time with whichever company the government wished to sue." The court concluded by ordering the parties to meet and confer regarding the government's production of discovery on the five-year rule claim.

Bradley Arant Boult Cummings LLP represents two codefendants in this matter. Neither was involved in this motion.

C. Knowledge

1. Failure to Plead

Adomitis ex rel. U.S. v. San Bernardino Mountains Community Hospital District, 816 F. App'x 64 (9th Cir. May 20, 2020)

Relator Frank Adomitis brought an FCA complaint against San Bernardino Mountains Community Hospital District alleging that the hospital district filed for Medicare reimbursements at rates for which it was not qualified. Specifically, these reimbursements were authorized only for Critical Access Hospitals (CAHs). The district court granted the hospital district's motion to dismiss the third amended complaint for failure to state a claim because Adomitis failed to adequately plead the knowledge element.

On appeal, the Ninth Circuit affirmed the district court's decision, concluding that despite the overly narrow scope of the district court's knowledge inquiry, Adomitis failed to allege sufficient facts to make it plausible that the hospital district knew, recklessly disregarded, or was deliberately ignorant of a false statement or fraudulent course of conduct with respect to the CAH distance requirement's "mountainous terrain" criterion. The mountainous terrain criterion allows a state to designate a facility a CAH if sufficient distances of roads between the hospital and the next nearest hospital fit the definition of mountainous terrain. In concurrence, Judge Daniel Collins commented on the interpretation of the statute at issue, stating that under a natural reading, the distance requirement for CAH can be satisfied by a combination of mountainous terrain and secondary roads.

Although Rule 9(b) states that scienter can be generally pled, the case suggests that when faced with a facially ambiguous or complicated statute, plaintiff must plead sufficient facts to make it plausible the defendant acted with reckless disregard as opposed to a reasonable interpretation or an honest mistake about the meaning of the regulation or statute.

U.S. ex rel. Complin v. North Carolina Baptist Hospital, 818 F. App'x 179 (4th Cir. June 15, 2020)

In *Complin*, a former employee of North Carolina Baptist Hospital (NCBH) alleged, among other things, that NCBH submitted false reports to Medicare related to its self-funded health benefits plan for its own employees. The allegation implicated the Related Party Rule for plans administered by third-party administrators, which requires hospitals to report their costs for providing care to their own employees as "related party transactions," and submit for Medicare reimbursement only their actual, out-of-pocket costs rather than the amount charged. Complin contended that by submitting reports to Medicare that did not comply with the Related Party Rule, NCBH knowingly presented false or fraudulent claims in violation of the FCA.

The district court granted NCBH's motion to dismiss Complin's complaint with prejudice, holding that Complin failed to meet the FCA's rigorous scienter requirement. Specifically, the lower court stated Complin's allegations were "conclusory and unsupported," which is insufficient to state a claim under the FCA.

On de novo review, the Fourth Circuit agreed with the district court that Complin failed to adequately plead scienter. "The disregard of a federal regulation, by itself, does not create liability under the Act." Complin's claim of Medicare fraud was missing specific facts

to support an inference of scienter, and failed to allege facts from which the court could infer knowledge on the part of the hospital. For example, if NCBH employees had conversations about the regulatory violations or NCBH instructed employees to ignore concerns about potential violations, then Complin may have properly plead scienter. But the court cautioned that this does not mean that a violation of an ambiguous regulation can never give rise to FCA liability. Rather, under these circumstances, NCBH's actions did not compel an inference that it acted with knowledge, deliberate ignorance, or reckless disregard.

2. Reasonable Interpretation of Ambiguous Guidance

U.S. ex rel. Drummond v. Best Care Laboratories Services, LLC, 950 F.3d 277 (5th Cir. Feb. 17, 2020)

Best Care Laboratories provided clinical testing services to nursing-home residents, many of whom were Medicare patients. After a billing manager for Best Care left and joined a competitor firm, the competitor — relator Drummond — learned about Best Care's billing practices and believed they were improper. Thereafter, Drummond brought an FCA whistleblower lawsuit against Best Care.

The whistleblower complaint alleged, among other things, that Best Care wrongfully billed Medicare for technician travel that did not actually occur. The government intervened, substantiated the claims, and filed two partial motions for summary judgment that were granted. In response, Best Care argued that its billing practices were lawful based on CMS policy manuals. The district court held that Best Care's reliance on unclear guidance in a policy manual was erroneous because policy statements do not override clear statutory language and that it was illogical to believe that the government should pay for travel that did not occur. The district eventually granted both partial motions for summary judgment (one based on common-law theories of unjust enrichment and payment by mistake and the other based on violations of the FCA.)

Best Care and its owner appealed the second partial motion for summary judgment, contesting the amount of damages awarded for travel billed to the government for trips travel that did not include technicians. Best Care admitted that technicians did not complete the travel but argued that their billing practices were lawful and, in the alternative, that they did not have the *scienter* to satisfy the FCA's knowledge requirement because they believed their actions were permissible.

The Fifth Circuit affirmed the lower court's holding that Best Care violated Medicare regulations by billing for travel that did not occur regardless of whether there was a policy statement that created some ambiguity on the topic; policy statements do not trump clear statutory language. The court rejected Best Care's argument that it did not have the requisite *scienter*, finding that Best Care's reading of the CMS guidance manual was not reasonable. The Fifth Circuit also affirmed the holding that Best Care's CEO was personally liable for the company's billing practices because he approved them.

3. Objective Scienter

U.S. ex rel. Proctor v. Safeway, Inc., 466 F.Supp.3d 912 (C. D. Ill. June 12, 2020)

Relator Thomas Proctor alleged that Safeway violated the FCA by overbilling government programs for prescription drugs when it did not treat certain discount prices provided to customers as its "usual and customary price." In its motion for summary judgement, Safeway argued that, during the relevant time period, no authoritative legal guidance existed that defined "usual and customary" pricing as it applied to certain discounts applied to prescription drugs. Given the lack of an applicable legal standard, Safeway claimed that it reported usual and customary drug pricing in a way that was "objectively reasonable" because "the FCA prohibits only knowing violations of clearly established law."

In response, the relator argued that Safeway did not act in an objectively reasonable manner because the company had ignored published guidance that warned away from the approach that Safeway took in billing government programs. The relator further argued that, in any case, Safeway could not have acted objectively reasonably because internal corporate documents showed that Safeway had "actual knowledge" that the company knew its legal interpretation of usual and customary pricing was likely impermissible.

The court granted summary judgment in favor of Safeway, holding that the objective scienter standard from the Supreme Court's ruling in Safeco Insurance Co. of America v. Burr applied to the FCA (551 U.S. 47 (2007)). The court found that Safeway's application of usual and customary pricing — later determined to be impermissible — had been objectively reasonable at the time because, despite published guidance suggesting against Safeway's billing practices, the existing published guidance was not legally binding authority. Further, the court was unpersuaded by the relator's argument that Safeway could not have acted objectively reasonably because it had "actual knowledge" that its billing practices would likely not withstand legal scrutiny. According to the court, a defendant's "subjective intent" is legally irrelevant under the FCA as long the legal interpretation that is adopted is one that could have reasonably found support in the courts.

II. Specific Types of Claims

A. Anti-Kickback Statute Violations

Stop Illinois Health Care Fraud, LLC v. Sayeed, 957 F.3d 743 (7th Cir. Apr. 29, 2020)

Stop Illinois Health Care Fraud, LLC (SIHCF) brought a *qui tam* lawsuit against Management Principles, Inc. (MPI), its two home healthcare companies, its owner and manager, Asif Sayeed, and the Healthcare Consortium of Illinois (HCI). HCI is an organization that contracted with the Illinois Department of Aging to coordinate services with low-income seniors. SIHCF alleged that MPI paid HCI gift cards in exchange for access to the detailed information that HCI gathered about clients during in-home health assessments, which MPI then used to contact seniors to see if they needed home health services. HCI and SIHCF settled out of court, but the other defendants proceeded to a bench trial.

The district court granted the defendants' motion for judgment based on partial filings, holding that the plaintiff failed to show that the payments were intended to induce referrals and rejecting the plaintiff's argument that getting access to HCI's open files was essentially getting referrals for any patient MPI wanted. On appeal, the court vacated the judgment. The court discussed the broad definition of "referral" in the Seventh Circuit, which encapsulates "both direct and indirect means of connecting a patient with a provider" and includes not only "explicit recommendations" but also "more subtle arrangements." The court was unable to tell whether or not the district court applied the correct definition of "referral," so it remanded the case for the district court to make the necessary findings.

B. Retaliation

Nesbitt v. Candler County, Georgia, 945 F.3d 1355 (11th Cir. Jan. 3, 2020)

Jamie Nesbitt, an emergency medical technician, appealed the district court's grant of summary judgment of his complaint of unlawful retaliation by his former employer, Candler County Ambulance Service, after it fired him following his filing of a *qui tam* case alleging the county falsified reports to increase its Medicare billings. The district court held that Nesbitt had engaged in protected conduct but that he had not created a genuine issue of material fact that he had been fired because of that conduct. The 11th Circuit upheld the dismissal.

On appeal, Nesbitt argued that the court should apply the "motivating factor" causation standard, which would only require a showing that the protected conduct was a motivating factor in the employment decision, even if other factors also motivated the decision. However, the court found that Congress clearly intended the "but for" causation standard in the statutory language prohibiting whistleblower retaliation because it used the phrase "because of." The 11th Circuit noted that the Third and Fifth Circuits also apply the "but for" standard, whereas the Sixth, Seventh, and D.C. Circuits apply a "motivating factor" standard. The court further noted that the circuits applying the "motivating factor" standard improperly looked beyond the unambiguous plain meaning of the statute's text to consider language in the legislative history.

Bharadwaj v. Mid-Dakota Clinic, 954 F.3d 1130 (8th Cir. Apr. 3, 2020)

In *Bharadwaj*, the plaintiff was an oncologist and shareholder with Mid-Dakota Clinic. After being pushed out of his practice because of his inability to get along with his coworkers, he sued the practice, its board of directors, its CEO and several individual directors for racial discrimination and retaliation under Title VII, disability discrimination under the ADA, retaliation under the FCA, and breach of fiduciary duties. With respect to his FCA claim, Jayaram Bharadwaj claimed that he was forced to resign for engaging in a statutorily protected activity — namely his disclosure of fraudulent billing practices of another doctor to clinic management. However, the district court found no proof to support his claim that his disclosure of the alleged fraudulent billing practices was the reason the clinic pushed him out. The district court granted summary judgment to the defendants on each of Bharadwaj's claims, including his FCA retaliation claim.

On appeal, the Eighth Circuit affirmed, noting that the causation standard under the FCA is "stringent" and the retaliation must be "motivated *solely* . . . by the protected activity." The court noted that there was simply no evidence, direct or otherwise, that Bharadwaj's decision to report the allegedly fraudulent billing practices of another doctor caused, much less solely caused, the clinic to force him out.

Sherman v. Berkadia Commercial Mortg. LLC, 956 F.3d 526 (8th Cir. Apr. 14, 2020)

Richard Sherman alleged that he was terminated by his former employer, Berkadia Commercial Mortgage. Berkadia is a commercial real estate lender that specializes in mortgage loans to develop multifamily housing, many of which are insured by the Federal Housing Administration. If a developer defaults on an insured loan, Berkadia may assign the mortgage to the United States Department of Housing and Urban Development (HUD). In 2011, one of Berkadia's offices was accused by HUD of "pushing the limits" of acceptable conduct under HUD regulations. Berkadia hired Sherman as an underwriter, hoping his presence would help its relationship with federal regulators.

By 2013, Sherman was senior vice president and the chief underwriter of Berkadia's HUD group. In this role, Sherman pushed for greater

transparency with HUD, which created tension between Berkadia's production and underwriting teams. This eventually led to Sherman giving the company an ultimatum in 2016 that if the production manager was envisioned to have a prominent role, then the company should "tee up the next Organizational Change Announcement with [Sherman's] name." A few months later, Berkadia terminated Sherman, stating that the termination was performance based. Sherman filed this suit alleging retaliation under the FCA. The district court granted Berkadia summary judgment.

The Eighth Circuit affirmed the district court's grant of summary judgment on appeal. First, the court found that there was no direct evidence of retaliation, only "stray remarks in the workplace, statements by nondecisionmakers, or statements by decisionmakers unrelated to the decisional process." Sherman's evidence consisted of a statement from his direct supervisor indicating he was unhappy Sherman circumvented the chain of command and statements from his direct supervisor and others expressing disagreement with Sherman's interpretation of HUD regulations. The court then applied the *McDonnell Douglas* framework to judge the viability of FCA retaliation claims when there is no direct evidence. One prong of this framework is that the retaliation was motivated solely by the employee's protected activity, a causal link that the court noted is "tighter than that required in other types of retaliation and discrimination claims." Even though Sherman produced evidence that Berkadia management did not implement and was sometimes critical of his suggestions regarding HUD compliance, there was also evidence that Sherman's supervisors disapproved of other parts of his job performance. Accordingly, the court affirmed the district court's grant of summary judgment in favor of Berkadia on the FCA retaliation claim.

Brown v. Morehouse College, 829 F. App'x 942 (11th Cir. Oct. 23, 2020)

James Brown brought an action alleging wrongful retaliation under the federal FCA. The 11th Circuit upheld the district court's summary judgment finding that Brown had not engaged in protected activity and therefore did not have a wrongful retaliation claim.

Specifically, the court found that Brown's reports of Morehouse College's "'mismanagement of funds,' abridging 'operation guidelines,' 'financial irregularities,' 'misuse of funds,' and 'abuse of funds'" were not sufficient to ground an FCA claim and failed to raise the "distinct possibility" of FCA litigation. The court stated that "FCA liability 'arises from the submission of a fraudulent claim to the government [and] not the disregard of government regulations or failure to maintain proper internal policies'" (citing *Urquilla-Diaz v. Kaplan Univ.,* 780 F.3d 1039, 1045 (11th Cir. 2015)). Nothing Brown reported to Morehouse College, alleged in his petition, or raised in the appeal stated that Morehouse College had submitted anything

to the government. As such, Brown had not engaged in protected conduct, and there could not be an FCA violation.

In addition, the court denied Morehouse College's request for Rule 38 sanctions against Brown, stating that "a losing appeal is not synonymous with a frivolous one."

Lestage v. Coloplast Corp., 982 F.3d 37 (1st Cir. Dec. 9, 2020)

Amy Lestage was a key account manager for medical device company Coloplast Corporation. While Coloplast has between 12,000 and 16,000 sales accounts, 40 to 50 of these accounts — called key accounts — provided over 95% of Coloplast's sales. In 2011, Lestage and others filed a *qui tam* action under the FCA against Coloplast and several of Coloplast's competitors and clients, including key account Byram Health Care. When the *qui tam* complaint was unsealed in 2014 and Byram discovered that Lestage was part of it, Byram stopped replying to Lestage's emails and phone calls. Byram's CEO sent an email to Coloplast's senior vice president stating he no longer wanted to work with Lestage and requested a new key account manager. Shortly thereafter, Coloplast placed Lestage on indefinite paid administrative leave. In 2016, after Coloplast settled the *qui tam* action, Lestage was asked to return. Lestage was reassigned three of her previous accounts and four new accounts, but Coloplast did not reassign her to one account she specifically requested, even after the manager of the account left the company. The parties disputed whether the accounts were high-performing accounts that would allow Lestage to meet her growth targets.

Lestage amended her *qui tam* complaint to allege that Coloplast retaliated against her in violation of the FCA. The jury found that Coloplast had retaliated against Lestage by placing her on leave and assigning her "inferior accounts" upon her return and awarded

The Court agreed with Coloplast and several other circuits and determined that the but-for causation standard should apply to FCA retaliation claims.

her $762,525. Coloplast filed a renewed motion for judgment as a matter of law and a motion for a new trial, both of which the district court denied.

Coloplast argued on appeal that the jury instruction was in error. To state an FCA retaliation claim, the employer must have discriminated "because of" the employee's protected conduct. The jury instruction below used a "substantial motivating factor" standard, and Coloplast argued that it should instead be a but-for causation standard. The court agreed with Coloplast and several other circuits and determined that the but-for causation standard should apply to FCA retaliation claims. However, because Coloplast did not object to this instruction below and because the First Circuit had not previously decided the question, this was not plain error.

The court also affirmed the district court's denial of Coloplast's motion for judgment as a matter of law. Coloplast argued that there was insufficient evidence to support the jury's conclusion that Coloplast put Lestage on leave and assigned her accounts "because of" her protected conduct, but the court disagreed — even when applying its newly adopted but-for causation standard. Further, Coloplast argued that there was insufficient evidence that the assignment of accounts following Lestage's return was an adverse employment action. The court again disagreed and pointed to the reassignment of the account Lestage specifically requested when its manager left.

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 statute of limitations, public-disclosure bar, first-to-file rule, and government-action bar.

A. 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).

Houpt v. Wells Fargo Bank, N.A., 800 F. App'x 533 (9th Cir. Apr. 6, 2020)

Relator Charles Houpt brought a *qui tam* lawsuit against Wells Fargo Bank, alleging Wells Fargo induced the U.S. Small Business Administration (SBA) to pay a loan guarantee based on alleged "false statements and certifications to the SBA" that Wells Fargo had the right to enforce Houpt's promissory note and had complied with SBA reporting regulations. The district court granted summary judgment in Well Fargo's favor based on the statute of limitations. Houpt appealed, and the Ninth Circuit affirmed.

The Ninth Circuit found the district court did not err in granting summary judgment on the FCA claim because Houpt's claims were time barred under 31 U.S.C. § 3731(b). Under that provision, the FCA's statute of limitations provides that a civil action under 31 U.S.C. § 3730 may not be brought "(1) more than [six] years after the date on which the violation of section 3729 is committed, or (2) more than [three] years after the date when facts material to the right of action are known or reasonably should have been known." Examining these provisions, the court determined Houpt's claims were time barred under both parts of § 3731(b). First, the FCA attaches liability to the claim for payment, not the underlying fraudulent activity. Thus, the court noted, the relevant date was the date on which Wells Fargo requested that SBA purchase the guaranteed portion of the loan — April 19, 2010. Houpt did not file suit until September 2017; therefore, his claim was time barred under 31 U.S.C. § 3731(b)(1). Likewise, the claim was also time barred under § 3731(b)(2) because the SBA should have known of the material facts to the right of action when Wells Fargo repaid the loan guarantee to SBA in April 2014, which falls more than three years before Houpt filed his complaint.

B. 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. Banigan v. PharMerica, Inc., 950 F.3d 134 (1st Cir. Feb. 19, 2020)

In 2007, relators James Banigan and Richard Templin first filed their complaint under the FCA alleging, *inter alia*, that long-term care pharmacy company PharMerica, Inc. used kickbacks to induce nursing homes to purchase its drugs. In 2012, the U.S. District Court for the District of Massachusetts dismissed the majority of the relators' claims as barred by the public-disclosure bar because the allegations were substantially similar to those in an earlier *qui tam* suit against PharMerica. The relators moved for reconsideration, claiming that they were permitted to file suit as "original sources" of the information. In 2018, the district court denied the defendants' request for reconsideration, finding that the relators were not "original sources" under the FCA because they did not have direct knowledge as it was required under the statute. The district court concluded that to be considered an "original source" a person must have direct knowledge stemming from participation in, or observation of, the fraud being committed. The relators appealed the district court's decision.

On appeal, the First Circuit rejected the district court's interpretation of what constituted "direct knowledge," and found that "nothing in the statutory text limited 'direct knowledge' to knowledge gained from participation in or observation of the fraud." Instead, the only requirement is "that the person have 'direct and independent knowledge of the information on which the allegations are based,' not direct and independent knowledge of the fraudulent acts themselves." Thus, the First Circuit overruled the idea of limiting who is an original source to only those who committed the fraud or observed the fraud firsthand, noting that doing so "would exclude a relator who discovered the fraud after the fact and brought it to the government's attention."

In reversing the lower court's dismissal of the FCA action, the First Circuit explained that it did "not think that Congress intended to reward as original sources only those who participated in the fraud." The court further concluded that the district court's narrow interpretation of who can be an "original source" is "incompatible with a core purpose of the FCA—to incentivize disclosures of fraudulent activity underlying claims for reimbursement from the government."

Vierczhalek v. MedImmune, 803 F. App'x 522 (2d Cir. Mar. 18, 2020)

Dr. Susan Vierczhalek brought a *qui tam* action against MedImmune and two other healthcare service providers alleging that they violated the FCA by promoting the off-label use of one of MedImmune's drugs. Vierczhalek's suit was stayed for several years as the United States and several states weighed intervention. The United States declined to intervene, but the State of New York chose to intervene as to the claims against the other two healthcare

entities and ultimately settled those claims. The State of New York continued its investigation into MedImmune and eventually filed a complaint-in-intervention against MedImmune. However, instead of focusing on the claim of off-label promotion as alleged in the original complaint, the State of New York alleged that MedImmune had engaged in an unlawful kickback scheme with one of the other healthcare entities. Shortly thereafter, Vierczhalek filed an amended complaint, designating herself a relator on behalf of the United States and states other than New York. In her amended complaint, Vierczhalek dropped her off-label use claim against MedImmune and instead alleged that MedImmune had engaged in an unlawful kickback scheme with the other healthcare entity. The district court dismissed Vierczhalek's amended complaint finding that her complaint was substantially similar to the State of New York's complaint-in-intervention and she was not an "original source" of the allegations in the amended complaint. The district court found that Vierczhalek was precluded by the FCA's public-disclosure bar from acting as a relator.

On appeal, the Second Circuit affirmed the district court's ruling. The Second Circuit noted that the parties did not dispute that the State of New York's complaint was a "public disclosure" for purposes of § 3730(e)(4)(B). Therefore, Vierczhalek could not maintain her *qui tam* action unless she was an "original source" of the allegations made in the New York complaint. As the Second Circuit found, Vierczhalek made no such claim. Instead, she asserted that the information she provided the New York attorney general with respect to the off-label promotion should be considered "core information" sufficient to make her an "original source." However, the Second Circuit noted that a relator "cannot qualify as an original source… merely by providing some core information. Rather, she must

provide information regarding the essential elements of the alleged fraud." Vierczhalek did not do so in this case. The Second Circuit also rejected Vierczhalek's argument that her allegations against MedImmune in states other than New York "are independent of and materially add to" the State of New York's complaint qualifying her as an original source because Vierczhalek admitted that she only investigated the kickback allegations in other states *after* the State of New York brought its complaint.

U.S. ex rel. Holloway v. Heartland Hospice, Inc., 960 F.3d 836 (6th Cir. Jun. 3, 2020)

Relator Kathi Holloway alleged that Heartland, a provider of hospice services, had implemented a corporation-wide healthcare fraud scheme. The government declined intervention, and the district court eventually dismissed the suit on its merits. On appeal, the Sixth Circuit found that her suit was barred by prior public disclosure and, consequently, declined to decide whether Holloway had sufficiently pled.

The Sixth Circuit rejected the notion that prior *qui tam* actions against industry competitors were public disclosures where the competitors had no relation to Heartland and the suits did not allege an industry-wide issue. It also rejected an HHS OIG report that found that 4% of claims did not meet the requirements for certification of terminal illness. It held that to constitute a disclosure, a report must carry an "inference of wrongdoing," and for this specific report, "There is no insinuation of fraud, but at most noncompliance." The court also found that a previous *qui tam* case is a proceeding "in which the Government or its agent is a party" under 31 U.S.C. § 3730(e)(4)(A)(i), even if the government did not intervene.

The Sixth Circuit also reviewed the issue in depth and held that its pre-amendment case law on a prior case's similarity was no longer controlling. Specifically, the pre-amendment FCA barred cases that were "based upon" allegations that had been previously disclosed. The 2010 amendments changed this to barring only suits that were "substantially the same." Because the pre-amendment test in most circuits asked whether there was a "substantial identity" between two cases, several circuits held that their pre-amendment caselaw remained controlling. The Sixth Circuit found that the change in language was significant enough that its previous opinions were not controlling. But it held that pre-amendment precedent was persuasive where it explicated the general principles of the public-disclosure bar.

U.S. ex rel. Maur v. Hage-Korban, 981 F.3d 516 (6th Cir. Dec. 1, 2020)

Plaintiff-relator Dr. Gurpreet Maur brought a *qui tam* case alleging defendant Dr. Eli Hage-Korban submitted false claims to Medicare for unnecessary cardiac testing and procedures. The Sixth Circuit upheld the district court's dismissal of Maur's complaint pursuant to the FCA's public-disclosure bar, focusing its analysis on whether Maur's allegations were "substantially the same" as those exposed in a prior *qui tam* action and whether Maur was an "original source" under the FCA.

Under the public-disclosure bar, a three-step analysis is taken. First, courts ask whether, prior to the filing of the *qui tam* complaint, any public disclosures had been made from which fraud might be inferred. Second, courts assess whether the allegations in the complaint are "substantially the same" as those contained in the public disclosures. And finally, the court asks whether the *qui tam* plaintiff is an "original source of the information" such that he (1) communicated his allegations to the government prior to the public disclosure, or (2) provided "material information to the government before filing the present complaint." The court quickly determined that a settlement agreement entered into by Hage-Korban and publicly available through the inspector general's website was a public disclosure and turned its attention to the second and third prongs of the analysis.

The court recognized that the question of whether a relator's information "'materially adds' to disclosures [] 'often overlaps' with 'whether the relator's allegations are substantially the same as [] prior revelations,'" thereby muddling the analysis of the two prongs. However, it found it critical that the two concepts remain distinct so as not to render the original source exception null. As such, it addressed them in turn. The court ultimately determined that Maur's complaint against Hage-Korban alleged the exact same fraud by the exact same person as the conduct described in the public disclosure. The addition of new defendants did not change the fact that the allegations were "substantially the same." The court then held that Maur did not satisfy either definition of an original source

under the FCA. Maur did not communicate anything regarding his allegations against Hage-Korban to the government prior to the public disclosure at issue, thereby failing to meet the first definition. Further, the temporal proximity of Maur's allegations to the ongoing settlement between Hage-Korban and the government meant that any "new" allegations by Maur did not materially add to the information the government already had. Because the government was actively monitoring Hage-Korban, and the conduct alleged by Maur was the exact same as that resulting in the government's monitoring of Hage-Korban, the additional information alleged by Maur was not material.

C. 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. Alexander Volkhoff, LLC v. Janssen Pharmaceutica N.V., 945 F.3d 1237 (9th Cir. Jan. 2, 2020)

In 2016, Alexander Volkhoff, LLC filed a *qui tam* complaint against a number of pharmaceutical companies (the Janssen defendants), alleging fraudulent marketing of certain pharmaceutical products. The Janssen defendants filed a motion to dismiss the original complaint, which Volkhoff did not oppose. Instead, Volkhoff filed an amended complaint removing itself as the relator and naming anonymous person Jane Doe as the amended relator.

Notably, the amended complaint not only substituted Jane Doe for Volkhoff as the relator but failed to mention any relationship between Volkhoff and Doe. A later filing acknowledged that Doe and Volkhoff were in reality the same person and that the technical replacement of relators was a tactical decision aimed at preserving a potential FCA retaliation claim.

On motion of the Janssen defendants, the district court dismissed the amended complaint on the grounds that it lacked subject matter jurisdiction. The court reasoned that since Jane Doe's allegations were identical to those in Volkhoff's first-filed complaint, Doe was statutorily precluded from pursuing an FCA claim. The court explained that Doe was not named in the original complaint, and therefore "had no power to file the amended complaint, and could not intervene because of the first-to-file rule."

Volkhoff (not Doe) appealed the district court's decision, which the Ninth Circuit dismissed for lack of appellate jurisdiction. It found that Volkhoff was a non-party and that Doe was only a purported appellant not named in the Notice of Appeal.

> We hold that the first-to-file bar is not jurisdictional. As the Supreme Court has recently instructed, unless Congress states clearly that a rule is jurisdictional, we will treat it as nonjurisdictional.

In re Plavix Marketing, Sales Practices and Products Liability Litigation (No. II), 974 F.3d 228 (3d Cir. Sept. 1, 2020)

In 2011, two doctors and a Sanofi sales representative formed a Delaware LLP (JKJ) for the purpose of filing a *qui tam* lawsuit against a number of pharmaceutical companies (Sanofi defendants). The lawsuit alleged that the defendants misled patients about the effectiveness of the anti-clotting drug Plavix. In 2016 one of the physician members of JKJ left the partnership and was replaced by another physician. The partnership filed an amended complaint to reflect this substitution, which prompted the Sanofi defendants to move to dismiss based on the FCA's first-to-file bar. Sanofi claimed the new JKJ partnership was a different entity than the original JKJ, and therefore the amended complaint was an intervention, in violation of the first-to-file rule.

The district court agreed and dismissed the suit, citing a 2009 U.S. Supreme Court decision, *United States ex rel. Eisenstein v. City of New York*, which the court read to hold that any nonparty joining a *qui tam* suit constitutes an intervention within the meaning of the first-to-file bar. The partnership appealed to the Third Circuit.

The Third Circuit, after establishing that the first-to-file bar is not jurisdictional, noted that other circuits misinterpret *Eisenstein* if they conclude that "any time a party enters (or becomes a party in) a lawsuit, it must have intervened." The court noted "we reject this overreading," and went on to find that the text of the first-to-file bar says nothing about alternative ways in which subsequent relators might enter a previously filed *qui tam*, such as joinder, substitution of parties, or amendment of a complaint. Therefore, JKJ's pursuit of the case was not barred.

D. Qualified Immunity

U.S. ex rel. Citynet, LLC v. Gianato, 962 F.3d 154 (4th Cir. June 22, 2020)

The Fourth Circuit held that qualified immunity does not protect government officials from fraud claims under the FCA. Citynet initiated a *qui tam* action against West Virginia officials Jimmy Gianato, Gale Given, and others alleging they knowingly defrauded the federal government's Broadband Technology Opportunities Program. Defendants Gianato and Given filed a motion to dismiss asserting, *inter alia*, that they were entitled to qualified immunity. The district court declined to rule on the qualified immunity issue until further evidence could be developed on Gianato's and Given's state of mind in allegedly violating the FCA. Defendants filed an interlocutory appeal to the United States Court of Appeals for the Fourth Circuit to decide whether they were entitled to qualified immunity and whether they qualified as "persons" under the FCA.

The Fourth Circuit declined to address the second issue, finding that pendent appellate jurisdiction was not justified because whether state officials are "persons" under the FCA was neither inextricably intertwined nor necessary to ensure meaningful review of the qualified immunity issue. As to qualified immunity, the Fourth Circuit held that "qualified immunity does not protect government officials when they act to violate the law with actual knowledge, deliberate ignorance, or reckless disregard of a risk to a constitutional or statutory right." By acting intentionally or recklessly, a government official forfeits any entitlement to qualified immunity, which only protects reasonable but mistaken judgments. Additionally, the court noted that qualified immunity serves the public interest by protecting the ability of public officials to exercise independent discretion in carrying out their official duties. However, the court admonished that "while immunity should protect discretion, it must not shield fraud."

IV. Pleading and Procedure

A. Government Motions to Dismiss Under Section 3730(c)(2)(A)

In January 2018, Michael Granston, the director of the Commercial Litigation Branch, Fraud Section, issued a memo providing DOJ lawyers guidance on the factors to consider in evaluating possible dismissal of an FCA case under 31 U.S.C. § 3730(c)(20(A). Before the Granston Memo, most circuit courts were undecided on the standard to apply to government requests for dismissal. The Ninth and D.C. Circuit Courts of Appeals issued the leading cases addressing the government's authority under this section of the FCA. In *Sequoia Orange,* the Ninth Circuit required the government to demonstrate a valid purpose for the request and a rational relationship between dismissal and that purpose. By contrast, in *Swift*, the D.C. Circuit took a more deferential view and held that the government has an "unfettered right to dismiss" an FCA case.

After 2018's Granston Memo, courts have faced an increasing number of requests by DOJ to dismiss FCA cases. The uptick in government-initiated motions to dismiss has forced courts to explore the nuances of § 3730(c)(2)(A) and define the parameters of the government's power. The *Sequoia Orange-Swift* divide remains the most prevalent issue, though courts have more recently wrestled with related issues, including whether the United States must first intervene to exercise its dismissal rights, whether the timing of the dismissal request (before or after intervention) affects the applicable legal standard, and whether a district court's ruling is immediately appealable.

United States v. Acad. Mortg. Corp., 968 F.3d 996 (9th Cir. Aug. 4, 2020)

In *Academy Mortgage,* the Ninth Circuit addressed whether a district court order denying a government motion to dismiss under § 3730(c)(2)(A) was an immediately appealable collateral order. An underwriter for Academy filed a *qui tam* suit against the company claiming it violated the FCA by certifying loans for FHA insurance that did not meet the required eligibility criteria. The government declined to intervene and moved to dismiss. In doing so, the government raised a cost-benefit analysis, asserting that further litigation of the matter was not in the public interest due to the cost of discovery.

Applying the Ninth Circuit's *Sequoia Orange* test, the district court denied the motion. The court found that the government had not meaningfully assessed the "benefit" of the suit because it had not sufficiently investigated the relator's claims. The government appealed, asserting appellate jurisdiction under the collateral-order doctrine.

On appeal, the Ninth Circuit found that an order denying a motion to dismiss was outside the collateral-order doctrine. As a result, the court concluded it lacked jurisdiction and dismissed the appeal. In reaching that conclusion, the Ninth Circuit reviewed the three "stringent" requirements for the collateral-order doctrine to apply: The district court order must (1) be conclusive on the issue at hand; (2) resolve important questions separate from the merits; and (3) be effectively unreviewable after final judgment. The court focused its analysis on the second factor and found that the district court's order did not resolve "important questions" separate from the merits of the lawsuit.

Specifically, the Ninth Circuit found the government's interests under § 3730(c)(2)(A) are "qualified" because the section acts as a check on the government's prosecutorial discretion by requiring the government to justify dismissal. The court further found these

interests become even more attenuated when the government declines to intervene. Finally, the court noted that the government's "true interest" of avoiding the cost of discovery was insufficiently important to justify an immediate appeal, in part, because it could vindicate that interest through other mechanisms such as motions to quash subpoenas or modify discovery requests. In so holding, the Ninth Circuit explicitly noted that it was not deciding whether the government could appeal the denial of a motion to dismiss in a case in which the government has intervened.

U.S. ex rel. CIMZNHCA, LLC v. UCB, Inc., 970 F.3d 835 (7th Cir. Aug. 17, 2020)

The relator (referred to as "Venari," the name of the corporate relator's parent) alleged that UCB paid kickbacks to induce physicians to prescribe a UCB-manufactured medication to fight Crohn's disease. The government declined to intervene and thereafter moved to dismiss the case under § 3730(c)(2)(A). Applying the Ninth Circuit's *Sequoia Orange* standard, the district court denied the government's motion to dismiss. The government appealed.

On appeal, the Seventh Circuit declined to directly apply either *Sequoia Orange* or *Swift*, instead ruling that the government must first intervene in the *qui tam* case and then move for dismissal under Fed. R. Civ. P. 41. Because the government sought to dismiss the case before the defendant had answered, under Rule 41(a)(1), its right to dismiss the case was virtually unfettered but for the qualifying language in Rule 41(a)(1)(A) that the case would be dismissed "subject to… any applicable federal statute." Based on that language, the court found that the FCA — which provides relators with right to notice and a hearing — qualified a plaintiff's unfettered right to dismiss under Rule 41(a)(1).

Notwithstanding that finding, the Seventh Circuit found such qualification very narrow. It suggested that the court might deny government dismissal only under the most egregious circumstances, such as denial of equal protection or fraud on the court. And because such circumstances did not exist here, the court granted dismissal. (Although not addressed here, we note that the Seventh Circuit's approach based on Rule 41 could result in a different analysis if the government moved to dismiss after an answer was filed, thereby implicating Rule 41(a)(2)'s more exacting standard for dismissal.)

U.S. ex rel. Borzilleri v. AbbVie, Inc., No. 19-2947-cv, 2020 WL 7039048 (2d Cir. Dec. 1, 2020)

Relator Dr. John Borzilleri brought a *qui tam* lawsuit against various drug manufacturers and pharmacy benefit managers, alleging the companies schemed to defraud the federal prescription program Medicare Part D. The government declined to intervene in the case and moved to dismiss. The government cited three grounds for dismissal: (1) The case would likely require significant resources without (2) any material recovery for the United States, and (3) the relator was not the appropriate person to represent the government. The district court granted the government's motion and dismissed the case. Borzilleri appealed.

The government has articulated a valid government purpose for seeking dismissal: to avoid the costs and burdens of further investigation so that it may expend its finite resources elsewhere.

On appeal, the Second Circuit noted that the FCA allows the government to dismiss a *qui tam* action if the relator has an opportunity for a hearing on the motion to dismiss. The FCA, however, is silent as to when the government can move to dismiss over the objections of the relator.

The Second Circuit declined to choose a standard in the *Sequoia Orange-Swift* circuit split (described above). Instead, it applied both standards and, finding each would be satisfied, it affirmed the dismissal. The court reasoned that the government articulated a valid purpose for seeking dismissal by stating its concern for the costs and burdens of the action, which would be lengthy and span several years. Moreover, the relator failed to make a colorable showing that the dismissal was fraudulent, arbitrary and capricious, or illegal. Finally, the Second Circuit noted the district court did not have to give Borzilleri an evidentiary hearing because the plain language of the FCA requires only the "opportunity" for a hearing, which is only granted if the relator can make a colorable claim that the dismissal is unreasonable in light of existing evidence. Because Borzilleri did not make such a showing here, the district court's dismissal was proper.

B. 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. Benaissa v. Trinity Health, 963 F.3d 733 (8th Cir. June 25, 2020)

In *Benaissa*, a former trauma surgeon alleged that a hospital and related entities (collectively, "Trinity") violated the Stark Law and AKS by paying several physicians at an excessively high level, in part, for referring patients to Trinity. Those tainted transactions, in turn, resulted in submission of false claims. To try to overcome his lack of specific details about the claims, Dr. Rafik Benaissa alleged that (1) Trinity had received a large Medicare reimbursement and (2) any claim for services provided by the illegally compensated physicians would be a false claim. The district court found those allegations insufficient to satisfy Rule 9(b) and dismissed. Benaissa appealed.

On appeal, the Eighth Circuit upheld the dismissal. The court explained that a relator must either "allege representative examples of false claims" or allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." The court held that, here, Benaissa's allegations did not meet this test, as his allegations only formed a "general inference" and were speculative. The court noted that, as a trauma surgeon, Benaissa did not have knowledge of Trinity's billing practices, could not provide dates and descriptions of services, and did not know details of the billing system. While a relator does not necessarily have to be a member of the defendant's billing department, the court noted, such persons will likely have the insider knowledge to be able to plead with particularity that the defendant presented a false claim for payment.

C. Rule 8

U.S. ex rel. Integra Med Analytica, L.L.C. v. Baylor Scott & White, 816 F. App'x 892 (5th Cir. May 28, 2020)

Integra Med Analytica illustrates the limitations of using statistical data as evidence to meet the pleadings requirements of Rules 8(a) and 9(b). Despite the relator's analysis of CMS claims data from 2007-2011 to show that Medicare claims submitted by Baylor Scott & White Health were higher than industry norms, the Fifth Circuit affirmed dismissal of the case for failing to meet pleading standards because the relied-upon statistics were "consistent with both Baylor having submitted fraudulent Medicare reimbursement claims to the government and with Baylor being ahead of most healthcare providers in following new guidelines from CMS" encouraging providers to adopt clinical documentation improvement programs "in order to increase reimbursement." In affirming dismissal, the Fifth Circuit held that such "statistical data cannot meet [Rule 8(a) and Rule 9(b)] pleading requirements if, among other possible issues, it is also consistent with a legal and obvious alternative explanation." The court based its conclusion on the principle that, while "Rule 8(a) prohibits any claims that are merely conceivable rather than plausible[,] [a] claim is merely conceivable and not plausible if the facts pleaded are consistent with both the claimed misconduct and a legal and 'obvious alternative explanation.'"

D. Damages

U.S. ex rel. Concilio De Salud Integral De Loiza, Inc. v. J.C. Remodeling, Inc., 962 F.3d 34 (1st Cir. June 15, 2020)

In *Concilio*, a dispute arose over a federally funded waterproofing project. Concilio De Salud Integral De Loíza, Inc. (CSILO), a non-profit that provides healthcare services to uninsured patients through the use of federal funds, paid J.C. Remodeling (JCR) to do the waterproofing on a building roof. When the roof later leaked, CSILO sought to have JCR repair it under the warranty. When those efforts failed, CSILO ultimately filed an FCA action, claiming that JCR made fraudulent misrepresentations that resulted in the misappropriation of federal funds.

In the complaint, CSILO sought $405,000 in damages — three times the contract price of $135,000. But CSILO never took discovery on damages or included a discussion of damages in the court's pre-trial order. After three years of investigation and one month before trial, CSILO moved to amend the pretrial order. The district court denied the motion, finding that JCR would be prejudiced because

discovery was no longer available and CSILO did not include a computation of damages in its initial disclosures, did not produce evidence or computation of damages during discovery, and did not include a request for discrete fraud damages in the Joint Pretrial Conference Report. The case proceeded to trial, but JCR was precluded from offering evidence about damages. The jury found JCR violated the FCA. With no evidence of damages, however, the recovery was limited to a $5,500 civil penalty. CSILO appealed.

On appeal, the Third Circuit affirmed. It noted that the FCA does not specify how damages are to be calculated but requires only that the government suffer damage because of violation of the FCA. The court further explained that in FCA cases where the entire contract price was awarded as damages, the government received no tangible benefit under the contract and any intangible benefit was impossible to calculate. In those cases, the contracts were never consummated. But, in this case, JCR did do some work on CSILO's roof. As a result, CSILO could not merely rely on the contract price. And because there was no evidence of damages in the record, the court was unable to determine the value, if any, of the work done by JCR. Therefore, given the high bar to amend a pretrial order and the lack of evidence regarding the benefit of the contract to the government, the court affirmed the district court.

U.S. ex rel. Chepurko v. E-Biofuels, LLC, No. 1:14-cv-377, 2020 WL 2085071, (S.D. Ind. April 30, 2020)

Alexander Chepurko was an employee for several biofuel companies. In 2011, he disclosed information to the government about several corporate and individual defendants' misconduct in obtaining tax credits and tax breaks by falsely claiming to have created biofuels. That information ultimately led to several successful government actions, including matters related to regulatory violations and criminal convictions against multiple parties.

Later, in 2012, Chepurko filed an FCA action against many of the same defendants. He moved for partial summary judgment against some defendants — arguing that the criminal convictions collaterally estopped defendants from challenging the FCA claims — and for default judgment against others. The court agreed and granted the motions against several defendants.

With respect to damages for the default judgment defendants, the court held that a damages hearing was not necessary against a defaulted defendant if the damages were liquidated or capable of calculation, and the restitution orders for the defaulted defendants in their criminal proceedings made the damages easily ascertainable. It found that the total amount of damages incurred by the government and subject to restitution in the criminal proceedings would serve as the damages in the FCA case. The court then trebled those damages as required by the FCA and added the then minimum statutory penalty of $5,500 per false claim, resulting in a total FCA award of $69,610,999 against the defaulted defendants.

With respect to damages for the default judgment defendants, the court held that a damages hearing was not necessary against a defaulted defendant if the damages were liquidated or capable of calculation, and the restitution orders for the defaulted defendants in their criminal proceedings made the damages easily ascertainable.

E. Fee Shifting

U.S. ex rel. Barko v. Halliburton Company, 954 F.3d 307 (D.C. Cir. March 27, 2020)

After long and contentious litigation, the district court granted Kellogg Brown & Root Services (KBR) summary judgment in this FCA case. KBR thereafter filed a bill of costs under 28 USC § 1920, which generally allows taxation of costs after a judgment. KBR's bill totaled over $100,000 from two categories: (1) various e-discovery fees and document-review processing costs and (2) deposition-related expenditures. The district court granted the requested costs. Barko appealed.

On appeal, the D.C. Circuit affirmed in part and reversed in part. With respect to the first category of costs (sought under § 1920(4) related to costs for "making copies"), the court found that KBR's request was too expansive and went beyond the statutorily authorized costs associated with "making copies." As a result, the only e-discovery costs that KBR could recover were its costs for converting electronic files to the production formats and transferring those production files to portable media because those tasks resembled photocopying responsive documents to provide to opposing counsel. Relatedly, the court also found KBR could recover its costs for binders, tabs, and folders to package the exhibits.

With respect to the second category of costs (sought under § 1920(2) related to transcript-related costs), the court rejected Barko's argument that the district court abused its discretion in finding the deposition-related costs were reasonably necessary for the litigation. Specifically, the court found no reason to meddle with the district court's findings that expedited deposition transcripts were both justified by pending motions to compel and necessary to prepare for trial, to use for impeachment, and to guarantee the availability of the witness' testimony at trial.

F. Enforcement of Settlements

Broadnax v. Sand Lake Cancer Center, P.A., 819 F. App'x 799 (11th Cir. July 6, 2020)

Relator Meria Broadnax, a former pharmacy technician, and defendants Sand Lake Cancer Center, P.A. and Vinicio Hernandez, M.D. reached settlement terms at a pre-trial settlement conference before a magistrate judge. At the settlement conference, the parties and their respective counsel signed a term sheet setting forth the basic terms of the parties' settlement. The district court was informed of the settlement, and it thereafter dismissed the lawsuit.

After dismissal, however, the parties were unable to agree upon certain other aspects of the settlement, including its duration and the incremental payment amounts. Defendants sought to reopen, and relator filed a cross motion to enforce the settlement. The district court denied the motion to reopen and granted relator's motion to enforce. The defendants appealed.

On appeal, the 11th Circuit affirmed, finding that under Florida law a term sheet was a binding and enforceable settlement agreement.

V. Parties

Pro Se Relators

Wojcicki v. SCANA/SCE&G, 947 F.3d 240 (4th Cir. Jan. 14, 2020)

The Fourth Circuit, agreeing with four sister circuits, held a pro se plaintiff cannot represent the government's interest in a *qui tam* lawsuit. The district court dismissed the suit, concluding Joseph Wojcicki's complaint was due to be dismissed because of his pro se status. On appeal to the Fourth Circuit, the court explained that, though a relator has an interest in a *qui tam* suit, it is not the sole interest at stake — the government also has an interest and is bound by the relator's actions for purposes of res judicata and collateral estoppel. The court acknowledged that 28 U.S.C. § 1654 provides a right for a party to proceed pro se in actions. But that right is for the interests of the pro se plaintiff; there is no corresponding right for an individual with no legal expertise to proceed pro se and negatively impact the interests of others. Therefore, the court found that because the government is the real party in interest in a *qui tam* lawsuit, a pro se litigant may not pursue a *qui tam* action on behalf of the government under the FCA.

Taylor v. The Multiplan Network, 817 F. App'x 947 (11th Cir. Aug. 18, 2020)

Relators John Taylor and Tunya Taylor brought this *qui tam* suit pro se. The district court dismissed their claims with prejudice for lack of subject matter jurisdiction because they did not obtain counsel for over four months after being advised by the district court that they needed counsel to assert their *qui tam* claims. The 11th Circuit affirmed the dismissal but held that it was an error for the district court to dismiss the *qui tam* claims with prejudice because "a dismissal for lack of subject-matter jurisdiction… is not on the merits."

Ajjahnon v. St. Joseph's University Medical Center, 830 F. App'x 74 (3d Cir. Nov. 27, 2020); *Downey v. United States,* 816 F. App'x 625 (3d Cir. June 11, 2020)

In *Ajjahnon*, relators brought an FCA action pro se. After the government declined to intervene, the district court dismissed the action with prejudice, holding that "a pro se litigant may not pursue a *qui tam* action on behalf of the government." On appeal, the Third Circuit affirmed, reasoning that the FCA allows private parties to bring enforcement actions on behalf of the United States, but "an individual proceeding pro se may not represent third parties in federal court." Because dismissals for lack of proper representation in *qui tam* suits are normally without prejudice to allow the relator a chance to retain an attorney, the Third Circuit amended the district court's judgement to reflect dismissal *without* prejudice.

Under the same reasoning, the Third Circuit in *Downey* also affirmed a district court's holding that a pro se relator could not pursue a *qui tam* action on behalf of the federal government.

VI. Insurance Coverage Issues

IberiaBank Corp. v. Ill. Union Ins. Co., 953 F.3d 339 (5th Cir. March 18, 2020)

In *IberiaBank,* the Fifth Circuit upheld the denial of professional liability coverage by Illinois Union Insurance Company (Chubb) and Travelers Casualty and Surety Company of America (Travelers) for their insured's settlement with DOJ in connection with FCA litigation.

IberiaBank, the insured, was a direct endorsement lender (DE lender) under the Department of Housing and Urban Development's (HUD) Direct Endorsement Program (DE Program). Under the DE Program, lenders analyze the credit risk of individuals seeking mortgage loans using HUD's guidelines and then certify to HUD that approved borrowers meet HUD's underwriting standards. In 2015, former and current IberiaBank employees brought a *qui tam* action against the company, alleging that it violated the FCA by (1) improperly paying commissions to underwriters; (2) providing false loan certifications to HUD; (3) improperly certifying compliance with HUD regulations; and (4) failing to report defective or fraudulent loans. In April 2017, IberiaBank reached a settlement agreement with DOJ under which IberiaBank acknowledged certain wrongdoing and agreed to pay $11,692,149. As a result of the settlement, the FCA claims in the *qui tam* action were dismissed.

Following the settlement, IberiaBank submitted a claim to its professional liability insurers, Chubb and Travelers. The insuring clause of the relevant policies obligated Chubb and Travelers to pay amounts that IberiaBank became "legally obligated to pay by reason of any Claim first made by a third party client of the Company against the Insureds . . . in rendering or failing to render Professional Services." The policies defined professional services as "services performed by or on behalf of IberiaBank for a policyholder or third party client of IberiaBank" that were "performed pursuant to a written contract . . . for consideration inuring to the benefit of IberiaBank."

Chubb and Travelers denied coverage for the DOJ settlement, after which IberiaBank sued for breach of contract. Ultimately, the district court granted the insurers' motion to dismiss based on its findings that (1) the government was not IberiaBank's client under the DE Program, and (2) IberiaBank did not provide "professional services" to the government in its role as a DE lender.

On appeal, the Fifth Circuit affirmed. The court found that HUD could not be IberiaBank's client under the policy because the certifications rendered to HUD were not provided "for consideration" — that is, HUD did not pay IberiaBank to provide the certifications. The court also found that IberiaBank could not procure coverage for a claim brought by the government based on professional services rendered to IberiaBank's borrowers. Accordingly, the Fifth Circuit held that, because the government was not IberiaBank's client and did not become IberiaBank's client as a result of the DE Program, IberiaBank's claim for the DOJ settlement was not covered by the professional liability policies.

Affinity Living Grp., LLC v. StarStone Specialty Ins., 959 F.3d 634 (4th Cir. May 26, 2020)

In an underlying FCA action, relator Stephen Gugenheim alleged that Affinity submitted false claims by seeking Medicaid reimbursement for nursing home services never provided. Affinity sought coverage under its policy with StarStone, but StarStone denied coverage because the damages were not "resulting from a claim arising out of a medical incident."

In response, Affinity brought a separate action seeking a declaratory judgment that its insurance policy with StarStone provided indemnification and defense against the FCA claim and alleged that StarStone breached the policy by denying coverage. The district court granted StarStone's motion for judgment on the pleadings. On appeal, the Fourth Circuit vacated the district court's order, finding that StarStone had a duty to defend and indemnify Affinity in the underlying FCA action.

In vacating the order, the Fourth Circuit first observed that the StarStone policy covered "damages resulting from a claim arising out of a medical incident." The parties agreed that a "medical incident" under the policy included Affinity's alleged failure to render services. While Affinity's effort to obtain reimbursement was not itself a "medical incident," the court determined that such conduct was still covered by the policy because it arose out of a medical incident. The court explained that North Carolina courts interpret "arising out of" language in insurance contracts broadly to require only a causal connection when used in a provision extending coverage. Because the policy term in this case fell within a provision extending coverage, the court only required some causal connection between the medical incident (i.e., failure to render services) and the injury for which coverage was sought (i.e., the FCA claims). Ultimately, the court found a causal connection, explaining that but for Affinity's alleged failure to provide the nursing home services, Gugenheim would have no claim for damages under the FCA.

VII. DOJ Memos and Policy Announcements

As in years past, DOJ issued several memorandums or other policy announcements that involved its approach to FCA cases.

Civil Division Issues Guidance on Inability to Pay Determinations

On September 4, 2020, the acting assistant attorney general issued a memorandum detailing the factors to assess when the government considers a defendant's assertion that it is unable to pay full liability to the United States. Although referred to as an "inability" to pay in this memorandum, FCA practitioners are familiar with this subject as ability to pay analyses that a defendant may request from the government. Importantly, once this discussion has begun, DOJ attorneys take the position that arguments as to liability are over. Thus, once a party is engaged in this process the only operative fact relevant to the settlement amount is the financial condition of the defendant.

The memorandum helpfully summarizes the process defendants will encounter, including the requirement that they complete DOJ's financial disclosure forms and submit supporting documents, including bank records, tax returns and other document probative of financial condition. All such information must be verified under penalty of perjury. The memorandum lists seven specific factors DOJ will evaluate, including:

1. Background and current financial information;
2. Alternative sources of capital;
3. Timing of payments;
4. Tax deductability;
5. Contingency arrangements;
6. Collateral consequences; and
7. Third-party liability.

Although these factors are already listed in the Justice Manual, the memorandum provides detail about how they are applied. The memorandum provides some transparency for what has often been an opaque process for FCA defendants.

Additional Rules on Agency Guidance Documents from HHS to Have Effect on FCA Cases

With a 2017 memorandum from then Attorney General Jeff Sessions, the government began a long march towards limiting the use of sub-regulatory guidance documents in enforcement actions. This year saw what appears to be the culmination of that effort at the Department of Health and Human Services with significant implications for healthcare FCA cases. On November 16, 2017, Sessions issued a memorandum entitled "Prohibition on Improper Guidance Documents" to all components of the Department of Justice. The memorandum distinguished between regulations established through notice-and-comment rulemaking and guidance and similar documents issued as "plain-language restatements of existing legal requirements" or "non-binding advise on technical issues." The attorney general noted that DOJ had published such "guidance" documents that effectively and improperly bound private parties without undergoing the rulemaking process. The memorandum forbade such practices and established principles for DOJ components when issuing guidance documents. Just over two months later, Associate Attorney General Rachel Brand extended these principles to DOJ affirmative civil enforcement actions, which include FCA actions, stating that "the Department may not use its enforcement authority to effectively convert agency guidance documents into binding rules" and that "Department litigators may not use noncompliance with guidance documents as a basis for proving violations of applicable law in ACE cases." The requirements of the Brand Memo were incorporated into the Justice Manual in 2018.

On top of these DOJ pronouncements the United States Supreme Court weighed in on the issue in 2019 in *Azar v. Allina Health Servs.*, 139 S.Ct 1804 (June 3, 2019). The Supreme Court tackled the question of whether certain new rules put in place by CMS were required to go through notice-and-comment rulemaking. The Supreme Court found that the Medicare Act required notice and comment for any rule that changes a "substantive legal standard." On the heels of the *Allina* decision, President Trump issued Executive Order 13891, reiterating that agency guidance documents do not bind the public except as authorized by law or pursuant to contract. A federal district court subsequently applied the *Allina* holdings to an FCA case holding that Medicare Manual guidance was a "substantive legal standard" and had not been promulgated pursuant to notice and comment, as required by the Medicare Act. The court granted summary judgment to the defendant on the FCA claims.

In December 2019, the Office of General Counsel for HHS issued a memorandum to CMS directing it to conform its guidance to the rulemaking obligations set forth in *Allina*. The memorandum generally lays out the circumstances under which guidance documents can be used in an enforcement action stating that "the critical question is whether the enforcement action could be brought absent the guidance document" — meaning is the regulation clear enough to bring the enforcement action? If not, then the case should not be pursued. With respect to healthcare FCA cases, the memorandum contained the rather important statement that "as a result of *Allina*, government enforcement actions based solely on LCDs[1] are generally unsupportable."

Two important developments in this area from the end of 2020 will have significant impact on FCA enforcement in the coming years. In early December 2020, the Office of General Counsel of HHS issued an advisory opinion on "Implementing Allina." This advisory

1 LCDs are Medicare Contractor Local Coverage Determinations, which, up to the time of this memorandum, were commonly used to establish rules pursuant to which providers were held in order to qualify for payment.

opinion slightly altered the standard from the 2019 memorandum, stating that the "critical question is whether the violations of the Medicare rule could be shown absent the guidance document."

In early December 2020, HHS finalized its Good Guidance Practice Rule with the dual purpose to "help ensure that the public receives appropriate notice of new guidance documents and that HHS guidance documents do not impose obligations on regulated parties that are not already reflected in statutes and regulations." Among the requirements are that all guidance documents:

- Self-identify as guidance;
- Carry a disclaimer indicating that the contents of the document generally cannot impose binding new obligations that exceed requirements set forth in statutes and regulations; and
- Include citations to any statutory or regulatory provisions that the guidance document is interpreting or applying.

It seems difficult to overstate the implications of these developments in healthcare FCA actions. We can expect many cases that develop the various legal questions raised by these new rules on sub-regulatory guidance.

Scrutiny of Third-Party Funding of *Qui Tam* Suits

Both the courts and DOJ noted concerns with what appears to be a rising trend of third-party financing of *qui tam* lawsuits. In *Ruckh v. Salus Rehabilitation,* 963 F.2d 1089 (11th Cir. June 25, 2020), the 11th Circuit was asked to determine if relator's "sale" of part of her share of recovery deprived relator of standing to pursue the case. The court found that it did not, but specifically noted that relator had sold only 4% of her potential recovery and the financing entity had no power to control or influence the case. Thus "the relator retains sufficient interest" to retain standing under Article III.

In June 2020, Principle Deputy Assistant Attorney General Ethan Davis said that DOJ was evaluating the role of third-party financing firms in *qui tam* litigation. Davis noted the concern that *qui tam* cases are brought in the name of the United States and therefore the United States has an interest in knowing who is behind them. For this reason, DOJ is now supposed to ask a series of questions of each relator to identify any third-party interests in the *qui tam* action and whether that entity is able to directly or indirectly control or influence the litigation.

Penalties Increase, 85 Fed. 37,004, 37,006 (June 19, 2020)

After skipping 2019, DOJ once again issued its annual increase of statutory penalties for FCA violations, increasing the minimum per claim penalty to $11,665 and the maximum to $23,331. These revisions are required each year by the Bipartisan Budget Act of 2015. Per the DOJ's notice in the Federal Register, these penalties are applicable to penalties assessed after June 19, 2020 — the date of publication in the Federal Register — for violations occurring after November 2, 2015 — the date of the Bipartisan Budget Act of 2015.

DOJ Dismissal Authority and Congressional Response

Recent increases in DOJ's efforts to dismiss relator FCA cases in light of the 2018 Granston Memo caught the attention of Sen. Chuck Grassley this year. Grassley is the main proponent for the FCA and whistleblowers on Capitol Hill and has spearheaded whistleblower-friendly amendments to the FCA over the years. Although DOJ has used its dismissal authority sparingly — too sparingly in the eyes of many — Grassley has objected to DOJ's legal view that its authority to dismiss *qui tam* cases under the FCA is entitled to extreme deference by the courts.

Section 3720(c)(2)(A) of the FCA states that DOJ has the authority to dismiss a *qui tam* complaint over relator's objection "if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion." As discussed previously in this review, the purpose of the hearing and the deference that should be afforded the government's position seeking dismissal have been the subjects of renewed focus now that DOJ is apparently seeking to dismiss more *qui tam* complaints under the guidance of the Granston Memo.

This activity resulted in a petition for *writ of certiorari* at the Supreme Court seeking to settle a circuit split on the proper standard to be applied to a government dismissal motion under 3720(c)(2)(A). In papers filed with the court, DOJ took its usual position that the government has an "unfettered" right to dismiss *qui tam* suits when it deems appropriate. This position triggered a strong response from Grassley in two letters to the attorney general opposing DOJ's position. Summarizing his position in one letter Grassley stated, "[h]aving unfettered dismissal authority will create a chilling effect on future whistleblowers that will ultimately end up costing the taxpayers a lot more." In a follow-up letter later in 2020, Grassley criticized several instances in which DOJ moved for dismissal under 3720(c)(2)(A) and demanded certain information from DOJ regarding the exercise of this authority since the publication of the Granston Memo.

Grassley followed these letters with a Senate floor speech on July 30, 2020 — National Whistleblower Appreciation Day — calling for congressional action to truncate DOJ's authority to dismiss *qui tam* FCA cases. Grassley criticized DOJ for dismissing *qui tam* cases without stating its reasons and maintained that his new legislation would "require the Department of Justice to state its reasons and provide whistleblowers who bring the cases an opportunity to be heard whenever it decides to drop a False Claims Act case."

WHAT TO WATCH IN 2021

Supreme Court Action on "Falsity" Circuit Split

Two petitions for a *writ of certiorari* are currently pending with the United States Supreme Court on the question of what constitutes "falsity" in FCA cases based on medical necessity.[2] At issue are three decisions from the United States Courts of Appeals that tackled the question of whether a difference of opinion between medical professionals can be the basis for "falsity" under the FCA. Two of these cases involve the specific requirements of the Medicare hospice benefit program — namely that a physician certify that a patient is terminally ill with a life expectancy of six months or less. The other involves the requirements for certifying a patient for in-patient hospital treatment as opposed to less expensive outpatient care.

In *United States v. AseraCare, Inc.,* 938 F.3d 1278 (11th Cir. 2019) — the first of the three appellate court opinions — the United States alleged that the defendant had admitted patients to hospice based on false physician certifications of terminal illness. The United States sought to establish the hospice claims as false with expert evidence that the patients were not actually terminally ill. The 11th Circuit framed the relevant question as "When can a physician's clinical judgment regarding a patient's prognosis be deemed 'false'?" The court went on to note that "physicians applying their clinical judgment about a patient's projected life expectancy could disagree, and neither physician [ ] be wrong." The 11th Circuit concluded that a subjective but honest disagreement on medical prognosis could not be the basis for falsity under the FCA. Instead something more "objective" must be demonstrated to show falsity, including, for example, (1) that the certifying physician failed to familiarize himself with the medical record; (2) that the physician did not in fact subjectively believe the prognosis to be true; or (3) proof that no reasonable physician could have concluded that a patient was terminally ill.

In contrast to the 11th Circuit's reasoning with regard to hospice-eligibility medical opinions, in *United States ex rel. Druding v. Care Alternatives,* 952 F.3d 89 (3rd Cir. 2020), the Third Circuit found that "medical opinions can be false" even if honestly held and reasonable. Thus, an after-the-fact expert opinion that the prognosis was incorrect presents a triable issue of fact for the jury for whether the claim may be "false." The Third Circuit stated directly that it disagreed with the reasoning in *AseraCare* in the 11th Circuit.

Shortly thereafter the Ninth Circuit also weighed in on this question in *United States ex rel. Winter v. Gardens Reg'l Hosp. & Med. Ctr., Inc.,* 953 F.3d 1108 (9th Cir. 2020). Unlike the Third Circuit, however, the Ninth Circuit took pains to reconcile its decision with *AseraCare*, stating that the 11th Circuit "identified circumstances in which a medical opinion would be false" and any "objective falsehood" requirement embraced by the 11th Circuit was limited to the hospice-benefit provision at issue in *AseraCare* — and not at issue in *Winters*, which involved the physician certification of need for inpatient hospital treatment. The Ninth Circuit concluded that a medical opinion can be false or fraudulent for the same reasons that other opinions could be false or fraudulent, including that "the opinion is not honestly held, or if it implies the existence of facts that do not exist."

Against this backdrop both Care Alternatives and affiliates of Gardens Regional Hospital filed motions for certiorari with the United States Supreme Court. The *Gardens Regional* petition broadly frames the question presented to the court as "Whether the False Claims Act requires pleading and proof of an objectively false statement?" Care Alternatives, perhaps because it is a hospice case like *AseraCare*, frames a narrower question for the court: "Whether a physician's honestly held clinical judgment regarding hospice certification can be 'false' under the False Claims Act based on solely on a reasonable difference of opinion among physicians."

Whether the Supreme Court grants certiorari on either or both of these cases could have profound consequences for future FCA cases based on medical necessity. Granting certiorari and adopting the petitioners' position in the *Gardens Regional* petition would eliminate the government's or a relator's ability to get to the jury on the question of falsity based solely on an expert opinion that treatment provided was not medically necessary. Instead, additional evidence of "objective falsity" of the type cited by the 11th Circuit in *AseraCare* would likely be necessary. On the other hand, adoption of the Third Circuit's position in the *Care Alternatives* case would mean hospice and other medical necessity cases would move on to a jury with a triable issue of fact any time the government or whistleblower's counsel could find any qualified expert willing to disagree with the medical judgment of physicians who ordered medical services. A more gradual, and careful, approach by the court would be to grant certiorari on the *Care Alternatives* case to address the narrower question related to medical necessity in the context of the Medicare hospice benefit in which the Third Circuit has plainly stated that it has split with the *AseraCare* decision out of the 11th Circuit. In any event, a grant of certiorari in either case is likely to have as momentous an impact on FCA jurisprudence for the healthcare industry as the *Escobar* decision in 2016.

2 *Care Alternatives v. United States of America, et al. Case No. 20-371* (filed September 16, 2020); *and RollinsNelson LTC Corp., et al. v. United States of America ex rel. Jane Winters Case No. 20-805* (filed December 3, 2020).

FCA Cases on COVID-19 Relief Programs

The government's fiscal response to the coronavirus pandemic resulted in an unprecedented level of government spending across the economy. On March 27, 2020, Congress passed the Coronavirus Aid, Relief and Economic Security (CARES) Act, authorizing over $2 trillion to mitigate the catastrophic economic impact of the pandemic. The act included multiple new government spending programs, including the high-profile Paycheck Protection Program (PPP) through the Small Business Program and the healthcare Provider Relief Fund (PRF) through the Department of Health and Human Services. The urgency with which this money was authorized and pushed into the economy caused many agencies to in effect build the plane in flight. In most cases agencies were forced to distribute funds and make up the rules later. The potential for misunderstandings, mistakes, and outright fraud make for an extremely rich enforcement environment in 2021.

Already, we have seen aggressive enforcement by the DOJ in PPP loans. Multiple high-profile criminal actions have demonstrated this program's vulnerability to fraud. Through the end of 2020, however, DOJ's enforcement actions in this area were criminal cases targeting egregious fraud, including bogus companies and employees, and misuse of program funds on personal luxury items such as high-end automobiles, designer watches and expensive jewelry. Early 2021, however, saw DOJ's first FCA case for PPP loans, based on a misrepresentation about the borrower's eligibility for the loan.

We anticipate significant FCA enforcement actions throughout 2021 for several reasons. First, borrowers made multiple representations with respect to their eligibility and need for the loans. Second, the SBA strictly limited allowable uses of PPP funds. Any inaccuracies in the representations or mistakes in use of funds could trigger liability. Third, SBA has already begun its audits for all loans over $2 million. SBA's latest PPP report indicates that it funded nearly 29,000 such loans. Audits often result in referrals to law enforcement when problems are uncovered. Finally, PPP loans were obtained by many businesses that had never dealt with government programs before and are not familiar with government regulations and the consequences of non-compliance. Such businesses could fail to take proper care and keep appropriate documentation to satisfy government audits.

Healthcare providers can also expect that the PRF will be the subject of vigorous enforcement efforts. HHS-OIG has already included PRF enforcement in its work plan for the coming year stating, "Our objective is to determine whether providers that received PRF payment complied with certain Federal requirements, and the terms and conditions for reporting and expending PRF funds." On June 26, 2020, Principle Deputy Assistant Attorney General Ethan Davis

addressed DOJ's preparations to combat fraud against CARES Act programs. Davis noted that healthcare providers agreed to a number of terms and conditions, and restrictions with respect to the use of PRF Funds. Davis noted that "[w]here a provider knowingly violates these requirements, the False Claims Act may come into play."

By now healthcare providers are well familiar with the shifting guidance with respect to PRF funds. Although this shifting guidance may be grounds for multiple defenses against enforcement actions, we expect a busy enforcement environment in 2021 for PRF funds. Key points of concern for healthcare providers will be whether they received the correct amount of funds, whether the funds were used properly, and whether they have properly accounted for their coronavirus-related expenses and losses.

Perhaps more troubling than government enforcement efforts, however, is the enormous potential for whistleblower actions based on alleged non-compliance with CARES Act rules. Although we might expect the government to take a reasonable approach to enforcement given the unprecedented speed with which these programs were instituted, whistleblowers may push the envelope on legal theories of liability and pursue cases that the government declines. One important development this year may be DOJ's willingness to more aggressively police whistleblower suits in this area given the uncertainty in guidance for much of the year.

Finally, the intersection of various overlapping enforcement authorities could further drive FCA action on CARES Act funds. The CARES Act established several oversight mechanisms, including the Pandemic Response Accountability Committee (PRAC), with a budget of $80 million and independent investigative authority. Additionally, Congress has established several committees, some of which have already set their eyes on CARES Act funds. Such entities could help drive enforcement priorities with hearings or other enforcement actions of their own.

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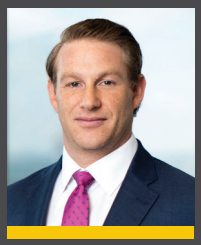

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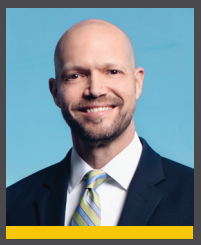

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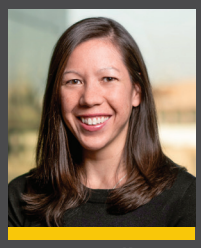

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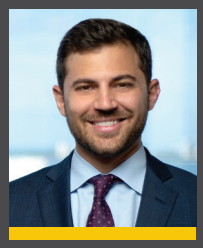

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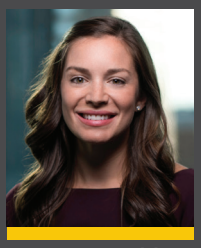

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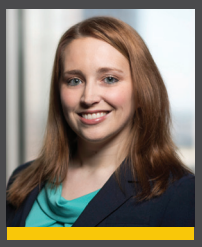

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