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False Claims Act
2019 Year in Review

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CONTENTS

INTRODUCTION

The year 2019 was another active year in False Claims Act (FCA) investigations and litigation. Although the year lacked a singular blockbuster case, there were decisions of particular note. The Supreme Court clarified the FCA's statute of limitation provisions in *Cochise*, the one FCA opinion issued by the Court in 2019. At the court of appeals level, among other notable opinions, the Eleventh Circuit issued its long-awaited opinion in *AseraCare*, a hospice-related FCA case that explored the evidence necessary to establish falsity when physicians reach different judgments. And several district and appellate courts wrestled with the standards required for the Department of Justice (DOJ) to exercise its dismissal authority in a non-intervened case — an issue of renewed vitality after the so-called Granston Memorandum in January 2018.

Particulars aside, 2019 shared many attributes with recent years. According to a just-released DOJ report, DOJ recovered over $3 billion in judgments and settlements in FY2019, a figure slightly up from FY2018's $2.9 billion in recoveries. Once again, healthcare led the way from an industry perspective, accounting for $2.6 billion — over 85% — of the $3 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 636 cases in FY2019, and their recoveries accounted for over $2.1 billion of the total. The whistleblowers themselves (and their attorneys) also reaped a significant benefit. The FCA permits whistleblowers — often referred to as "relators" — to recover varying percentages of a recovery depending on whether the government intervenes. In 2019, whistleblowers received over $271 million from intervened and non-intervened cases. Although that remains an impressive figure, it marks the lowest such figure for whistleblowers' share in a decade and approximately half of what whistleblowers received as recently as 2016-2017.

As we continue to watch for new trends in 2020, we review the key decisions and policy developments from 2019 below.

DOJ RECOVERED OVER

$3 BILLION

IN JUDGMENTS AND SETTLEMENTS IN

FY2019.

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

United States v. AseraCare, Inc., 938 F.3d 1278 (11th Cir. Sept. 9, 2019)

The Eleventh Circuit's ruling in *AseraCare* has been heralded as a significant victory for hospice and other healthcare providers that face after-the-fact scrutiny in FCA litigation of subjective clinical judgments.

In *AseraCare*, the court considered how Medicare's requirements for hospice eligibility — which are centered on a physician's subjective "clinical judgment" as to a patient's life expectancy — intersect with the FCA's falsity element. The case began when three former employees alleged that AseraCare had routinely submitted unsubstantiated Medicare claims. The government later intervened, alleging that AseraCare had submitted documentation falsely representing that certain Medicare patients were terminally ill — that is, had a life expectancy of six months or less. The initial phase of trial on the issue of falsity boiled down to a classic "battle of the experts" as to whether the patients' medical records supported AseraCare's certifications of terminal illness for approximately 100 patients at issue. Significantly, the government's expert conceded that he could not say whether AseraCare's medical expert was wrong and that he himself had changed his own opinion concerning the eligibility of certain patients over the course of the proceedings. Nonetheless, the jury found that AseraCare had submitted false claims for roughly 85 percent of the patients at issue.

Following the jury's phase one findings, the district court ordered a new trial and *sua sponte* reconsidered and granted summary judgment based on the principle that a mere difference of opinion between physicians, without more, was not enough to show falsity. The Eleventh Circuit agreed, holding that a clinical judgment of terminal illness warranting hospice benefits under Medicare cannot be deemed false, for purposes of the FCA, where there is only a reasonable disagreement between medical experts as to the accuracy of that conclusion, with no other evidence to prove the objective falsity of the assessment. Rather, to properly state a claim under the FCA in the context of hospice reimbursement, a plaintiff alleging that a patient was falsely certified for hospice care must identify facts and circumstances surrounding the patient's certification that are inconsistent with the exercise of a physician's clinical judgment. Where no such facts or circumstances are shown, the FCA claim fails as a matter of law.

In so holding, the court found that the regulatory framework required only that physicians exercise their clinical judgment considering the facts at hand and document their rationale. The court took the government to task for reading requirements into the regulations that were not present — namely, that the supporting documentation must, standing alone, prove the validity of the physician's initial clinical judgment. According to the court, a physician's clinical judgment dictates eligibility. Pointing to CMS's own recognition that "predicting life expectancy is not an exact science," the court concluded that "the law [was] designed to give physicians meaningful latitude to make informed judgments without fear that those judgments [would] be second-guessed after the fact by laymen in a liability proceeding." The court, however, vacated the district court's order granting summary judgment in favor of AseraCare and remanded the case with instructions that the district court reconsider its summary judgment decision in light of all the evidence proffered by the government at the summary judgment and trial stages. Among other things, the court required that any such evidence be linked to the specific patients at issue for the government to avoid summary judgment on remand. The court stated, "having given the Government the green light to once again try to persuade the district court that a triable issue exists on both

falsity and knowledge, we emphasize that we do not know that this effort will succeed."

Bradley Arant Boult Cummings LLP represents AseraCare in this matter.

U.S. ex rel. DeFatta v. United Parcel Serv., Inc., 771 Fed. Appx. 735 (9th Cir. May 8, 2019)

Relator DeFatta brought a *qui tam* lawsuit against his employer, United Parcel Service, Inc. (UPS), alleging that it violated the FCA by (1) fraudulently inducing shipping contracts with the government, (2) submitting false invoices to the government, and (3) falsely implying certification of compliance with applicable freight traffic rules. The district court dismissed DeFatta's claims for failure to allege with particularity the circumstances constituting fraud or mistake as required by the heightened pleading standard for fraud claims under Federal Rule of Civil Procedure 9(b). On appeal, the Ninth Circuit affirmed.

DeFatta argued that UPS fraudulently induced shipping contracts by failing to offer its ground shipping service in its response to the government's request for proposal (RFP). The court found that ground service was not responsive to the RFP because it did not satisfy its expedited shipping requirements. Thus, the failure to offer that service was neither fraudulent nor misleading.

DeFatta also alleged that UPS overcharged the government by submitting invoices for air shipments that were actually delivered using ground transportation. The court dismissed this claim because the contract between the parties permitted UPS to choose the transportation method (i.e., truck or plane) regardless of the service selected (i.e., ground or air). Finally, the court affirmed the dismissal of DeFatta's claim that UPS falsely implied certification with freight traffic rules that required carriers to charge the government at the rate applicable to the service performed. The court explained that DeFatta failed to plead sufficient facts to support a reasonable inference that UPS charged air shipping prices for packages delivered using ground transportation.

B. Materiality

U.S. ex rel. Lemon v. Nurses To Go, Inc., 924 F.3d 155 (5th Cir. May 7, 2019)

Former employees brought an FCA complaint against Nurses To Go, Inc., alleging that it failed to complete and maintain certifications for hospice patients, failed to maintain physician narratives in support of certifications, failed to have required face-to-face encounters, and improperly submitted claims for payment for "continuous home care" for patients who did not qualify for this type of hospice service, among several other allegations. The government declined to intervene. After relators proceeded, the district court granted

> A clinical judgment of terminal illness… cannot be deemed false, for purposes of the FCA, where there is only a reasonable disagreement between medical experts…

Nurses To Go's motion to dismiss, finding that relators failed to adequately plead materiality.

On appeal, the Fifth Circuit reversed. The court found that certain documentation deficiencies were material to the government's payment decision for the Medicare hospice benefit. In analyzing materiality, the court weighed whether the statutes allegedly violated were express conditions of payment, whether the government would have denied payment if it had known of the alleged violations, and whether the noncompliance was minor or substantial. The court held that these factors weighed in favor of materiality: The Medicare statute expressly named proper certifications of hospice patients as a condition of payment; relators had alleged recent enforcement actions taken by OIG against similarly offending providers; and the fact that qualification for Medicare in these instances is premised on the patient having been certified as terminally ill made clear that these improper certifications were not minor or insubstantial.

C. Knowledge

U.S. ex rel. Coffman v. City of Leavenworth, 770 Fed. Appx. 417 (10th Cir. May 10, 2019)

In her FCA *qui tam* complaint, relator Michele Coffman claimed the City of Leavenworth, Kansas submitted monthly sewer bills to the United States Army, the Bureau of Prisons, and the Veterans Administration that falsely implied the city had complied with all applicable environmental laws. The district court granted summary judgment for the city based on Coffman's failure to establish knowledge and materiality.

On appeal, the Tenth Circuit affirmed summary judgment for the city based on the lack of scienter. The court reiterated the FCA's "rigorous and strictly enforced" scienter requirement and held Coffman did not sufficiently establish that the city "knowingly"

presented a false claim to the government for payment or approval. Coffman claimed that the city's organizational structure prevented it from learning of the facts that made its claims for payment false and therefore it acted in deliberate ignorance or reckless disregard of the falsity of its invoices.

The court held that Coffman had not sufficiently shown the requisite scienter because she did not show that the city's organizational structure affirmatively prevented it from learning the relevant facts that made its claims for payment false. She argued that the city's wastewater treatment plant was not responsible for submitting invoices to federal agencies, that the city submitted invoices to the Army based on the agency's flow level and its portion of operation and maintenance costs, and that there was no evidence the wastewater treatment plant employees inquired into the plant's compliance with environmental laws before submitting its invoices. The court found that such evidence was not sufficient for a reasonable trier of fact to find that the city acted in deliberate ignorance or reckless disregard.

D. Claim for Payment

U.S. ex rel. Kraus v. Wells Fargo & Co., 943 F.3d 588 (2d Cir. Nov. 21, 2019)

In an FCA case arising out of the 2008 financial crisis, relators Paul Bishop and Robert Kraus alleged that Wells Fargo entities fraudulently misrepresented the entities' financial condition to one or more of the Federal Reserve Banks (FRBs) so they could obtain emergency loans at favorable interest rates. The district court dismissed the action on the grounds that loan requests to FRBs did not meet the definition of a "claim" in 31 U.S.C. § 3729(b)(2)(A). On appeal, the Second Circuit vacated the decision and held that the FCA applies to FRBs. It found that claims for emergency loans submitted to the FRB were "claims" under the statutory definition even though the FRB is not a government agency and the money at issue did not come from the United States Treasury or stand to be reimbursed by the Treasury.

The court found that these requests for loans were claims under either the definition in § 3729(b)(2)(A)(i) — a request for money or property that "is presented to an officer, employee, or agent of the United States" — or § 3729(b)(2)(A)(ii) — a request for money or property made to another recipient "if the money or property is to be spent or used on the Government's behalf or to advance a government program or interest, and if the United States Government provides or has provided any portion of the money or property requested or demanded." It found that the FRB was an "agent" of the United States under § 3729(b)(2)(A)(i) because the United States created the FRB to act on its behalf, and the FRB has to act within Congress' mandate. While the funds loaned from the FRB do not come from or get reimbursed by the Treasury, the court found the money was "provided" by the United States under § 3729(b)(2)(A)(ii) because FRB has power vested from Congress to create federal reserve notes — essentially increasing the overall money supply — to provide loans to ailing banks.

The court said that the legislative purpose of the FCA is most faithfully executed by recognizing that "the FCA applies, in some cases, to functional instrumentalities of the government and to agents pursuing its ends."

E. Causation

United States v. Luce, No. 11 CV 5158 (N.D. Ill. July 10, 2019)

In *Luce*, the Northern District of Illinois interpreted and strictly applied the "proximate cause" standard to award the defendant summary judgment on an FCA claim. This district court opinion was the final act in the Seventh Circuit's divergence from its peers regarding the appropriate standard for causation. In 2017, defendant Robert S. Luce persuaded the Seventh Circuit to switch from "but-for" causation in FCA cases to a "proximate cause" standard grounded in common law. After the Seventh Circuit partially reversed the district court's award of summary judgment to the government, the matter was remanded to the Northern District of Illinois, resulting in this opinion.

On remand, the district court held that the government could not prove a nexus between Luce's "false statements about the existence of a federal investigation (particularly one unrelated

to the operation of Luce's mortgage business) and loan defaults [the harm to the government]." Although Luce obtained summary judgment on the FCA claim, he was unable to prevent judgment from being re-entered against him under the Financial Institutions Reform, Recovery and Enforcement Act (FIRREA) to which the question of proximate cause is inapplicable.

United States v. Hodge, 933 F.3d 468 (5th Cir. Aug. 8, 2019), as revised (Aug. 9, 2019)

The Fifth Circuit in *Hodge* reached a different conclusion regarding proximate cause in a Federal Housing Act (FHA) mortgage insurance fraud case. Unlike *Luce*, the misstatements by the *Hodge* defendants related to the identity of the branches, which originated loans being endorsed for FHA insurance.

In affirming the verdict, the Fifth Circuit rejected the strict nexus requirement argued by the defendants, and instead, required only that it be foreseeable that defendants' false statements could have led to an increased risk of default.

II. Specific Types of Claims

A. Anti-Kickback Statute Violations

Guilfoile v. Shields, 913 F.3d 178 (1st Cir. Jan. 15, 2019)

Thomas Guilfoile was employed by John Shields, the CEO of a collection of healthcare companies operating as a single integrated entity ("Integrated Entity"). Guilfoile discovered that Shields entered Integrated Entity into a contract with Michael Greene requiring Integrated Entity to pay Greene's consulting firm $35,000 per quarter for each hospital contract that the firm successfully referred to Integrated Entity. Guilfoile informed Shields that he believed the contract violated the federal Anti-Kickback Statute (AKS) because (1) Integrated Entity had paid Greene to secure contracts with hospitals that Greene was working for, and (2) the contract would result in Integrated Entity making claims for payment to federal insurance programs. Further, Guilfoile told Shields that certain Integrated Entity contracts contained false representations that the entity maintained a fully staffed 24/7 call center. Shields allegedly warned Guilfoile not to go to the board with this information. Shortly thereafter, Guilfoile was terminated from Integrated Entity.

Guilfoile subsequently filed a retaliation action under the FCA. The district court dismissed the claim after determining that Guilfoile had failed to adequately plead he was engaged in protected conduct. Guilfoile appealed.

On appeal, the First Circuit vacated and remanded the dismissal of the retaliation claim regarding the potential AKS violation and affirmed dismissal of the retaliation claim as to the 24/7 call center issue. It found that Guilfoile was only required to plead that his actions in reporting or raising concerns about his employer's conduct "reasonably could lead to an FCA action." Because claims resulting from an AKS violation are statutorily false under the FCA, the court found Guilfoile sufficiently pled conduct that could reasonably lead to an FCA action. The court found that the relationship between Integrated Entity and Greene "has the hallmarks of a kickback scheme" and though the connection to federal claims was attenuated, the alleged payment scheme fell "within the compass of the AKS."

On the other hand, with regards to the 24/7 call center allegations, the court noted that for a contractual breach to reasonably lead to an FCA action, the claimant must adequately plead causation and materiality. The First Circuit affirmed the district court's holding that Guilfoile had not sufficiently pleaded a connection between the 24/7 call center term and submission of any claim to the government.

U.S. ex rel. Arnstein v. Teva Pharmaceuticals USA, Inc., (S.D.N.Y. Feb. 27, 2019)

Former sales representatives of Teva Neuroscience, Inc., a pharmaceutical manufacturer, brought a *qui tam* FCA complaint against Teva alleging that its promotional speaker program "was a conduit through which prescribers were bribed with speaker fees, expensive meals, and alcohol in exchange for prescribing two Teva drugs." Teva moved for summary judgment, arguing that (1) there was no genuine issue of material fact that Teva's speaker program did not violate AKS; and (2) there was no link between the purported AKS violation and the prescription reimbursement claims. The court denied Teva's motion.

First, the court held that there was a genuine issue of material fact as to whether one purpose of the speaker program was to reward prescription writing. The court further found that the AKS does not require evidence of a quid pro quo arrangement because relators proffered several indicia of unlawful relationships, including evidence that Teva tracked speakers' prescriptions of Teva's drugs; Teva did not compensate speakers at fair market value; Teva chose speakers based on the number of prescriptions they wrote; Teva's speaker programs had little educational value; and Teva repeatedly presented the same programs to the same attendees. In contrast, "in a case where all facets of the business arrangements between a payor and doctor are aboveboard, the jury might require evidence of a quid pro quo to enable it to make the difficult factual determination of distinguishing between a motivating factor and a collateral hope or expectation."

Second, the court held that relators sufficiently linked the purported AKS violation to specific prescription reimbursement claims. The court did not require the kickback to be the but-for cause of a prescription. Noting, however, that relators cannot satisfy their causation burden by merely showing correlation, the court relied

on a "middle of the road" approach requiring evidence of a link between a kickback and a reimbursement claim. The court held that relators satisfied causation by identifying prescriptions that Teva speakers wrote and then submitted for reimbursement within six months after Teva paid them to speak.

Bingham v. HCA, Inc., 783 Fed. App'x 868 (11th Cir. July 31, 2019)

Relator Thomas Bingham alleged that HCA violated the AKS and Stark Law based on HCA's "sweetheart deals" to physicians who leased space in HCA-developed office buildings in return for patient referrals. Specifically, Bingham alleged HCA hired a third-party developer to build certain medical office buildings and then provided the developer with millions of dollars of improper subsidies. The developer, in turn, passed those subsidies on to physicians who leased the office space through certain cash-flow agreements and other benefits such as free office improvements.

The district court granted HCA's motion for summary judgment, and Bingham appealed.

On appeal, the Eleventh Circuit affirmed. It concluded that, with respect to the AKS claims, Bingham failed to show that any of the rents to the physician tenants were actually below fair market value or that any of the profits paid to physician tenants through cash-flow agreements were above fair market value. Without a showing that payments differed from fair market value, Bingham failed to demonstrate that HCA provided any remuneration to physician tenants. As to the Stark Law claims, the court determined that there was no "indirect compensation agreement," as Bingham did not show the alleged benefits given by HCA to the physician tenants were "at all correlated with the volume or value of referrals from" physician tenants.

B. Stark Law Violations

United States ex rel. Bookwalter v. UPMC, No. 18-1693 (3d Cir. 2019) (Decision on Rehearing issued Dec. 20, 2019)

In *Bookwalter*, the Third Circuit considered — and then reconsidered — its controversial definition of "varies with volume or value" under the Stark Law. Relators filed the case in 2012, alleging that the reimbursement arrangements for various neurosurgeons employed by UPMC physician practice entities and performing procedures at UPMC-owned hospitals violated the Stark Law. The surgeons' reimbursement arrangements provided for a base salary plus an annual productivity bonus based on the amount of work personally performed by the surgeon — a compensation structure common in hospital settings. The relators claimed this structure constituted an impermissible indirect compensation arrangement not meeting any exception under the Stark Law.

The government intervened as to the claims for the surgeons' professional billings, which UPMC ultimately settled in 2016. The claims related to the hospital billings in connection with these services continued without government intervention and were soon dismissed by the district court.

But in September 2019, the Third Circuit reversed, adopting a worrisome standard that a relator can establish a prima facie Stark Law violation with only three elements: referrals for DHS, a compensation arrangement (or ownership or investment interest), and a Medicare claim for the referred services. According to the Third Circuit, this "combination of factors suggests potential abuse of Medicare. When they are all present, we let plaintiffs go to discovery." Here, the relators alleged the second element was an indirect compensation arrangement, which under Stark Law exists where the physicians' aggregate compensation "varies with" or "takes into account" the volume or value of referrals. In its opinion, the Third Circuit concluded broadly that "compensation varies with referrals if the two are correlated." Thus, a relator need only show that compensation correlates with the value or volume of referrals to reach discovery in a Stark Law case.

UPMC petitioned the Third Circuit to rehear the case, and in December 2019, the court vacated its original decision and issued a revised opinion walking back its conclusions regarding when

compensation "varies with" referrals:

> We need not resolve the meaning of *varies with* here. Regardless, the complaint plausibly alleges that the compensation *takes into account* the volume or value of their referrals. Under the Stark Act and its regulations, compensation *takes into account* referrals if there is a causal relationship between the two. And here, the surgeons' suspiciously high compensation suggests causation.

With this new precedent, the case has been remanded to the district court for discovery.

C. Medicare Advantage

U.S. ex rel. Poehling v. UnitedHealth Group, Inc., No. 16-CV-08697, 2019 WL 2353125 (C.D. Cal. March 28, 2019)

The Centers for Medicare and Medicaid Services (CMS) pays Medicare Advantage (MA) organizations, such as UnitedHealth Group, Inc. ("United"), a predetermined base monthly payment for each Medicare beneficiary enrolled in MA plans. Under 42 C.F.R. § 422.310(e), MA organizations are required to "submit a sample of medical records for the validation of risk adjustment data." In this FCA case, the government argued that (1) this requirement required MA organizations to validate submitted diagnosis codes with beneficiaries' medical records, and (2) United knowingly retained overpayments for unsupported diagnosis codes submitted for various MA patients.

United argued that the government's requirement to delete unsupported codes would contravene the "actuarial equivalence" and "same methodology" provisions of § 1853 of the Social Security Act, which require that CMS ensure actuarial equivalence between groups of people under both traditional Medicare and MA plans and that CMS use unaudited claims data to calculate risk scores and payments of MA beneficiaries.

The court held that "[i]n light of competing regulatory, statutory, and contractual requirements" between CMS and MA organizations, it "cannot determine that it is clear as a matter of law that United was required to delete unsubstantiated diagnosis codes." In reaching its decision, the court analyzed a 2018 decision by the U.S. District Court for the District of Columbia, which found that a CMS overpayment rule violated the statutory mandates of "same methodology" and "actuarial equivalence" by measuring overpayments based on audited patient records rather than unaudited traditional Medicare records. DOJ requested summary judgment on whether regulations or contracts required United to delete from its MA submissions those diagnosis codes unsupported by medical records. The court's denial of the DOJ's motion further calls into question the DOJ's ability to bring FCA cases against MA plans based on unsupported diagnosis codes for MA beneficiaries.

> **Without a showing that payments differed from fair market value, [relator] failed to demonstrate that [defendant] provided any remuneration.**

D. Reverse False Claim and Overpayments

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

Overpayments are a related concept to reverse false claims. The 2010 Affordable Care Act established a requirement under the FCA that any overpayment from a government payor "be reported and returned [within] 60 days after the date on which the overpayment was identified." Since then, providers have questioned what it means to "identify" such a payment.

In 2014, CMS published its final rule governing overpayments, which specified, among other things, that an overpayment to a CMS-contracted insurer under the Medicare Advantage Program would be considered "identified" when the insurer determined, or *should have determined* through reasonable diligence, that it had received an overpayment. The rule also established several other requirements for insurers, including that they undertake "proactive compliance activities conducted in good faith by qualified individuals to monitor the receipt of overpayments."

U.S. ex rel. Kasowitz Benson Torres LLP v. BASF Corp., 929 F.3d 721 (D.C. Cir. July 5, 2019)

This case involves the intersection of an environmental regulatory regime, the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601, *et seq.,* and the "reverse false claims" provisions of the FCA. The law firm Kasowitz Benson Torres LLP asserted the defendants, several large chemical manufacturers, violated the TSCA by failing to report information regarding certain toxic chemicals they were manufacturing to the Environmental Protection Agency (EPA), the enforcer of the TSCA, and by failing to pay TSCA penalties. Kasowitz alleged that the defendants' failure to self-report and pay the penalties constituted reverse false claims violations because the penalties are automatically assessed upon violation.

The D.C. Circuit rejected this theory. Analyzing the enforcement mechanisms of the TSCA, the court noted the TSCA does not automatically assess penalties for violations. Instead, the EPA is authorized to impose a penalty or no penalty at all: "TSCA does not create an obligation to pay a civil penalty at the moment of a statutory violation; an obligation arise[s] only if and when the EPA decides to impose a penalty." Here, the EPA had not assessed penalties against the defendants arising out of their TSCA violations. As such, the defendants had not failed to pay an obligation under the FCA. The court held that an "unassessed potential penalty for regulatory noncompliance does not constitute an obligation that gives rise to a viable FCA claim," and affirmed dismissal.

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

E. Claims Based on Data Analytics

U.S. ex rel. Integra Med Analytics, LLC v. Baylor Scott & White, No. 5:17-CV-886 (W.D. Tex. Aug. 5, 2019) and *U.S. ex rel. Integra Med Analytics LLC v. Providence Health and Services,* No. 17-CV-01694 (C.D. Cal. July 16, 2019)

In 2019, two courts reached different conclusions on FCA claims that were founded almost entirely on a whistleblower's analytics of Medicare claims data, accenting the hurdles and risks of FCA actions based on data analytics. In *Baylor Scott* and *Providence*, the courts grappled with motions to dismiss complaints that presented analytics of government claims data to allege that hospitals' elevated levels of certain major complication or comorbidity (MCC) codes indicated fraudulent upcoding. The complaints also alleged that the upcoding resulted from the providers' clinical documentation improvement programs.

Medicare reimbursements for specific hospital services are, in simplified fashion, based on three types of codes: the principal

diagnosis code, any surgical diagnosis code, and any secondary diagnosis code. Certain secondary diagnosis codes can result in a claim being considered a complication or comorbidity (CC) or a major complication or comorbidity (MCC), which can increase the reimbursement for treatment. In these two cases, the relator alleged that, through a variety of methods, the defendants caused their staffs to code claims as having an MCC to inflate Medicare reimbursements, including through providing unnecessary treatment. The relator uncovered the alleged fraud through proprietary statistical analysis of CMS claims data, which formed the basis of the allegations in its complaints.

In *Baylor Scott*, the court dismissed the complaint, stating that the analytics showed elevated levels of certain procedures, but that providing "a certain treatment at rates higher than average, even significantly higher than average, is not by itself indicative of fraud or unnecessary treatment." The court also stated that allegations that the defendant provided documentation tip sheets and training to physicians to seek opportunities to code MCCs is equally consistent with an upcoding scheme as it is with an effort "to improve revenue through accurate coding of patient diagnoses in a way that will be appropriately recognized and reimbursed by CMS." While the complaint contained allegations that medical coders were pressured to code unethically, the court found that these allegations did not sufficiently allege the who, what, where, or why required for pleading fraud claims with particularity.

The court in *Providence* reached the opposite conclusion, stating that "while the coding rates alone likely would not be enough to state a claim for fraud," the additional allegations the relator included about the use of documentation tip sheets and the hospital's coding vendor's guarantee that it would increase the hospital's case mix were enough to give rise to a plausible inference that the increased coding rates were caused by upcoding. Notably, the court also found that the Medicare claims data analyzed by the whistleblower was a publicly disclosed government report, but that the other information — available on the internet — did not qualify as a public disclosure for FCA purposes.

F. Retaliation

Dhaliwal v. Salix Pharmaceuticals, 752 Fed. App'x 99 (2nd Cir. Feb. 12, 2019)

Dhaliwal brought retaliation claims against Salix Pharmaceuticals, Ltd. under the FCA and the New York False Claims Act. Dhaliwal claimed that she engaged in protected activity when she voiced concerns about Salix's marketing materials, payments for continuing medical education programs, price protection arrangements, and one of its speaker programs. The district court granted Salix summary judgment, which Dhaliwal appealed.

On appeal, the Second Circuit affirmed in part and reversed in part. It agreed that summary judgment against Dhaliwal was appropriate on some claims because Dhaliwal's general concerns about payments and criticism to her superiors that the marketing materials "[do] not set us up for success" were not sufficient to infer that Dhaliwal was raising FCA-related concerns. But the Second Circuit reversed the district court's judgment regarding Dhaliwal's claims pertaining to one of Salix's speaker programs. It found that her statement to a superior that the speaker program was "improper marketing activity" was sufficient for a jury to reasonably infer that Dhaliwal's concerns were related to AKS and FCA violations.

U.S. ex rel. Bias v. Tangipahoa Parish School Board, 766 Fed. Appx. 38 (5th Cir. March 22, 2019)

Relator Ronald Bias filed a *qui tam* action asserting violations of the FCA, 42 U.S.C. § 1983, and Louisiana state law by defendant Tangipahoa Parish School Board. After the FCA, § 1983, and state law claims were either dismissed or settled, the school board argued that Bias' remaining FCA retaliation claim was barred by judicial estoppel because Bias had not disclosed the claim in his Chapter 13 bankruptcy case (filed by Bias in 2008).

To establish judicial estoppel, one must show that (1) a party is asserting a legal position plainly inconsistent with a prior position; (2) the court had accepted that prior position; and (3) the party asserting the potentially inconsistent position did not act inadvertently in doing so. The court assessed all three elements and determined that Bias' claim was barred.

Specifically, the court found that Bias had an affirmative duty to disclose any post-petition causes of action to the bankruptcy court and his failure to disclose the FCA *qui tam* action impliedly represented that he had no such claims. To claim now that he had an FCA cause of action was "plainly inconsistent" with his earlier omission. The court then determined that the bankruptcy court had accepted Bias' prior position that he had no FCA cause of action by granting him a discharge. Finally, the court found that Bias' failure to disclose his FCA claim was not inadvertent because, despite not knowing or being certain about his obligation to disclose post-petition actions, Bias did know about the facts underlying his FCA claim prior to the bankruptcy discharge. Moreover, he had a financial motive to hide the FCA claim from the bankruptcy court, which also indicated his actions were not inadvertent.

U.S. ex rel. Reed v. KeyPoint Gov't Sols., 923 F.2d 729 (10th Cir. Apr. 30, 2019)

In this case, the Tenth Circuit held, to sustain a retaliation claim under 31 U.S.C. § 3730(h), a relator who also works as a compliance official must show the allegedly retaliated-upon conduct went above and beyond the relator's normal job duties.

The defendant, KeyPoint Government Solutions, contracted with government agencies, primarily the Office of Personnel Management, to conduct background investigations of prospective government employees. In executing its duties, KeyPoint was required to meet certain benchmarks and comply with extensive quality control procedures. Relator Julie Reed worked as a quality control analyst within the compliance department. On numerous occasions, she identified shortcomings in KeyPoint's quality control practices and asserted those practices resulted in fraudulent claims for payment. Subsequently, KeyPoint terminated Reed. Shortly thereafter, Reed filed an FCA complaint. The district court later granted summary judgment to KeyPoint.

On appeal, the Tenth Circuit affirmed dismissal of the retaliation claim. It found that Reed's complaint failed to show a sufficient nexus between her reporting activities and notice of an FCA violation. "Compliance employees," such as Reed, "typically must do more than other employees to show that their employer knew of the protected activity." In essence, the court held that Reed failed to distinguish her regular compliance responsibilities — identifying quality control issues — from protected activity such that KeyPoint would be on notice of potential FCA violations. The Tenth Circuit separately rejected the district court's analysis of whether Reed constituted an original source and vacated and remanded for further proceedings.

U.S. ex rel. Lin v. Mayfield, DDS, 773 Fed. App'x 789 (5th Cir. July 19, 2019)

In *Mayfield*, two former employees brought FCA claims against Kool Smiles. They also brought retaliation claims under state law, but not under the FCA. The federal government investigated these claims for several years, after which the relators entered a settlement releasing their claims and reserving their rights to assert FCA retaliation claims. Kool Smiles then moved to dismiss, and relators sought leave to amend to add FCA retaliation claims. The district court denied leave to amend. Relators appealed. On appeal, the Fifth Circuit affirmed, stating that the relators offered no explanation for failing to assert their FCA retaliation claims at the outset of the case.

Garcia v. Professional Contract Services, Inc., 938 F.3d 236 (5th Cir. Sept. 11, 2019)

Defendant Professional Contract Services, Inc. (PCS) provided custodial and grounds maintenance services on government-owned properties. Garcia was senior operations manager for PCS before being fired in 2013. While PCS claimed that Garcia was fired for failing to properly service multiple jobs, Garcia claimed that he was fired in retaliation for raising concerns to the government regarding PCS's operations, including billing the government for work that was not done and manipulating PCS's disability numbers to reach certain thresholds under the Javits-Wagner-O'Day Act. The district court granted summary judgment in favor of PCS, which the Fifth Circuit reversed.

On appeal, the Fifth Circuit clarified the causation standard to be used in retaliation cases. For an FCA retaliation claim, the employee must first establish a prima facie case of retaliation by showing that (1) he engaged in protected activity; (2) the employer knew about the protected activity; and (3) there was retaliation because of the protected activity. Once the employee establishes a prima facie case, the burden shifts to the employer to state a legitimate, non-retaliatory reason for its decision. After the employer provides that benign reason, the burden shifts back to the employee to demonstrate that the employer's reason is actually a pretext for retaliation. The Supreme Court previously made it clear that retaliation claims must be proven according to traditional principles of but-for causation. However, it was not clear whether but-for causation applies only to the final pretext stage, as Garcia asserted, or if it also applies to the initial prima facie stage, as PCS asserted.

After acknowledging a circuit split, the court held that the but-for causation test applies only to the final pretext stage. The prima facie case's causation requirement may be satisfied by showing "close timing" between an employee's protected activity and the adverse action against him, and it was satisfied here by the 76 days between Garcia's whistleblowing and his firing.

Singletary v. Howard University, 939 F.3d 287 (D.D.C. Sept. 20, 2019)

In *Singletary*, the plaintiff claimed that Howard violated the FCA's anti-retaliation provision when it fired her for mounting both internal and external objections to Howard's "failure to maintain the humane laboratory animal living conditions on which [Howard's] receipt of federal funds was conditioned." The district court later denied Singletary's motion to amend her complaint a second time. On appeal, the D.C. Circuit reversed, finding "the district court's decision reflected too narrow a view of the False Claims Act's protection for whistleblowers."

The court held Singletary's proposed amended complaint sufficiently alleged that her actions were undertaken to prevent what she reasonably believed would be the presentation of false claims by Howard. The court found that the district court erred by requiring Singletary to have investigated matters that could lead to a viable FCA case, which would only be necessary if Singletary were pleading the first form of protected activity under 31 U.S.C. § 3730(h)(1) — "lawful acts done . . . in furtherance of [an FCA action]." The court explained that Singletary was not required to allege such investigation because she was proceeding under the second prong of 31 U.S.C. § 3730(h)(1) — "other efforts to stop 1 or more violations [of the FCA]" — which protects a whistleblower's efforts to stop violations of the FCA before they happen or recur.

The court also found the district court further erred by requiring Singletary to allege her actions were outside the scope of her employment responsibilities because the scope of Singletary's employment was only relevant to whether Howard was on notice of Singletary's protected activity. Lastly, in response to the district court's suggestion that Singletary's proposed complaint might not satisfy the heightened pleading standard for fraud claims under Rule 9(b), the court observed that Rule 9(b) only applies to *qui tam* actions under the FCA, but "does not extend to retaliation claims because such claims do not themselves assert or seek to prove actual fraud."

III. Bars and Limitations on Actions

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

A. 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).

Cochise Consultancy, Inc. v. U.S. ex rel. Hunt, 139 S. Ct. 1507 (May 13, 2019)

Relator Bill Joe Hunt filed a complaint alleging petitioners — two defense contractors (collectively, "Cochise") — defrauded the government by submitting false payment claims for providing security services in Iraq up until early 2007. The United States declined to intervene in the action, and Cochise moved to dismiss the complaint as barred by the statute of limitations. The district court dismissed the action, deciding that either § 3731(b)(2) does not apply to relator-initiated actions in which the government chooses not to intervene, or that § 3731(b)(2) applies in non-intervened actions, and the limitations period begins when the relator knew or should have known the relevant facts. On appeal, the Eleventh Circuit reversed based on a third interpretation: that § 3731 applies in non-intervened actions, and the limitations period begins when the government official responsible for acting knew or should have known the relevant facts.

The Eleventh Circuit's holding conflicted with several other circuits. The Fourth and Tenth Circuits held that § 3731(b)(2) does not apply in cases where the government declined to intervene. The Eleventh Circuit's interpretation also conflicted with a Ninth Circuit decision that held that in non-intervened cases, the relator was the "official of the United States" for purposes of § 3731(b)(2).

In a unanimous opinion, the Supreme Court affirmed the Eleventh Circuit's opinion. The Court held that the FCA's limitations discovery rule applies to a *qui tam* action in which the United States does not intervene and that commencement of the limitations period under the discovery rule depends on the knowledge of the United States official charged with the responsibility to act, not the knowledge of the relator. Further, the Court found that civil actions under § 3731(b)(2) include suits initiated by the government and relators alike, and relators are not the statutory equivalent of "the official of the United States" under § 3731(b)(2).

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. Denis v. Medco Health Solutions, Inc., 17-3562 (3rd Cir. June 18, 2019)

Relator Paul Denis alleged that Medco, a pharmacy benefit manager, unlawfully accepted kickbacks in the form of discounts from drug manufacturer AstraZeneca, and those kickbacks in turn tainted requests for reimbursement for those prescription medications to federal health benefit programs. The government declined to intervene. Denis proceeded, but the district court dismissed the case for lack of subject jurisdiction, finding that the alleged misconduct was previously publicly disclosed, and Denis was not an original source. Denis appealed.

The Third Circuit affirmed. It found that Denis was not an original source because he was not directly involved in negotiating the agreements between Medco and drug manufacturers that produced an allegedly fraudulent discount arrangement. The court affirmed dismissal based on the pre-2010 FCA public-disclosure bar. Before 2010, a relator qualified as an original source only if he or she had "direct and independent knowledge of the information on which the allegations are based." Post-amendment the statutory requirement is less stringent, requiring only that a relator have "knowledge that is independent of and materially adds to" information that has been publicly disclosed. Here, the court held that Denis was not an original source because his information was secondhand or came from agreements that were already in place.

Given the recent *Cochise* clarifications on the statute of limitations applicable to FCA suits, awareness of the different original source requirements remains important. Here, the Third Circuit applied the pre-2010 standard, but some courts have applied the post-amendment standard regardless of the date of the allegations, and others have applied both standards, depending on the date of specific information and allegations, for continuing frauds that contain pre- and post-2010 conduct.

Pharmerica Corp. v. U.S. ex rel. Silver, No. 16-4418 (Oct. 7, 2019)

In October 2019, the Supreme Court declined Pharmerica's petition for certiorari, challenging the Third Circuit Court of Appeals' 2018 decision in *U.S. ex rel. Silver v. Omnicare, Inc.* In *Omnicare*, the Third Circuit reaffirmed the principle "that the FCA's public disclosure bar is not implicated in such a circumstance, where a relator's non-public information permits an inference of fraud that could not have been supported by the public disclosures alone." Due to the denial of Pharmerica's petition, the Third Circuit's *Omnicare* decision, which held the public-disclosure bar did not require dismissal of Silver's *qui tam* action because Silver relied on non-public information to make out his claim of hidden fraud, remains intact.

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.

United States v. Millennium Laboratories, Inc., 923 F.3d 240 (1st Cir. May 6, 2019)

In *Millennium*, the First Circuit reversed earlier precedent and held that the FCA's first-to-file rule is not jurisdictional, modifying an existing circuit split on the issue. The FCA's first-to-file rule prohibits relators other than the first to file from bringing a related action based on the same facts underlying the pending action. Here, several relators brought similar *qui tam* actions against Millennium Laboratories. After the government intervened and obtained a settlement in the case, one relator filed a crossclaim for declaratory relief arguing he was the first to file on the case; the other relator moved to dismiss, arguing he was instead the first to file.

Following First Circuit precedent, the district court evaluated the motion to dismiss under Rule 12(b)(1), which permits jurisdictional issues to be raised at any time and to be decided on facts outside the pleadings. In doing so, the district court determined that one relator (Cunningham) was the first to file, and it dismissed the cross claim by the other relator (McGuire) for lack of subject matter jurisdiction. McGuire appealed.

On appeal, the First Circuit analyzed recent decisions from the Supreme Court, as well as the D.C. and Second Circuits, and reversed its prior stance, holding that the first-to-file rule is not jurisdictional. Accordingly, parties seeking to make a first-to-file challenge must now do so under 12(b)(6), using only facts in the pleadings. Applying the new correct standard, the court determined that McGuire was the first-to-file relator. Accordingly, the court reversed and remanded for further proceedings.

D. Issue Preclusion

U.S. ex rel Gage v. Rolls-Royce North America, 760 Fed. Appx. 314 (5th Cir. Jan. 28, 2019)

Relator Gage brought FCA claims against Rolls-Royce, alleging that it was among the companies involved in submitting false claims related to the sale of certain defective aircraft parts to the Air Force. The lawsuit was the third action arising out of the same facts but with different defendants. Gage, a one-time consultant with Rolls-Royce, acted as an expert witness in the first case, but then filed his own FCA lawsuit later against several aviation companies but not Rolls-Royce. After that case was dismissed on Rule 9(b) grounds, Gage filed the instant case in 2016, alleging essentially the same facts and theories but naming Rolls-Royce as a defendant.

The district court dismissed the action, holding that the claims were barred under the doctrine of issue preclusion. On appeal, the Fifth Circuit affirmed dismissal and held that issue preclusion barred Gage's claims that an aviation parts supplier submitted false claims relating to the sales of aviation equipment to the Air

Force because he had previously filed identical claims against other defendants. The only meaningful difference between the suits was the named defendant. Calling the case "the perfect candidate for issue preclusion," the court noted that (1) the alleged facts were identical and that nearly every paragraph in the complaint was copied and pasted from the earlier suit; (2) the issue, whether the allegations were sufficient under Rule 9(b), was litigated fully in the earlier case; and (3) the district court's determination of the issue was necessary and decided.

E. Entire Controversy

U.S. ex rel. Charte v. Am. Tutor, Inc., 934 F.3d 346 (3d Cir. Aug. 12, 2019)

American Tutor brought claims against Charte for defamation, tortious interference with advantageous economic relations, and product disparagement in New Jersey state court. While that lawsuit was pending, Charte brought a *qui tam* action against her former employers related to their allegedly fraudulent billing practices. After entering into a settlement agreement with American Tutor and dismissing the state court action, Charte proceeded with the *qui tam* claims.

At summary judgment, the district court found that the *qui tam* action was barred by New Jersey's equitable entire-controversy doctrine and dismissed the complaint. On appeal, however, the Third Circuit disagreed and concluded that the entire controversy doctrine was inapplicable for three reasons.

First, the court held that the resolution of the state court litigation did not preclude Charte's *qui tam* claims because it would be unfair to Charte, as the named-party relator, and as to the government, as the real party in interest. Because Charte's *qui tam* claims belong to the government, Charte could not dispense with them by settling the state court litigation. The Third Circuit reasoned that a decision to the contrary would be unfair to the government's interests and would conflict with the FCA's rule that pending *qui tam* actions may not be dismissed without written consent from the court and the attorney general.

Second, the court found that Charte followed all statutory requirements applicable to *qui tam* relators and was not "trying to hide the ball." This included attempting to litigate the case out in the open and trying to lift the seal and consolidate the state court action with the *qui tam* action.

Third, the Third Circuit held that applying the entire controversy doctrine in this case would incentivize potential FCA defendants to "smoke out" *qui tam* actions by suing potential relators, settling those claims, and then relying on the settlement to bar the subsequent *qui tam* action.

The FCA's limitations discovery rule applies to a *qui tam* action in which the United States does not intervene and commencement of the limitations period under the discovery rule depends on the knowledge of the United States official charged with the responsibility to act, not the knowledge of the relator.

IV. Pleading and Procedure

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

1. Standard for Dismissal

After 2018's Granston Memo, courts have faced an increasing number of requests by government attorneys to dismiss FCA cases. The recent 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 most prevalent issue on which district courts have been forced to take sides is the *Sequoia Orange-Swift* divide.

Before the Granston Memo, most circuit courts were undecided on the standard to apply to government requests for dismissal. Two courts have typically defined the debate. 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.

U.S. ex rel. Kammarayil v. Sterling Operations, Inc., No. 15-CV-01699 (D.D.C. Feb. 6, 2019)

In *Kammarayil*, the District Court for the District of Columbia emphasized the great discretion afforded the government under *Swift*. Relators Gopalakrishma Kammarayil and Mohammed Shabbir filed an FCA suit alleging that a government contractor, defendant Sterling Operations, Inc., engaged in an armed robbery of its subcontractor to justify Sterling seeking equitable adjustments to its contract price with the government. Despite the fact that the subcontractor prevailed at trial on trespass and breach-of-contract

claims against Sterling, thereby demonstrating some merit to the theories pleaded by Kammarayil and Shabbir, the court nonetheless granted the government's motion to dismiss over the relator's objection that a motion, rather than a notice, was inappropriate.

The court found that, under *Swift*, the government is not required to file a formal notice of its intent to dismiss under Fed. R. Civ. P. 41. Under the FCA, the filing of a motion, rather than a notice, is the proper vehicle to obtain dismissal, and the government satisfied its minimal obligations under § 3730(c)(2)(A) by emailing counsel for Kammarayil and Shabbir and offering them the opportunity to be heard prior to filing the motion.

United States v. Gilead Sciences, Inc., No. 11-CV-00941 (N.D. Cal. Nov. 5, 2019)

In *Gilead*, relators Jeff and Sherilyn Campie alleged that defendant Gilead Sciences, Inc. made misrepresentations to the Food and Drug Administration (FDA) regarding the facilities from which Gilead had obtained the active ingredient for its HIV drug therapies. In June 2015, the court granted Gilead's motion to dismiss the allegations. The Ninth Circuit reversed in July 2017, and the Supreme Court denied Gilead's petition for certiorari in January 2019.

For years, the government, without expressly taking a position on the ultimate merits of the lawsuit, filed statements of interest favorable toward the Campies. Only in November 2018, after Gilead petitioned for certiorari and upon the Supreme Court's request that the government take a position, did the government assert for the first time that, if the case were remanded, it would move to dismiss on resource preservation grounds. According to the government, the discovery demands of the case, among other issues, would "detract from the agency's public-health responsibilities." When the government moved to dismiss, the Northern District of California granted the request over the Campies' objections that the government was required to prove precise quantitative governmental costs.

Recognizing that *Sequoia Orange*, although more demanding than *Swift*, is still "limited in nature" and not intended to "pose a significant barrier to the executive branch's exercise of its prosecutorial authority," the court declined to require the government to "do some kind of mathematical calculation." Because the government engaged in years of investigation and because of the complexity of the materiality determination, the court found a rational relationship between dismissal and governmental resource preservation and no arbitrary or capricious intent.

Ultimately, *Gilead* is notable for the amount of time which elapsed between the unsealing of the complaint and the filing of the government's motion to dismiss, as well as the Northern District of California's emphasis of the limits of a *Sequoia Orange* review.

U.S. ex rel. Sibley v. Delta Reg'l Med. Ctr., No. 4:17-CV-000053 (N.D. Miss. Mar. 21, 2019)

Faced with a *qui tam* based on alleged violations of the Emergency Medical Treatment and Labor Act (EMTALA), the Northern District of Mississippi held, without hesitation, that the government possesses unfettered discretion to dismiss an FCA suit. Although the Fifth Circuit has not expressly resolved the question, the court adopted the Swift standard based on precedent recognizing unlimited governmental power in other contexts, as well as a strict reading of § 3730(c)(2)(A) compared to other subsections of the FCA. The court also found that "it is unnecessary for the government to formally intervene before moving to dismiss," and whether the defendant has been served with the complaint has no impact on the government's discretion to dismiss.

In the alternative, the court held that, even under *Sequoia Orange,* the government stated a rational basis for dismissal given the proclivity for interference in the Department of Health and Human Services - Office of the Inspector General's EMTALA enforcement efforts demonstrated by counsel for relator Candi Sibley in other cases and the costs associated with ongoing monitoring of the

litigation. The court likewise rejected Sibley's efforts to obtain discovery on the government's reasons for dismissal.

U.S. ex rel. Borzilleri v. AbbVie, Inc., No. 15-CV-7881 (S.D.N.Y. July 16, 2019)

In *Borzilleri*, relator John Borzilleri opposed the government's motion to dismiss, arguing, among other things, that the government failed to properly investigate the claims of fraud alleged in the complaint. In considering the government's motion and Borzilleri's opposition, the Southern District of New York acknowledged that it lacked guidance from the Second Circuit sufficient to resolve the question and declined to determine whether *Sequoia Orange* or *Swift* correctly state the appropriate standard.

Because the government's desire to direct "its finite resources elsewhere" is a valid purpose related to, and warranting, dismissal under even the more stringent *Sequoia Orange* approach, the court granted the government's motion.

Polansky v. Executive Health Resources, Inc., No. 12-CV-04239 (E.D. Pa. Nov. 5, 2019)

Like *Gilead*, Polansky also demonstrates the government's power to dismiss an FCA action regardless of the stage of litigation to which the matter has progressed. In this *qui tam*, relator Jesse Polansky alleged that defendant Executive Health Resources, Inc. inappropriately billed federal healthcare providers for inpatient medical services which should have been billed as outpatient. The matter was pending before the district court for more than five years after unsealing and involved extensive discovery and three amendments to the complaint before the government filed its motion to dismiss in August 2019.

Months prior to filing its motion to dismiss, the government had notified counsel for Polansky and Executive that it intended to dismiss the case. Polansky convinced the government not to file for dismissal at the time by offering to narrow his claims in a manner that "substantively and materially changed the … cost/benefit analysis" of invoking § 3730(c)(2)(A). Although the government continued to monitor the litigation, disagreements regarding the extent to which Polansky had actually narrowed the litigation ultimately spurred the government to file for dismissal.

To date, the Third Circuit has expressly refused to resolve the *Sequoia Orange-Swift* dispute, leaving the Eastern District of Pennsylvania to surmise the appropriate standard with disparate results. Unwilling to take a side, the court in Polansky held only that the government satisfied the more rigorous rational relationship standard. Although Polansky argued that the government's reversal of position, after previously agreeing not to move to dismiss, was arbitrary and capricious, the court disagreed, finding instead that the government carefully considered the cost of pursuing litigation after "Relator failed to narrow the universe of his claims in the way he had promised," as well as the consequences of significant discovery issues that had arisen in the months between the government first considering dismissal and ultimately filing its motion. Polansky has appealed.

The recent 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.

2. White Coat Marketing Cases

Several district courts have taken up the subject of how their circuits might decide the standard to apply to governmental requests for dismissal in a series of cases filed across the country involving "white coat" marketing allegations. These cases were filed by limited liability shell companies established by an investment company for the sole purpose of filing pharmaceutical *qui tam* litigation. In its motions to dismiss, filed across the country and identical for the most part, the government took the unprecedented step of chastising the "business model" of these professional relators, while lauding the defendants' services as "appropriate and beneficial to federal healthcare programs and their beneficiaries." A selection of some of these cases is below. Note that Bradley represents defendant entities in certain of these matters.

U.S. ex rel. Harris v. EMD Serono, Inc., 370 F. Supp. 3d 483 (E.D. Pa. Apr. 3, 2019)

In *Harris*, the Eastern District of Pennsylvania adopted the *Sequoia Orange* standard, but nonetheless found that the government's 18-month, cross-country investigation was sufficient to justify the request for dismissal and that relators Panzey Harris and SMSPF, LLC, failed to demonstrate that the government's decision to dismiss was arbitrary and capricious.

U.S. ex rel. CIMZNHCA, LLC v. UCB, Inc., No. 17-CV-765 (S.D. Ill. Apr. 15, 2019)

In *CIMZNHCA*, the Southern District of Illinois applied the *Sequoia Orange* standard, but it diverged from Harris and other courts discussed below by finding the government's decision to move for dismissal was arbitrary. The court based its decision on the government's collective, rather than individualized, investigation into the series of cases and the government's failure to submit a detailed cost-benefit analysis supporting its reason for dismissal. The government has given notice of interlocutory appeal, and the Seventh Circuit is primed to not only decide between the *Sequoia Orange* and *Swift* standards but also determine whether the uncharacteristically strict version of *Sequoia Orange* applied by the Southern District of Illinois was appropriate.

Health Choice Alliance LLC ex rel. U.S. v. Eli Lilly & Co., Inc., No. 5:17-CV-00123 (E.D. Tex. Sept. 27, 2019) and *Health Choice Alliance LLC ex rel. U.S. v. Bayer Corp.*, No. 5:17-CV-00126 (E.D. Tex. Sept. 27, 2019)

In the *Health Choice Alliance* cases, a magistrate judge in the Eastern District of Texas forecasted that the undecided Fifth Circuit would likely apply *Swift*, before determining that, even if *Sequoia Orange* applied, the government satisfied the more arduous standard. The district court adopted the magistrate judge's recommendation but analyzed only whether "controlling costs" were a legitimate interest under *Sequoia Orange*. Ultimately, the court held "if the Government dismisses Health Choice's claims, it will not have to expend those resources. That is a rational relationship: dismissal reduces Governmental burdens." Relator Health Choice Alliance LLC has appealed both cases, but, given the limits of the district court's order, it is unclear whether the Fifth Circuit will take the opportunity to decide between *Swift* and *Sequoia Orange* in this case.

U.S. ex rel. SCEF, LLC v. AstraZeneca, Inc., No. 2:17-CV-1328 (W.D. Wash. Nov. 5, 2019)

In *SCEF,* the Western District of Washington applied Ninth Circuit precedent *Sequoia Orange*, but, like *Harris*, granted the government's motion to dismiss.

3. No Hearing Requirements

U.S. ex rel. Davis v. Hennepin Cty., No. 18-CV-01551 (D. Minn. Feb. 13, 2019)

In *Davis*, the District of Minnesota suggested how it believes the Eighth Circuit might resolve the standard for dismissal and the question of whether a relator is entitled to a hearing. The court sided with *Swift*, believing that Eighth Circuit opinions, referencing the government's "significant control over the course of the litigation," determined the issue. Continuing, the court held that relators are required only to receive notice of a motion to dismiss and the *opportunity* for a hearing, "nothing more or less," and there is no entitlement to an evidentiary hearing.

Of note, the tortured history of the case may have influenced the court. Relators previously filed three *qui tam* actions against the defendants, two of which were *pro se* and later dismissed, based on the same set of facts. The District of Minnesota also rejected the relators' argument that the government must intervene in order to move for dismissal. One relator's appeal has been dismissed by the Eighth Circuit on procedural grounds, while the second relator's appeal (filed *pro se*) will likely follow suit, guaranteeing the wait continues for resolution of these questions by the Eighth Circuit.

Chang, U.S. ex rel. v. Children's Advocacy Center of Delaware, 938 F.3d 384 (3rd Cir. Sept. 12, 2019)

Relator Weih Steve Chang filed a *qui tam* action under both the FCA and the materially identical Delaware False Claims Act (DFCA) against the Children's Advocacy Center of Delaware alleging that the center had applied for and received funding from state and federal governments by misrepresenting material information. When both the governments declined to intervene, Chang filed an amended complaint, and the center answered. Three years later and after investigating Chang's allegations, the United States and Delaware each moved to dismiss the case because the allegations were "factually incorrect and legally insufficient." In response, Chang filed a consolidated opposition that did not request oral argument or a hearing, and the District of Delaware granted the motions to dismiss without conducting an in-person hearing or issuing a supporting opinion.

On appeal, the Third Circuit first noted that it need not take a side in the *Sequoia Orange-Swift* circuit court split to resolve the appeal because Chang failed even under the more restrictive standard. Continuing, the court held that the dismissal provisions in the FCA and DFCA do not guarantee an automatic in-person hearing. Rather, an in-person hearing is unnecessary unless the relator expressly requests a hearing or makes a colorable threshold showing of arbitrary government action. Neither scenario was present in *Chang*, and thus the Third Circuit determined that the district court's dismissal was appropriate.

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. Strubbe v. Crawford County Memorial Hospital, No. 18-1022 (8th Cir. Feb. 11, 2019)

Relators Stephanie Strubbe, Carmen Trader, and Richard Christie sued Crawford County Memorial Hospital (CCMH) and its CEO, alleging that CCMH had violated the FCA by, among other things, submitting false claims for breathing treatments and laboratory services performed by paramedics. The district court dismissed the suit for failure to meet the heightened pleading standards of Rule 9(b). Specifically, the court found the complaint failed to allege facts that showed that claims from the elaborate schemes were actually submitted to the government for payment.

On appeal, the Eighth Circuit affirmed the district court, pointing out that while Strubbe and her fellow relators had described the allegedly fraudulent schemes in detail, "[t]he FCA attaches liability, not to the underlying fraudulent activity, but to the claim for payment" (quoting *Olson v. Fairview Health Servs. of Minn.,* 831 F.3d 1063, 1070 (8th. Cir. 2016)). While the court gave relators credit for doing more than had been done in *United States ex. rel. Joshi v. St. Luke's Hosp., Inc.,* the complaint failed to provide representative examples of the conduct alleged or to create a reasonable belief that the claims were actually submitted, falling short of meeting the specificity standard of Rule 9(b).

Relators appealed to the Supreme Court, which denied certiorari on November 25, 2019.

Godecke ex rel. U.S. v. Kinetic Concepts, Inc., 937 F.3d 1201 (9th Cir. Sept. 6, 2019)

Relator Geraldine Godecke worked for Kinetic Concepts, Inc. and KCI USA, Inc. (collectively "KCI") as the director of Medicare and Cash Collections. Godecke alleged that KCI delivered durable medical equipment to Medicare patients before obtaining a detailed written order from a physician, which was a requirement for Medicare reimbursement. Godecke presented her findings to her boss and was fired a few weeks later. She later filed a *qui tam* action under the FCA. The district court dismissed the lawsuit on the grounds that Godecke failed to plead a fraudulent scheme with reliable indicia, scienter, and specific examples.

On appeal, the Ninth Circuit reversed the district court. The court explained that a relator is not required to identify specific examples of a false claim and only needs to allege a "scheme to submit false claims paired with reliable indicia that lead to a strong inference that the claims were actually submitted." The court also found that the complaint plead the requisite scienter as Godecke alleged that KCI knowingly submitted claims without the requisite modifier. Finally,

the court held that Godecke had plausibly alleged materiality as she alleged that Medicare would not reimburse the charges if it knew that there was no prior written order.

U.S. ex rel. Gelbman v. City of New York, -- Fed. App'x --, No. 18-3162 (2d Cir. Oct. 17, 2019)

Relator Andrew Gelbman, a former information specialist with the New York Department of Health (NYDOH), brought an FCA *qui tam* complaint against the City of New York. In the complaint, Gelbman alleged that the city submitted false Medicaid reimbursement requests to the U.S. government. At the center of the allegations was the automated computer screening process that NYDOH used to determine whether a claim was reimbursable and ultimately submitted to the government. Gelbman contended that the city conspired to manipulate that system such that ineligible claims were still submitted to the federal government.

The district court dismissed the complaint for failure to state a claim under Rule 12(b)(6) and failure to plead fraud with sufficient particularity under Rule 9(b). Gelbman appealed, and the Second Circuit affirmed. In doing so, the court noted that the complaint did not allege actual submission of false claims. Nor did it set forth any reasons why the information submitted to the government was uniquely within the defendant's knowledge or control, or adduce any facts to create a strong inference of fraud. Finding that it was "left to speculate as to the specific design and implementation of a scheme that purportedly defrauded the federal government of more than $14 billion," the court agreed that Gelbman failed to satisfy Rule 9(b) and affirmed dismissal.

C. Non-Intervened Claims

U.S. ex rel. Brooks v. Stevens-Henager College, Inc., 359 F.Supp.3d 1088 (D. Utah Jan. 14, 2019)

Relators Katie Brooks and Nannette Wride brought a *qui tam* action against five colleges and an individual alleging violations of the FCA. The relators claimed that the colleges knowingly submitted false claims to the government for Title IV funds. The government chose to intervene in the case on some claims and declined to intervene on other claims. The relators sought to continue to pursue non-intervened claims on their own.

Following the filing of the colleges' motion to dismiss, the court *sua sponte* ordered the parties to brief whether the FCA gave relators the right to pursue non-intervened claims when the government chooses to intervene in only certain parts of the case. In the court's January 14, 2019, opinion ruling on the motion to dismiss, the district court held that, pursuant to the language and legislative history of the FCA, a relator has no independent right to litigate the non-intervened portions of a case.

D. Government Use of Temporary Restraining Order

United States v. Oakley Pharmacy, Case No. 19-cv-000009 (M.D. Tenn. Feb. 7, 2019)

In an *ex parte* motion, the DOJ sought a temporary restraining order against two pharmacies, the pharmacies' majority owner, and certain pharmacists, requesting that the court enjoin the pharmacies from distributing or dispensing any more controlled substances due to purported violations of the Controlled Substances Act. The government alleged that, between at least January 2015 and August 2018, the pharmacies "illegally filled thousands of prescriptions for powerful opioid painkillers and other controlled substances that had no legitimate medical purpose." Specifically, the government alleged that the pharmacies knowingly dispensed controlled substances without a valid prescription in violation of 21 U.S.C. § 842(a)(1). The government also alleged FCA violations related to Medicare funds used to pay for the controlled substances, as well as customers who were Medicare beneficiaries and who had been treated for drug overdoses. The court granted the government's motion and ordered that the pharmacies stop distributing and dispensing controlled substances, surrender all controlled substances in their possession, custody, and control, and maintain all records relating to their distribution of controlled substances. The court issued the TRO without advanced notice to the pharmacies, finding that notice would result in immediate and irreparable injury, loss, or damage in the form of harm to the pharmacies' customers and potential destruction of evidence. The court held that the government may serve the TRO on the same date on which it executed search warrants on the pharmacies.

E. Sanctions

1. Fee Shifting

Pack v. Hickey, 776 F. App'x 549 (10th Cir. Jun. 11, 2019)

The incentive for many relators' attorneys to pursue FCA claims may often be the attorneys' fees awarded at the conclusion of a successful lawsuit. In *Pack*, however, the Tenth Circuit upheld the District of Wyoming flipping the tables and awarding attorneys' fees to the defendants.

After a romance with his business partner went sour, relator Roy Pack alleged that his former company, Cloud Peak Initiatives, Inc., and partner, Maureen Hickey, committed Medicaid fraud by improperly billing therapy services. Pack appealed after the district court entered summary judgment and awarded fees against him.

Under the FCA, § 3730(d)(4) provides for an award of fees to defendants in non-intervened *qui tams* where the relator pursues claims that are "clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment." This standard is much higher than § 3730(d)(1)-(2), because defendants must not only prevail, but also prove conduct meeting the strictures of Fed. R. Civ. P. 11 for sanctionable behavior. Reviewing the district court's determination for abuse of discretion, the Tenth Circuit upheld summary judgment and the award of fees because Pack "failed to depose or obtain a sworn statement from any of the key individuals, most notably Hickey. Moreover, in both his deposition and discovery responses, Pack admitted he was unable to identify a single concrete example

of a fraudulent bill." In short, an FCA *qui tam* is not the appropriate mechanism by which to seek retribution against former lovers.

2. Dismissal

Rangarajan v. Johns Hopkins University, 917 F.3d 218 (4th Cir. Feb. 22, 2019)

Plaintiff Mitra Rangarajan was discharged as a nurse practitioner by Johns Hopkins University and proceeded to file four separate actions arising out of the same course of events, including claims under the FCA and the Maryland False Health Claims Act. The university filed a motion for sanctions following Rangarajan's failure to comply with discovery requests and the Federal Rules of Civil Procedure. The district court dismissed one of Rangarajan's actions for failure to prosecute and dismissed the remaining three actions as a sanction based on the finding that she "flagrantly and unremittingly violated the rules governing discovery and summary judgment motions practice."

Rangarajan appealed the district court's dismissal arguing that the court abused its discretion in dismissing the three causes of action. The Fourth Circuit upheld the district court's decision, holding that Rangarajan's "conduct under the procedural rules was inept and abusive to the degree that . . . it rendered virtually useless five years of proceedings before the district court."

F. Effect of Guilty Pleas

U.S. ex rel. Doe v. Heart Solution, PC, 923 F.3d 308 (3d Cir. May 3, 2019)

The two individual defendants, Kirtish and Nita Patel, pleaded guilty to defrauding Medicare. Before their pleas, a relator had filed a suit against Nita Patel, her company, Heart Solution, Kirtish Patel, and his company, Biosound, under the FCA and several New Jersey common law claims. After the Patels' convictions, the United States filed for partial summary judgment, arguing that Ms. Patel's admissions in her plea colloquy estopped her, her husband, and their companies from contesting FCA liability. The trial court granted summary judgment. Ms. Patel and Heart Solution appealed.

The primary issue in the appeal was whether the plea colloquy should estop Ms. Patel and Heart Solution from contesting their liability under both the FCA and the common law claims. At the colloquy, Ms. Patel admitted that she or her husband "falsely represent[ed] to Medicare that the neurological testing being performed at Biosound Medical Services was being supervised by a licensed neurologist, when, in fact, it was not" (alterations in original). The court found that Ms. Patel's statements related only to Biosound's schemes to Medicare and, consequently, the colloquy did not estop Heart Solutions from contesting its liability. The court vacated summary judgment as to Heart Solution.

As to Ms. Patel, the court affirmed summary judgment on the FCA claims and common law fraud, but reversed summary judgment on the other common law claims. With regard to the FCA, the court focused primarily on materiality and causation under *Escobar*, finding both elements satisfied. The government had introduced evidence that Medicare did not pay the types of claims submitted by Ms. Patel and Heart Solution with the fraudulent certification. Ms. Patel and Heart Solution did not present any evidence to rebut this.

G. Protection of Investigation Materials

U.S. ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc., No. 13-CV-3003 (D. Minn. July 19, 2019)

In August 2017, the United States intervened in a *qui tam* case that was filed against the Cameron-Ehlen Group, Inc., d/b/a Precision Lens, alleging that Precision Lens provided kickbacks to physicians to persuade them to use its eye-surgery products. Following the unsealing of the *qui tam* complaint, Precision Lens filed a motion to compel discovery seeking, *inter alia*, to compel the government to identify and detail each alleged false claim, as well as all reports and notes of witness interviews prepared during the government's investigation.

In April 2019, the magistrate judge granted Precision Lens' motion, ordering the government to both provide information on each allegedly false claim and to turn over all reports and notes of witness interviews. In analyzing the work-product doctrine, the magistrate judge noted that, while the FBI began its investigation into the defendants in 2012, the U.S. Attorney's Office did not become involved in the investigation until 2014, and it could not demonstrate that the pre-2014 materials should be protected by the work-product doctrine. Further, the judge found that Precision Lens had "demonstrated both substantial need and the inability to otherwise obtain the information without undue hardship" required to obtain documents that contained factual post-2014 work-product information. The judge then ordered an *in camera* review take place to determine whether the post-2014 notes and reports at issue contained fact work product or opinion work product, the latter of which was protected. The government appealed the magistrate judge's order.

On July 2019, the district court affirmed the magistrate judge's order. In doing so, the court rejected the government's argument that all post-2014 interview materials should be considered opinion work product because an assistant U.S. attorney was involved in all witness interviews, finding that such a definition of opinion work product was incorrect. The analysis of the work-product doctrine in both of the decisions may be important to determine what investigational materials may be considered discoverable in future FCA cases.

H. Trial Issues

U.S. ex rel. Oberg v. Penn. Higher Educ. Assistance Agency, 912 F.3d 731 (4th Cir. Jan. 8, 2019)

Relator Oberg sued four student loan servicing companies, alleging that they had violated the FCA by improperly reclassifying student loans to obtain Department of Education subsidies. After years of litigation, only one defendant, the Pennsylvania Higher Education Assistance Agency (PHEAA), remained. After a week-long jury trial, the jury found in PHEAA's favor. Oberg appealed, raising arguments related to evidentiary issues and exclusion of certain jury instructions. The Fourth Circuit affirmed. The court found no abuse of discretion as to the evidentiary issues and, reviewing under a plain-error standard, found the trial court's instructions covered substantially the same points as Oberg's requested instructions.

I. Settlement Share

United States v. L-3 Communications EOTech, Inc., 921 F.3d 11 (2d Cir. Apr. 4, 2019)

DaSilva was a quality control engineer at EOTech. After being convicted of unrelated criminal conduct and fleeing to Brazil before his sentencing, DaSilva filed a *qui tam* action alleging EOTech manufactured and knowingly sold the government defective holographic firearm sights in violation of the FCA. DaSilva's *qui tam* counsel moved to voluntarily dismiss his case, which the government consented to, and the case was ultimately dismissed without prejudice.

Over a year after DaSilva's voluntary dismissal, the government commenced its own FCA lawsuit against EOTech. The parties quickly settled, with EOTech agreeing to pay the government $25.6 million. Several months later, DaSilva filed a motion to be declared eligible to share in the government's recovery, claiming that he filed a valid *qui tam* lawsuit that was dismissed only after intense pressure from the government. He further argued that the FCA did not require his original claim to continue or succeed in order for him to share in the government's settlement proceeds. The district court denied DaSilva's motion, finding that, although the FCA generally entitles a relator to share in the government's recovery, DaSilva was precluded from such share because he had voluntarily dismissed his lawsuit before the government brought suit. DaSilva appealed.

On appeal, the Second Circuit held that nothing in the record supported DaSilva's claim that he was unfairly pressured to dismiss his *qui tam* action and that the legal effect of a voluntary dismissal is that it is as if the action had never been filed. The court further noted that the FCA entitles a relator to share in the government's recovery from an alternative action if the relator's *qui tam* action was pending when the government was deciding on what action to take. Since voluntary dismissal made DaSilva's action a nullity, there was no pending *qui tam* action that entitled him to share in the government's recovery in its own subsequent proceeding.

J. No Standing to Intervene in Criminal Actions

United States v. Wegeler, 941 F.3d 665 (3d Cir. Oct. 28, 2019)

Relator Jean Charte filed an FCA action alleging that various defendants, including James Wegeler, submitted false reimbursement claims to the U.S. Department of Education. As required under § 3730(b)(2), Charte disclosed evidence and information related to her complaint to the government. That information led to the criminal prosecution of Wegeler for tax fraud and tax evasion. Wegeler entered a plea agreement that, among other things, required him to pay $1.5 million in restitution, which he paid before he was sentenced. Later, the government declined to intervene in FCA action brought by Charte.

Under the § 3730(b)(5), if the government elects to pursue an "alternate remedy" instead of intervening in a relator's complaint, the relator retains "the same rights in such proceeding" as she would have had if the action had continued under the FCA. When Charte learned of the Wegeler plea agreement, she attempted to intervene in the criminal case to claim a share of the restitution pursuant to § 3730(b)(5). The district court denied her motion, and Charte appealed.

On appeal, the Third Circuit affirmed, holding that Charte had no standing to intervene and that "the rights to participate in a proceeding that the alternate-remedy provision provides a relator does not extend to a criminal proceeding." As to standing, the court noted the long-held tradition in American jurisprudence that a private citizen lacks "a judicially cognizable interest in the prosecution or nonprosecution of another." In that regard, it found that Charte was "no different than any other member of the public in terms of the concrete harm she suffered" and, accordingly, she lacked standing. Charte claimed that she sought to intervene only insofar as to protect her share of restitution and that the FCA gave her a procedural right to do so. The court rejected this too, noting that the "sole remedy" the FCA provides is to commence or continue an FCA action — not to intervene to assert a share in proceeds.

V. Parties

A. Private Equity Fund as Defendant

U.S. ex rel. Medrano v. Diabetic Care Rx, LLC, No. 15-cv-62617 (S.D. Fla. Mar. 6, 2019)

In *Medrano*, the government intervened in a suit involving an alleged kickback scheme orchestrated by compounding pharmacy Patient Care America (PCA) and its private equity owner Riordan,

Lewis & Halden, Inc. (RLH). The government alleged that PCA hired marketing companies to generate patient referrals for compounded topical creams and paid its marketers kickbacks based on the profit it derived from Tricare reimbursements. The government also alleged that PCA, and one of its marketers, covered patients' copayments and submitted claims to Tricare that did not result from a valid prescriber-patient relationship. PCA and RLH moved to dismiss the government's claims.

On referral, the magistrate judge issued a report recommending dismissal of the government's FCA claim, *with* prejudice, on the grounds that it failed to satisfy the heightened pleading standards under Federal Rule of Civil Procedure 9(b). The district court agreed. Specifically, the court found that to state an FCA claim based on an anti-kickback violation, the government must allege a claim under either an express or implied certification theory, both of which it found to be absent from the government's complaint.

Rejecting the government's objections, the court concluded that an alleged violation of the AKS is not sufficient in and of itself to state a claim under the FCA — otherwise, the heightened pleading standards for FCA claims would be rendered meaningless. The district court did not, however, adopt the magistrate judge's recommendation to dismiss the claim with prejudice and granted the government leave to amend.

B. Individual Liability

U.S. ex rel. Clarke v. Aegerion Pharmaceuticals, Inc., No. 13-CV-11785 (D. Mass. Mar. 31, 2019)

Former sales representatives at Aegerion Pharmaceuticals, Inc. brought an FCA lawsuit claiming that Aegerion's off-label marketing scheme caused false claims for reimbursement to be submitted to the government. The government intervened as to defendant Aegerion and later reached a settlement agreement. The government declined to intervene as to the remaining defendants.

Thereafter, the remaining defendants jointly filed a motion to dismiss all remaining claims based on, among other arguments, failure to plead with sufficient particularity under Fed. R. Civ. P. 8 and 9(b) and the public-disclosure bar. The court denied the joint motion in full. The remaining defendants also individually argued that the claims against them should be dismissed. The court denied the motion to dismiss as to the claims against all Aegerion employee defendants, but granted the motion to dismiss as to the sole board member defendant because the relators failed to allege sufficient facts to meet the relaxed standard for indirect claims.

VI. DOJ Memos and Policy Announcements

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

Guidance to Prosecutors on FCA Investigations

In May 2019, DOJ issued guidance regarding cooperation credit for defendants in FCA investigations. Covered in detail in *DOJ Provides Guidelines for Reducing False Claims Act Settlements through Cooperation*, the new guidance outlined three ways FCA defendants could potentially earn cooperation credit — through voluntary disclosure, cooperation, and remedial measures. It went on to list 10 non-exhaustive types of cooperation, including identifying individuals substantially involved in the misconduct, disclosing relevant facts and opportunities for the government to obtain evidence relevant to its investigation, and assisting in the determination or recovery of losses. Under the guidance, the most common credit available will be reduced penalties or damages at the discretion of DOJ.

Codified at Section 4-4.112 of the Justice Manual, the guidance marked a continued refinement of DOJ's approach in the wake of the 2015 Yates Memorandum and a move toward increased flexibility for federal prosecutors. While the guidance provides greater clarity and opportunities for FCA defendants seeking cooperation credit, its purposefully flexible standards leave DOJ attorneys with broad discretion in determining whether and to what extent to grant such credit.

Further Comments on the Granston Memo

As we discuss above, in the wake of the 2018 Granston Memo, courts have increasingly been asked to wrestle with § 3730(c)(2)(A) and

define the parameters of the government's power. While the courts have taken varying approaches with equally varying results, DOJ officials have also made noteworthy public statements regarding their view of policy toward dismissal of non-intervened *qui tam* complaints. In March 2019, Michael Granston, director of DOJ's Civil Fraud Section and namesake of the memo, spoke at the Federal Bar Association's FCA Conference. There, he stated that DOJ would not dismiss *qui tam* actions solely based on potentially burdensome discovery requests to the government. Rather, the decision would be made on a case-by-case basis, focusing on whether the relator can prove the allegations. Granston explicitly cautioned that a defense strategy of "pursuing undue or excessive discovery" will not be successful "for getting the government to exercise its dismissal authority," a step that will "remain the exception rather than the rule."

Deputy Associate Attorney General Stephen Cox delivered related remarks at the 2019 American Conference Institute Advance Forum on False Claims and *Qui Tam* Enforcement. He characterized the relationship between relators and the government as a "partnership," while noting that DOJ played an important "gatekeeping role" in ensuring the government's financial and legal interests are not harmed in non-intervened *qui tam* cases. In later remarks at a different event, Cox stated that DOJ's "more consistent[]" use of its dismissal authority is intended to prevent "overreach in whistleblower litigation."

Finally, in late December 2019, DOJ responded to Sen. Chuck Grassley's September 2019 letter raising questions about DOJ's implementation of the Granston Memo. The response did not address many of Grassley's questions, but it did summarize DOJ's recent use of its dismissal authority under § 3730(c)(2)(A). Among other information, the response noted that since the Granston Memo, DOJ filed 45 motions to dismiss under § 3730(c)(2)(A) out of over 1,100 qui tam actions filed. Of the 26 such motions that were decided, only one was denied by the court.

Updated Guidance on Corporate Compliance Programs

On April 30, 2019, Assistant Attorney General Brian Benczkowski issued an updated version of DOJ's *Evaluation of Corporate Compliance Program*, a document intended to guide prosecutors in evaluating corporate compliance programs and corporations in creating them. Bradley analyzed the new guidance shortly after its release in *DOJ Evaluation of Corporate Compliance Programs*.

The April 2019 guidance updates a similar document issued February 2017 and consolidates several DOJ sources used to evaluate compliance programs. According to DOJ, the goal in the effort was to "better harmonize the guidance with other Department guidance and standards while providing additional context to the multifactor analysis of a company's compliance program."

The updated guidance provides significant detail, including concrete descriptions and specific requirements for effective compliance programs. Echoing related provisions in the Justice Manual, the guidance focuses on three "fundamental questions" a prosecutor should ask in evaluating a compliance program — is the program well designed? is the program "applied earnestly and in good faith"? does the program work in practice? — and provides a detailed discussion of assessing each. Among the key points, companies should tailor their plans to their specific business and high-risk issues; effective plans should track, monitor, and measure results; companies should regularly review and refresh their plans so they stay current and don't get stale; and senior management remain critical in setting the proper tone for a compliance culture.

Overall, the updated guidance provides companies with a helpful benchmark for evaluating their existing, or creating their new, compliance programs. For a more detailed discussion of the updated guidance, see *Justice Department issues new guidance on corporate compliance programs*.

Criminal Penalties: Guidance on Inability-to-Pay Claims

On October 8, 2019, Assistant Attorney General Brian Benczkowski issued a new memorandum entitled *Evaluating a Business Organization's Inability to Pay a Criminal Fine or Criminal Monetary Penalty.* The memo sets out guidance, based on various factors, for federal prosecutors to follow when corporations claim that they are unable to pay a criminal fine or monetary penalty. The guidance applies to criminal division lawyers handling criminal — not civil — cases, but it has relevance for FCA defendants facing parallel criminal-civil investigations and as a general indicator of DOJ's evolving view toward corporate defendants. According to the memo, the guidance's goal is to "demystify[] the considerations commonly confronted by white-collar prosecutors" and provide companies with the "information and security they need to invest fully in compliance on the front end, and to make good decisions in the face of misconduct on the back end."

Under the new guidance, the burden of establishing an inability to pay continues to rest with the corporation or other entity making the claim and requires it to provide information in response to DOJ's inquiries. That now includes responding to the memo's "Inability-to-Pay Questionnaire," which is attached to the memo. The questionnaire requests various financial information, including (1) cash flow projections; (2) operating budgets and projections for future profitability; (3) capital budgets and projections of annual capital expenditures; (4) proposed changes in financing or capital

structure; (5) acquisition or divestiture plans; (6) restructuring plans; (7) claims to insurers; (8) related-party transactions; (9) encumbered assets; and (10) liens on assets.

The memo instructs prosecutors to consider an array of factors when considering a company's inability-to-pay claim. For context, the memo notes the factors in 18 U.S.C. § 3572(a) that courts are required to consider when determining whether to impose a fine and how much to impose, as well as the commentary regarding fines for business organizations in the U.S. Sentencing Guidelines. The memo also lists specific factors to consider, including (1) background on current financial condition; (2) alternative sources of capital; (3) collateral consequences; and (4) victim restitution considerations.

Based on a consideration of the factors in the memo and the corporation's responses, federal prosecutors can consider recommending adjustments to fines or penalties to avoid "threatening the continued viability of the organization" or "impairing the organization's ability to make restitution to victims." The memo further allows that other "severe" collateral consequences, even if they do "not necessarily threaten the continued viability of the organization," may warrant an adjustment.

Memorandum of Understanding: Federal Housing Administration Violations and the FCA

On October 28, 2019, DOJ and the Department of Housing and Urban Development (HUD) jointly issued a memorandum of understanding describing broad guidelines on how the agencies will coordinate to use the FCA to enforce violations of federal housing requirements. The memorandum indicates that, in general, HUD will enforce violations through the usual HUD administrative proceedings and refer potential FCA litigation to DOJ "only where such action is the most appropriate method to protect the interests of FHA's mortgage insurance programs, would deter fraud against the United States, and would generally serve the best interests of the United States." It goes on to describe the procedural steps — via the Mortgage Review Board, HUD, and DOJ — such referrals will typically follow. For additional information, see *HUD and DOJ Release Memorandum on the Application and Enforcement of FHA Violations Involving the FCA*.

WHAT TO WATCH IN **2020**

Ninth Circuit Ruling on Whether Information Online Is "News Media"

In an interlocutory appeal of a case discussed further above in this publication, the Ninth Circuit may expound on the definition of "news media" for the public-disclosure bar. In *U.S. ex rel. Integra Med Analytics LLC v. Providence Health and Services*, the allegations in the relator's complaint are based entirely on data analytics of Medicare claims data, as well as information about the defendants that is available online. After denying the defendants' motion to dismiss, the Central District of California certified "whether all online information is disclosed from the 'news media' such that it would fall under the public disclosure bar of the False Claims Act" for appeal to the Ninth Circuit.

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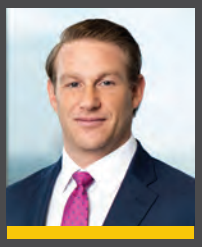

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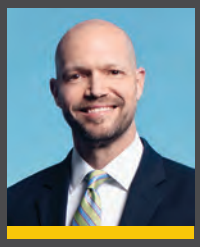

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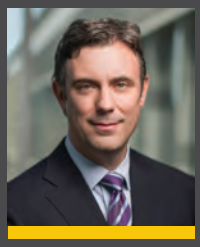

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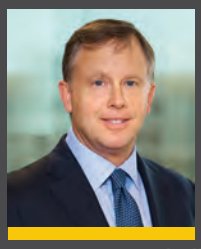

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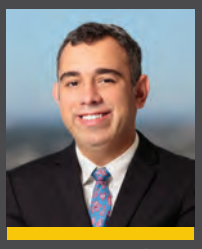

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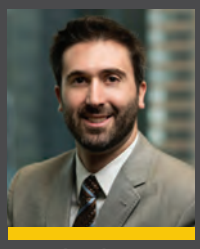

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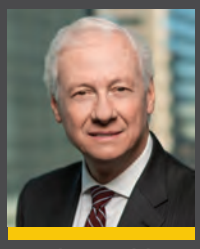

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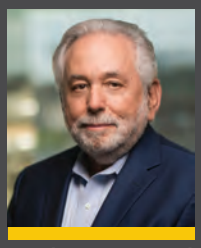

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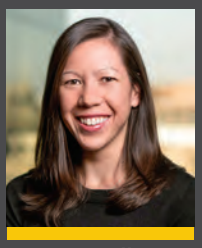

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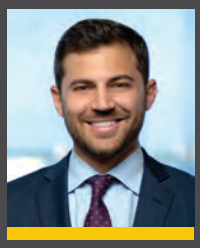

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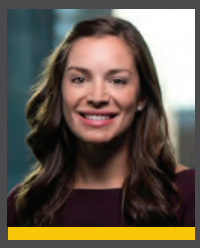

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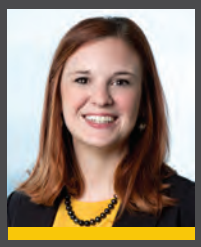

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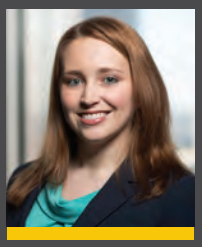

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