Bradley

Bradley Arant Boult Cummings LLP

FALSE CLAIMS ACT
2021 YEAR IN REVIEW

10TH ANNIVERSARY EDITION

FALSE CLAIMS ACT
2021 YEAR IN REVIEW

The year 2021 marks the 10th anniversary of the Bradley False Claims Act Year in Review. In that decade, much has remained the same in FCA enforcement. To start with the obvious: It continues to result in billions of dollars in recoveries to the United States at the expense of FCA defendants. Over the years, we've described that enforcement as "robust," "significant," and "aggressive" multiple times, and this year is no different with over $5.6 billion in judgments and settlements — the second highest total ever. But FCA jurisprudence has also changed in important ways, too, as significant court decisions, Department of Justice (DOJ) policies, and evolving industry practices shape the type of cases brought and how they are resolved.

We examine those trends and much more in this year's review. We begin this year with a brief look back at the decade since we first published the FCA Year in Review in 2012, focusing particularly on Supreme Court decisions and other large-scale developments related to the FCA.

Turning to the year just passed, you'll find a succinct guide to FCA issues from 2021, with case summaries, statistics, and emerging areas of focus. And if you'll forgive a bit of self-promotion on our anniversary, we also celebrate notable 2021 accolades for Bradley's nationwide FCA practice, including our status as one of the top three most active False Claims Act firms in the country (per Lex Machina's 2021 report) and our Tier 1 national ranking for Criminal Defense: White Collar Litigation in *U.S. News & World Report.*

Finally, to all our clients and readers alike: thank you. We hope you've enjoyed the FCA Year in Review over the years, and we look forward to the next decade of covering this interesting, dynamic area of the law.

10 YEARS

of the Bradley
False Claims Act Year in Review

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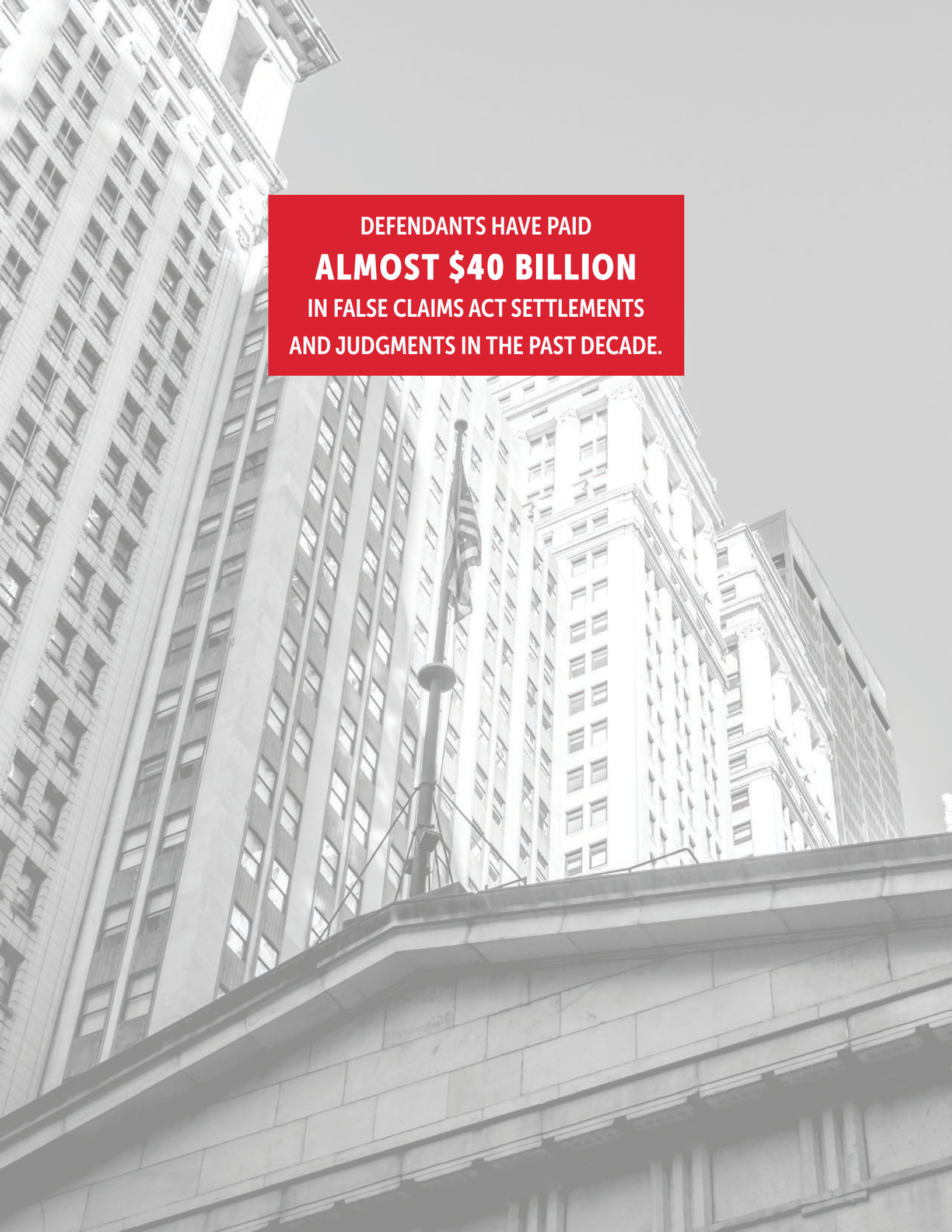
Bradley ranks in the
TOP 3
most active False Claims Act litigation law firms in the United States.
-Lex Machina 2021 False Claims Litigation Report



DEFENDANTS HAVE PAID

ALMOST $40 BILLION

IN FALSE CLAIMS ACT SETTLEMENTS AND JUDGMENTS IN THE PAST DECADE.

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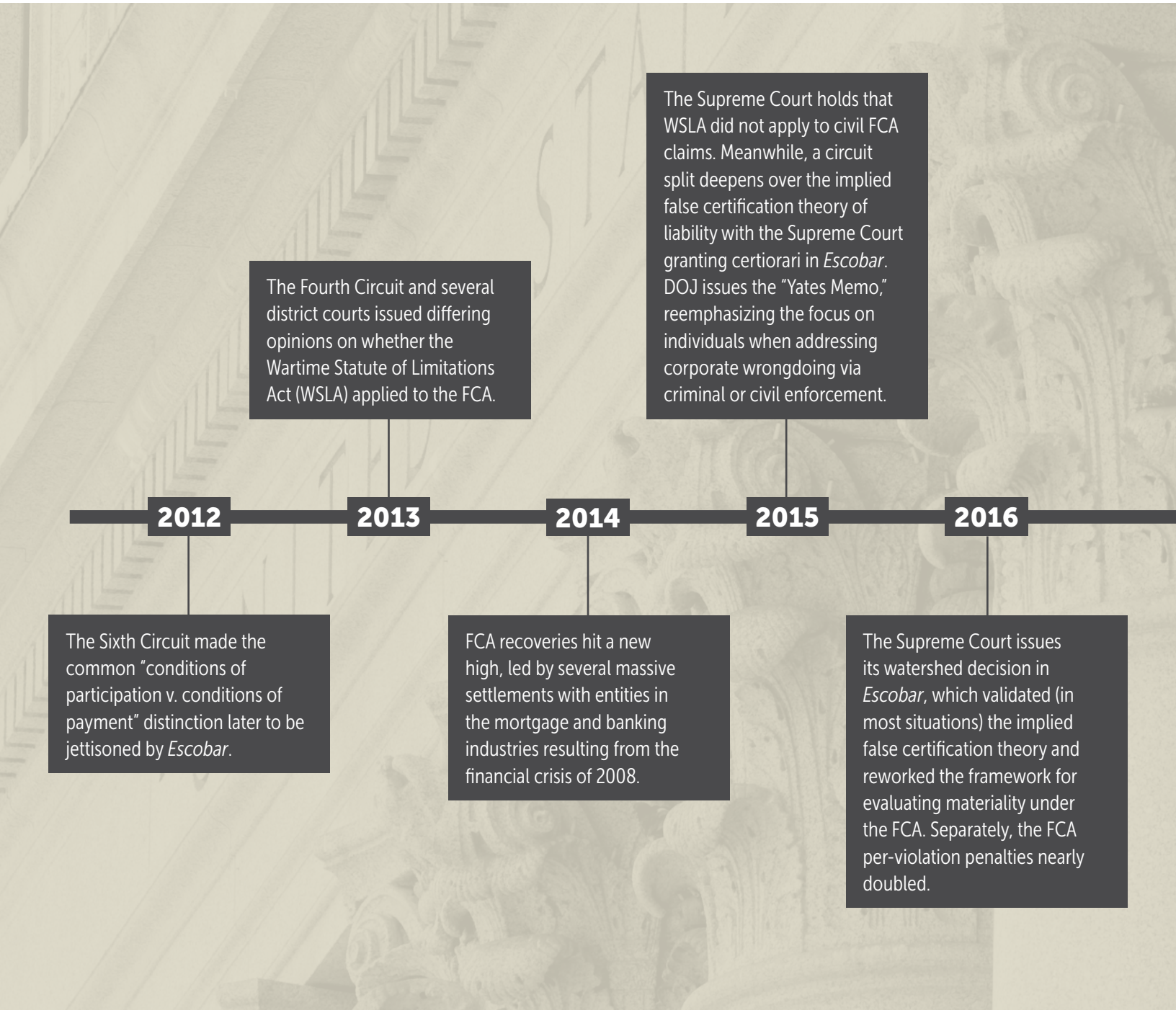
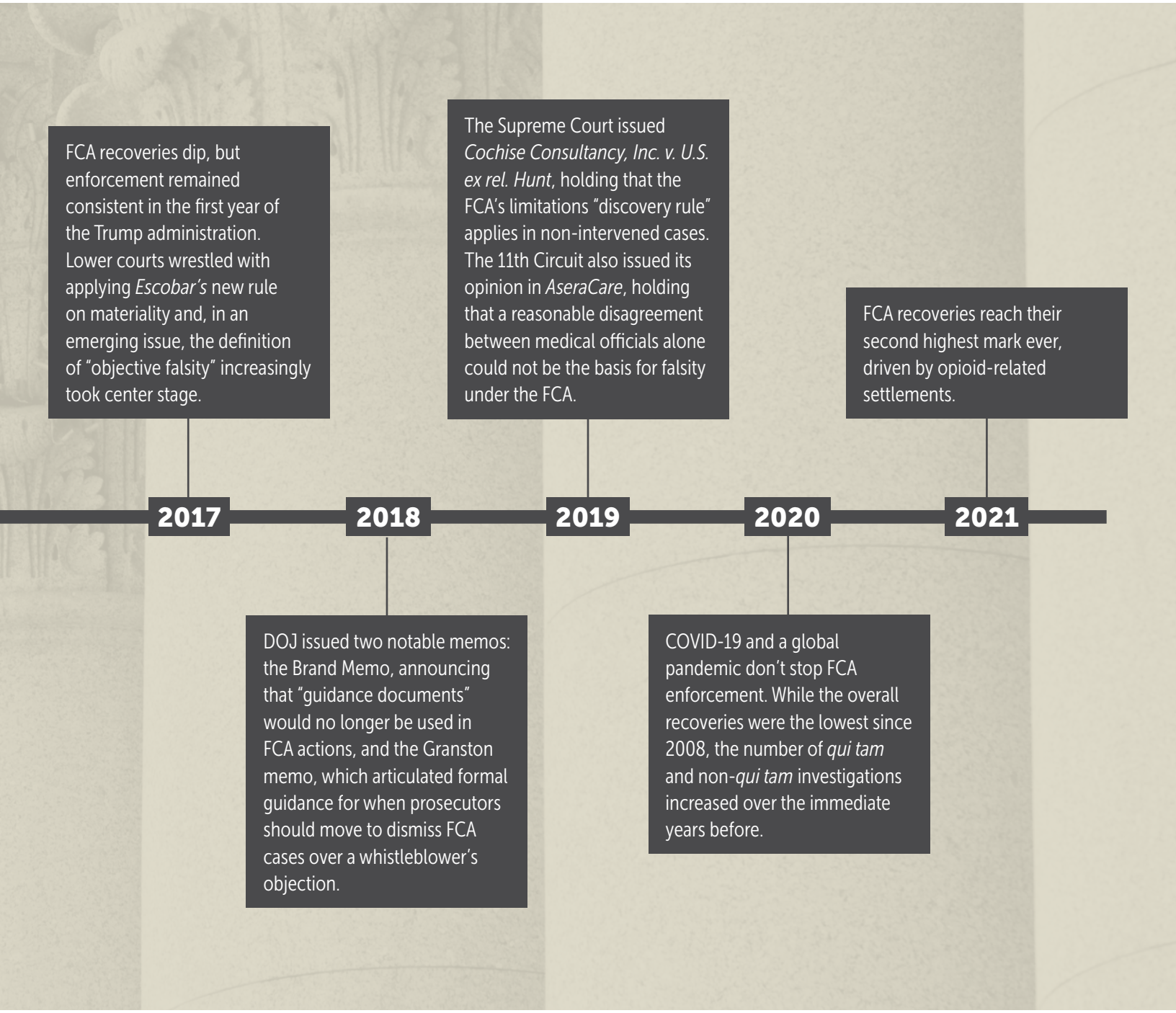
2012-2021: A LOOK BACK

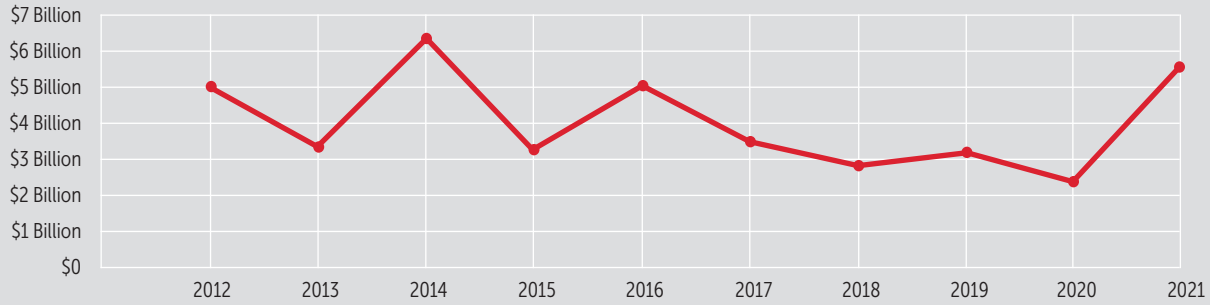



FCA recoveries dip, but enforcement remained consistent in the first year of the Trump administration. Lower courts wrestled with applying *Escobar's* new rule on materiality and, in an emerging issue, the definition of "objective falsity" increasingly took center stage.
2017
DOJ issued two notable memos: the Brand Memo, announcing that "guidance documents" would no longer be used in FCA actions, and the Granston memo, which articulated formal guidance for when prosecutors should move to dismiss FCA cases over a whistleblower's objection.
2018
The Supreme Court issued *Cochise Consultancy, Inc. v. U.S. ex rel. Hunt*, holding that the FCA's limitations "discovery rule" applies in non-intervened cases. The 11th Circuit also issued its opinion in *AseraCare*, holding that a reasonable disagreement between medical officials alone could not be the basis for falsity under the FCA.
2019
COVID-19 and a global pandemic don't stop FCA enforcement. While the overall recoveries were the lowest since 2008, the number of *qui tam* and non-*qui tam* investigations increased over the immediate years before.
2020
FCA recoveries reach their second highest mark ever, driven by opioid-related settlements.
2021

DOJ YEAR-END STATS

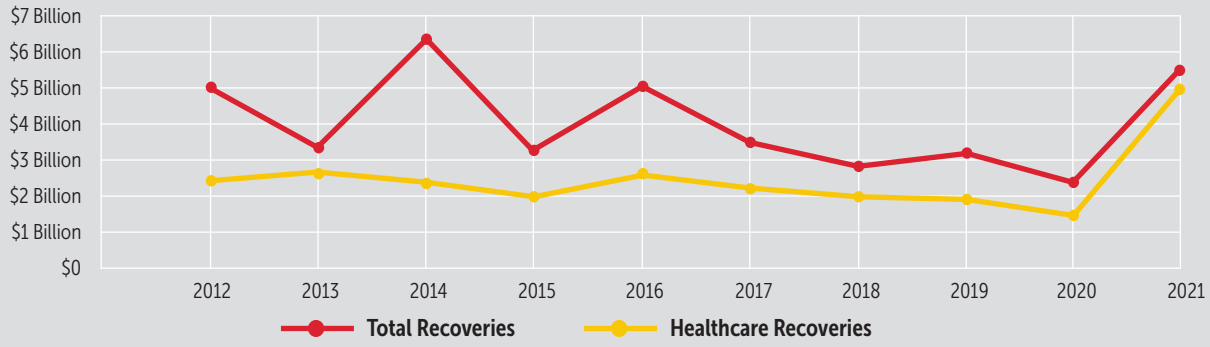
In fiscal year 2021, FCA recoveries topped $5.6 billion. The charts below and throughout the FCA Year in Review track notable trends in recoveries and other key metrics over the last decade.

Total FCA Recoveries 2012-2021

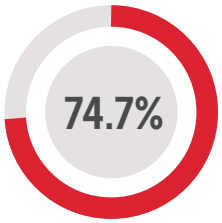


In the past decade, the FCA resulted in defendants paying billions of dollars each year, with notable spikes in 2014, 2016 and 2021.

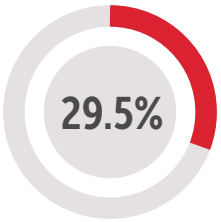
Healthcare Recoveries vs. Total Recoveries 2012-2021



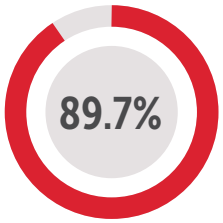
FCA recoveries from the healthcare industry make up the largest portion of FCA recoveries with no sign of changing over the past 10 years.



Percentage of new FCA matters in 2021 originated by relators



Percentage of recoveries in 2021 from relator-filed cases



Percentage of recoveries in 2021 from healthcare cases

KEY DECISIONS & DEVELOPMENTS

FALSITY

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

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

***U.S. ex rel. Bell v. Cross*, No. 21-11064, 2021 WL 5544685 (11th Cir. Nov. 26, 2021)**
For clinical judgments to be "false" under the FCA, they must be objectively false; mere differences of opinion will not suffice.

In *Bell*, the Eleventh Circuit applied the logic set forth in its landmark AseraCare hospice opinion to the skilled nursing and therapy context. Relator Delia Bell, a registered nurse employed by skilled nursing facility defendant Cross Garden Care Center (CGCC), alleged that CGCC and its owner Karl Cross violated the FCA by providing unnecessary therapy services, artificially inflating RUG scores, improperly refusing to discharge patients during their first 100 days at the facility, and improperly re-admitting patients to reset the 100-day period during which Medicare would reimburse for therapy services. The district court granted defendants summary judgment, and Bell appealed.

The Eleventh Circuit affirmed judgment in favor of the defendants, holding that "in order for a clinical judgment to be 'false' in the context of the FCA, it must be objectively false," which Bell had failed to prove during discovery. Specifically, Bell was not a licensed therapist or medical director, never saw any billing statements for the patients referenced in the complaint, and offered no testimony from a professional qualified to order therapy or write prescriptions. Without evidence establishing a verifiable, factual flaw in clinical judgment, Bell's testimony regarding her beliefs that therapy was unnecessary established nothing more than a mere difference of opinion, insufficient to establish FCA falsity. Bell's efforts to prove falsity with emails from Cross also fell short. The Eleventh Circuit held that emails from Cross, who "inquired about raising RUG scores" and "instructed [Bell] to raise one patient's RUG score without offering a reason for the change," did not show that such adjustments were inappropriate and therefore failed to demonstrate an objectively false claim.

***United States v. McKesson Corp.*, 19-cv-02233-DMR, 2021 WL 583506 (N.D. Cal. Feb. 16, 2021)**

Relators' implied certification claim dismissed for failing to plead, per *Escobar*, that there was any representation that could be considered a misleading half-truth.

Relators alleged that McKesson ran afoul of the FCA by violating various laws and regulations that govern the distribution of pharmaceuticals while selling pharmaceuticals to the United States under contracts that required it "to comply with all applicable Federal, State and local laws, executive orders, rules and regulations applicable to its performance." Relators identified no actual representations of any kind in claims submitted to the government. They alleged the claims were false under both express and implied certification theories of falsity, because by filing claims, McKesson falsely represented to the government that it was compliant with those laws and regulations as required by the contract.

The court summarily rejected the express certification theory noting that there was no allegation whatsoever that the actual claims certified compliance with laws and regulations and "[requiring compliance as part of a contractual agreement is not the same as requiring express certification of compliance each time a claim is made."

The court then rejected the implied certification theory because the relators failed to plead that the claims contained any representation that could be considered a "misleading half-truth." The court noted that post-*Escobar*, Ninth Circuit precedent required that an implied false certification claim must rest on two requirements: (1) the claim must make specific representations about goods or services, and (2) the defendant's failure to disclose non-compliance with material, statutory, regulatory, or contractual requirements makes those representations misleading half-truths. Thus, relators must allege some content in the claims that could be deemed representations about the nature of the goods or services provided. Here, the relators made no such representations.

MATERIALITY

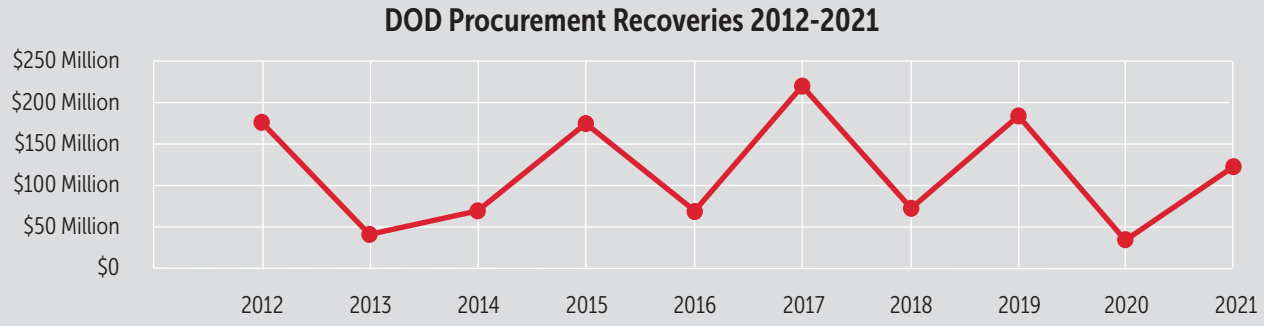
***U.S. ex rel. Bibby v. Mortgage Investors Corp.*, 987 F.3d 1340 (11th Cir. Feb. 17, 2021)**

In a relator-friendly decision, the Eleventh Circuit downplays the government's continued payment of claims in its materiality analysis, finding other factors deserved more weight and reversing summary judgment for defendants.

In the latest instance of courts interpreting the Supreme Court's landmark FCA ruling in *Universal Health Services, Inc. v. Escobar*, the Eleventh Circuit recently departed from the trend of giving great weight in the analysis of whether a violation was material to the fact that the government continued payment, finding that other efforts by the government to redress noncompliance may prevent judgment in a defendant's favor.

As a prerequisite to obtain a Veterans Affairs (VA) loan guaranty, lenders are required to certify compliance with various VA regulations, including limitations on the fees charged to veterans. Here, former mortgage brokers who specialized in originating VA mortgage loans brought suit against a mortgage lender, alleging that it charged veterans unallowable fees and lied to the VA about it.

Relators notified the VA of the alleged fraud in 2006, and the VA's own audit samples pointed out the potential noncompliance. As a result, between 2009 and 2011, the VA issued post-audit deficiency letters directing the defendant to review VA policies and make adjustments to its loan origination process to ensure future compliance. Between 2010 and 2011, the VA also implemented more frequent and rigorous audits focused on rooting out improper fees and charges. However, the VA did not revoke payment on guarantees of loans with purportedly fraudulent fees.



FCA claims against Department of Defense contractors result in millions of dollars of recoveries each year.

Citing the Supreme Court's emphasis in *Escobar* that "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material," the district court granted summary judgment for the defendant.

The Eleventh Circuit reversed. Despite agreeing that, under the standard promulgated by sister courts, the VA had knowledge of the alleged violations based on the deficiency letters, the Eleventh Circuit minimized the import of evidence of continued payment because the VA was obligated by law to pay the mortgage guarantees. The Eleventh Circuit "divorce[d] [its] analysis from a strict focus on the government's payment decision," emphasizing instead that "the significance of continued payment may vary depending on the circumstances." In this case, because 38 U.S.C. § 3721 requires the VA to pay holders in due course (who in this case were assignees without involvement in the original charging of fees), the Eleventh Circuit concluded that continued payment should carry little weight in the analysis, and that the court should consider the VA's other actions, such as issuing a circular to lenders and implementing more frequent audits of this issue. Finding that there was sufficient evidence on the record to create a genuine dispute of fact with regard to materiality, the Eleventh Circuit reversed the summary judgment decision.

Defendants should pay attention to this relator-friendly ruling when assessing the likelihood of success on motions practice in the ever-changing world of *Escobar* — continued payment by the government may not always be a winning argument, depending on the facts of the case. The fact that the government submitted an amicus brief in support of the relators' appeal is also noteworthy as an indication that the government considers the meaning of *Escobar* to be far from settled.

***U.S. ex rel. Prose v. Molina Healthcare of Illinois, Inc.*, 17 F.4th 732 (7th Cir. Nov. 15, 2021)**
The Seventh Circuit finds allegations sufficient under Rule 9(b) and materiality issues dealing with government knowledge better addressed after discovery; the dissent strongly disagrees.

In *Prose*, a split panel of the Seventh Circuit reversed the district court's dismissal. Over a strong dissent, the majority concluded that the relator Thomas Prose had sufficiently pleaded the elements of an FCA claim. In particular, both the majority and dissent offered extended analysis of the materiality element based on the Supreme Court's standards announced in *Escobar*.

Prose's FCA lawsuit arose from Molina's provision of Medicaid services via a capitation contract, which is a contract in which the parties agree to a fixed per-patient fee for services within the plan. For skilled nursing facility (SNF) services, one subset of services within this plan, Molina subcontracted with another provider, GenMed. When that subcontract was terminated, however, Molina continued to accept the same capitation payments despite no longer providing the SNF services. Prose — the founder of GenMed — brought the FCA action alleging that Molina submitted false claims under various theories of liability by continuing to accept these payments.

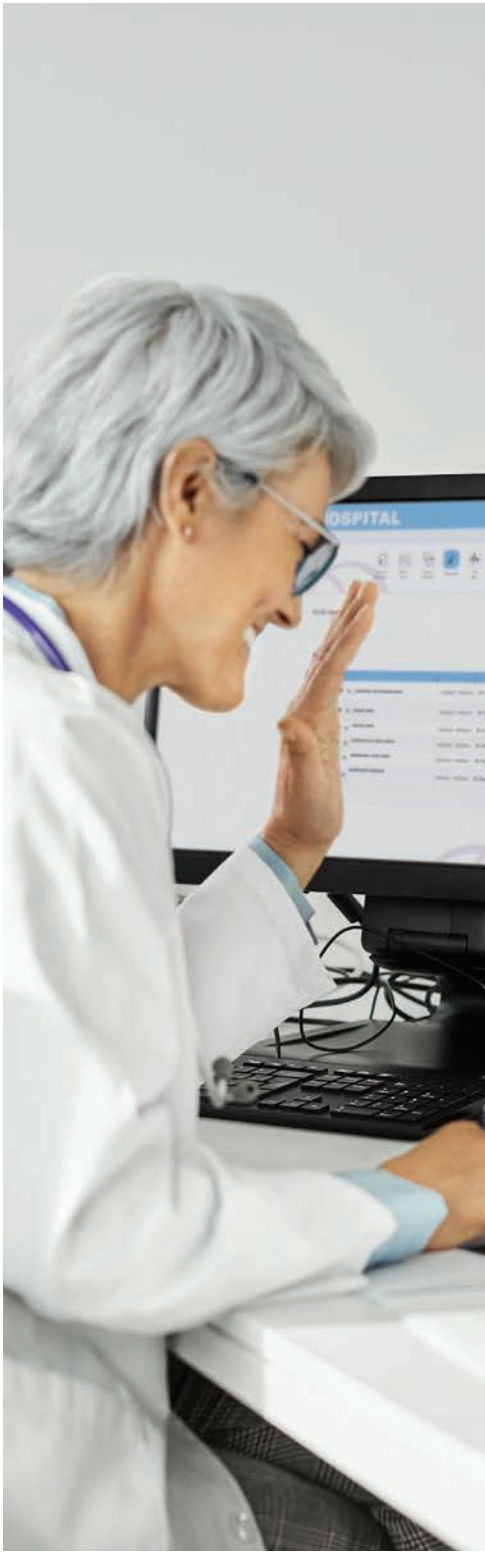
The district court dismissed the case, concluding that Prose had failed to adequately plead his claims under Rule 9(b). The Seventh Circuit reversed. The majority found that under any of the forwarded theories — false certification, promissory fraud, or implied false certification — the allegations were sufficient to survive a motion to dismiss.

The materiality issue at the core of the opinion arose primarily under the implied certification theory. There, Prose alleged that by submitting enrollment forms for new beneficiaries after GenMed terminated the SNF services, Molina impliedly falsely certified that the beneficiaries had access to SNF services, which they did not. Molina countered that the government had renewed Molina's contract twice during this time and knew that the SNF requirements were not met — the type of "actual knowledge" that *Escobar* had found to be "very strong evidence" that the requirements were not material to the payment decision.

The majority found Prose's allegations adequate under *Escobar* and that the "actual knowledge" arguments by Molina were "better saved for a later stage" in the litigation after discovery. The dissent strongly disagreed, reasoning that Prose had failed to plead the "who, what, when, where, and how" of the fraud as required by Rule 9(b). For the implied false certification theory, the dissent noted that the majority failed even to address the threshold *Escobar* conditions for that theory — that a claim makes specific representations about the goods or services provided and that the failure to disclose the noncompliance made the misrepresentation a misleading half-truth. On the materiality element in particular, the dissent found that Prose's "generic statements" about SNF services and differences in the capitation rates did not meet Rule 9(b)'s "demanding" standard for materiality at the pleading stage.

***U.S. ex rel. Foreman v. AECOM*, 19 F.4th 85 (2d. Cir. Nov. 19, 2021)**
The Second Circuit affirms dismissal, finding that government knowledge of noncompliance negates materiality — except where that conclusion is improperly based on materials extraneous to the complaint.

Relator Hassan Foreman alleged that defense contractor AECOM violated the FCA by improperly billing the Army for work that was never performed, by inflating a statistic used to measure how much time AECOM personnel worked on the Army's projects compared to their overall time on



duty (man-hour utilization), and by improperly purchasing, tracking, and returning government property. The district court granted AECOM's motion to dismiss because Foreman failed to show that these allegations were material to the Army's decisions to pay AECOM's claims.

On appeal, the Second Circuit reversed the district court's dismissal of the FCA claims based on improper labor billing. The court determined the district court erred when it consulted a report that was neither mentioned in Foreman's complaint nor formed the basis for any claims in the complaint, thereby improperly relying on material extraneous to the complaint to establish government knowledge of the alleged violations.

The Second Circuit, however, affirmed the dismissal of the remaining claims for lack of materiality. It found that the district court properly dismissed claims based on an inflated man-hour utilization rate and the mishandling of government property because the complaint and related documents showed the government had actual knowledge of AECOM's noncompliance, continued to pay AECOM's claims, extended the contract, and increased funding under the contract.

The court affirmed the district court's dismissal of Foreman's reverse false claims theory because it was impermissibly based on the same conduct as the false claims allegations.

***Druding v. Care Alternatives, Inc.*, No. CV 08-2126, 2021 WL 5923883 (D.N.J. Dec. 15, 2021)**
In this hospice-eligibility case, on remand the court finds that the doctor-relators failed to establish materiality when the government had long known of Care Alternatives' documentation shortcomings and still paid its claims.

In this significant hospice-eligibility case, the district court originally granted summary judgment for Care Alternatives. Relying heavily on similar reasoning in *AseraCare*, the court found that the mere difference of medical opinion on a patient's terminal diagnosis was not enough to establish falsity under the FCA. In March 2020, the Third Circuit reversed and departed from the Eleventh Circuit's reasoning in *AseraCare,* concluding instead that falsity could turn on evidence other than just the physician's clinical judgment and that subjective medical opinions could be "false" under the FCA.

This opinion followed the remand from the Third Circuit where the district court addressed summary judgment again, but this time focusing on the FCA's materiality element. Care Alternatives argued that relators — doctors who worked for Care Alternatives — had adduced insufficient evidence of materiality for the case to proceed to trial.

The court found relators had produced sufficient evidence to support falsity of the claims because the medical records and certifications did not comply with Medicare's hospice requirements. But relators failed to produce evidence establishing that the deficiencies were material to the payment decision. In particular, the court noted that, despite Care Alternatives' long-standing documentation problems, the government kept paying after it was aware of the poor documentation. The court stated: "it is incumbent upon the Relators to present some evidence suggesting the Government's apparent disregard of the inadequacies in Care Alternatives' billing documentation was not the result of its having concluded those inadequacies were immaterial to its decision to make those payments anyway." Because materiality was lacking, the district court again granted summary judgment for Care Alternatives.

Commentary

Proposed FCA Amendments

Long-time FCA champion Sen. Chuck Grassley (R-Iowa) proposes amendments to statutorily loosen the FCA's materiality standard in the wake of *Escobar* and modify the standard for government dismissal.

Following the Supreme Court's 2016 holding in *Universal Health Services, Inc. v. Escobar*, lower courts have wrestled with *Escobar's* guidance on what must be pleaded to establish materiality. In particular, many courts have found that an FCA claim lacks materiality when a defendant can show that the government continued to pay a claim with knowledge of the alleged false representation.

In response, Sen. Grassley introduced, and the Senate Judiciary Committee later approved, a bill that would amend the FCA in several ways, including — most significantly — changing the materiality standard. As now drafted, the bill states that "the Government's decision to forego a refund or to pay a claim despite knowledge of fraud or falsity shall not be considered dispositive if other reasons exist for the decision of the Government with respect to such refund or payment." That amendment was amended itself from an earlier version introduced in the summer that contained a muddled (and much-criticized) burden-shifting framework for materiality. The current language, while more relator friendly and arguably at odds with traditional understandings of materiality, effectively just codifies the reasoning of one line of post-*Escobar* cases, most notably *U.S. ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d. 890 (9th Cir. 2017). Campie and similar cases found that the government may continue to pay for many reasons and such continued payment was not dispositive as to materiality. If enacted, the bill's most practical effect is likely to allow more FCA cases to survive a motion to dismiss.

Separately, the bill would amend certain standards when the government seeks to dismiss a *qui tam* action itself. Codifying the Ninth Circuit's "*Sequoia Orange*" standard, the amendment would require the government to explicitly identify "a valid government purpose and a rational relation between dismissal and accomplishment of that purpose" before dismissing a *qui tam* action over a relator's objection. This proposed amendment also puts a heavy burden on relators who object to the government's dismissal by requiring them to demonstrate that the government's dismissal is "fraudulent, arbitrary and capricious, or illegal."

If these amendments are enacted, they should not affect pending cases. The amendments explicitly provide that they should only apply to cases filed after the amendments are enacted.

SCIENTER – RECKLESS DISREGARD

To satisfy the FCA's scienter element, a defendant must either have actual knowledge of the falsity of information, act in deliberate ignorance of its truth or falsity, or act in reckless disregard of its truth or falsity.

***U.S. ex rel. Schutte v. SuperValu, Inc.*, 9 F.4th 455 (7th Cir. Aug. 12, 2021)**

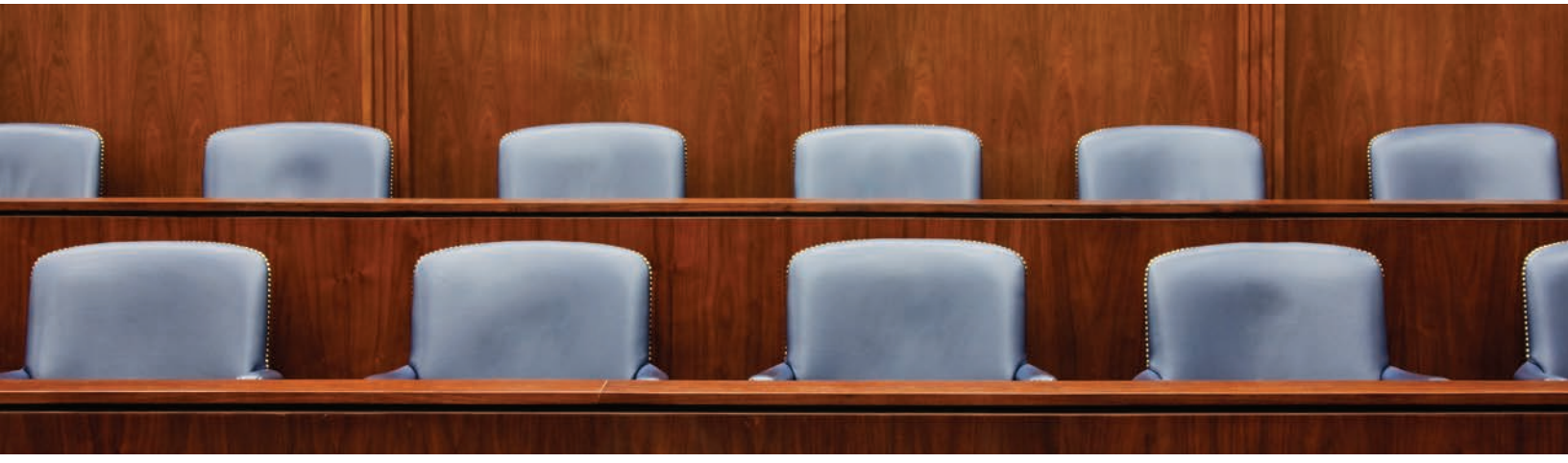
Joining four other circuits, the Seventh Circuit concludes that the definition of "reckless disregard" in the FCA should be interpreted in the same way as the Supreme Court interpreted that term in the Fair Credit Reporting Act in *Safeco Ins. Co. v. Burr,* 551 U.S. 47 (2007).

Relator Tracy Schutte sued the SuperValu grocery chain alleging that it had violated the FCA by reporting that the usual and customary (U&C) price of certain pharmaceuticals it sold was the retail cash price. Schutte claimed that the U&C price should include the discounts SuperValu offered to any customer who requested a price match based on a competitor's lower price.

Between the time Schutte filed her suit and this decision, the Seventh Circuit determined that SuperValu's method of calculating the U&C price was legally incorrect. Thus, there was no question in this case as to whether SuperValu's claims were false. The only question that remained was scienter: Did SuperValu submit the false claims knowingly?

Joining the D.C., Third, Eighth, and Ninth circuits, the Seventh Circuit applied the Supreme Court's reasoning in *Safeco Ins. Co. v. Burr* to interpret "reckless disregard" in the FCA context. Specifically, acting under an incorrect interpretation of a relevant statute or regulation is not reckless disregard if the defendant's interpretation was objectively reasonable and no authoritative guidance cautioned against the defendant's interpretation.

Here, the Seventh Circuit concluded that SuperValu's interpretation of the U&C price was objectively reasonable. The interpretation was permissible, and there was no government guidance to warn SuperValu away from its interpretation. The court rejected the argument that a defendant could still be liable under the FCA under the actual knowledge or deliberate ignorance scienter standards, stating that reckless disregard is the lowest level of scienter and if it is not established then neither of the other standards can be established. The court stated that "[a] defendant might suspect, believe or even intend to file a false claim, but it cannot know that its claim is false if the requirements for that claim are unknown."



CAUSATION

***U.S. ex rel. Cimino v. Int'l Bus. Machs. Corp.*, 3 F.4th 412 (D.C. Cir. July 6, 2021)**
The D.C. Circuit holds that but-for causation is a required element of a fraudulent inducement claim.

In *Cimino*, the D.C. Circuit held that but-for causation is a necessary element of a fraudulent inducement claim under the FCA. In the operative complaint, the relator, Paul Cimino — a former senior sales representative for defendant IBM — alleged that IBM fraudulently induced the IRS to enter a $265 million license agreement for unwanted and unneeded software. Specifically, Cimino alleged that IBM violated the FCA in two ways: first, by fraudulently inducing the IRS to enter the agreement by using a false audit and referencing false compliance penalties, and second, by presenting false claims when it charged the IRS for prospective licenses it never provided. The district court granted IBM's motion to dismiss, holding that Cimino had failed to plead but-for causation and had also failed to plausibly plead his presentment claims.

On appeal, the D.C. Circuit acknowledged that it had not yet explicitly addressed the requirement of causation in fraudulent inducement claims under the FCA. It reasoned that "the nature of the common law tort of fraudulent inducement as well as the Supreme Court's decisions interpreting the FCA make clear that a successful claim for fraudulent inducement requires demonstrating that a defendant's fraud caused the government to enter a contract that later results in a request for payment." According to the court, "[i]f a fraudster's misrepresentations do not cause a party to enter a contract, no fraudulent inducement has occurred." In so holding, the D.C. Circuit found that to plead fraudulent inducement, Cimino had to allege both proximate causation and actual cause under the but-for test.

Applying its holding, the D.C. Circuit ultimately held that Cimino had adequately pleaded but-for causation because he alleged facts that plausibly demonstrated that the IRS would not have entered into the agreement at issue but for IBM's fraudulent conduct. The D.C. Circuit, however, affirmed the lower court's dismissal of Cimino's presentment claims on the ground that he had not pled them with sufficient particularity.

Commentary

Questioning the Validity of the Fraudulent Inducement Theory

In an interesting move that may open doors for defendants facing FCA allegations based on fraudulent inducement, the D.C. Circuit's Judge Neomi Rao concurred with her own opinion in the *U.S. ex rel. Cimino v. IBM* case to question whether fraudulent inducement is a separate cause of action at all under the FCA. She reasons that the text of the FCA creates liability for fraudulent claims, not non-fraudulent claims submitted under fraudulent contracts.

Judge Rao traces the fraudulent inducement theory to its origins in the Supreme Court's *U.S. ex rel. Marcus v. Hess* opinion. She notes that the opinion is not clear that it is creating a new FCA cause of action and that it could be understood to involve actual fraudulent claims, rather than just a fraudulently induced contract. Analyzing precedent, she finds that it is unclear whether a separate cause of action for fraudulent inducement has been definitively established in matters without the presentation of a false or fraudulent claim.

She points out that reconsideration of the fraudulent inducement cause of action also may be warranted because it is in tension with recent Supreme Court decisions that focus on the specific language of the FCA and warn against threats to transform the FCA into an all-purpose antifraud statute, stating that "[f]raudulent inducement may be one of those threats that has gone unnoticed." Paired with the FCA's *qui tam* provisions, she posits that fraudulent inducement may pose particular separation-of-powers problems because it is "a judicial expansion of a statutory cause of action layered on top of a congressional expansion of prosecution outside the executive branch."

Defendants, particularly those in the D.C. Circuit, should be aware of Judge Rao's reasoning and ready to preserve these arguments in appropriate fraudulent inducement cases.

Commentary

IRS Rule on Deductibility of FCA Settlements

On January 14, 2021, the IRS implemented a final rule on the deductibility of settlement payments, including payments made to settle FCA allegations. The rule followed a change to Internal Revenue Code (IRC) Section 162(f), which prevents a taxpayer from deducting any amount paid to a governmental entity in relation to the violation of any law or the investigation into a potential violation of law. The section also comes with key exceptions that allow a taxpayer to deduct restitution or remediation payments. To qualify for these exceptions, the order or settlement agreement must clearly identify these payments as restitution or remediation payments (identification requirement), and the taxpayer must establish that these payments were made as restitution or remediation payments (establishment requirement).

The IRS final rule clarified the section and offered guidance to taxpayers on the exceptions. The rule clarified that Section 162(f) applies to settlement payments and *qui tam* cases. The rule also clarified that the order or agreement requiring the payment does not need to use any specific terms to fulfill the identification requirement, so long as the order or agreement requires payments to remediate non-compliance with the law. The rule also gives the conditions for a taxpayer to satisfy the establishment requirement, including using receipts, judgments, and communications with the government, among other things.

DAMAGES

***United States v. Honeywell Int'l Inc.*, No. CV 08-0961 (PLF), 2021 WL 2493382 (D.D.C. June 18, 2021)**

U.S. District Court for the District of Columbia certifies for interlocutory appeal the question of whether other defendants' settlements should be a proportionate or pro tanto offset of damages.

In 2008, the government filed FCA suits against Honeywell International Inc. and other defendants related to Z Shield bulletproof vests. After other defendants had settled, Honeywell argued that it was entitled to a pro tanto offset of damages for the government's settlements with other defendants. In 2020, D.C. District Court Judge Paul Friedman instead applied the proportionate share approach for offsets and found Honeywell liable for $35 million in damages.

On June 18, 2021, Judge Friedman certified for an interlocutory appeal the question of whether the pro tanto approach or the proportionate share approach was the appropriate method for calculating damages offsets for FCA defendants. The D.C. Circuit has discretion to permit or deny the appeal and has not yet made a decision. If the D.C. Circuit decides to apply a pro tanto offset, Honeywell's FCA statutory damages would reduce to zero.

***U.S. ex rel. IBEW Local 98 v. The Farfield Co.*, 5 F.4th 315 (3rd Cir. Jul. 13, 2021)**

In an FCA case about wages, the Third Circuit applies the burden-shifting damages model from the Fair Labor Standards Act.

A labor union filed a *qui tam* suit against an open-shop contractor for misclassifying electrical workers on a track and signal improvement project for a local transportation authority, which was partially funded by the federal government. The union alleged that the misclassification resulted in the contractor violating the prevailing wage provisions of the Davis-Bacon Act. The government declined intervention and the case eventually went to trial before a special master. The special master found that the contractor had misclassified the workers and violated the FCA.

The Third Circuit affirmed — emphasizing the complex, fact-specific nature of worker classifications under the Davis-Bacon Act. It rejected the defendant's argument that Davis-Bacon compliance was not material under *Escobar*. The court evaluated *Escobar* materiality in three ways. First, Davis-Bacon compliance was an objective condition for payment under Farfield's contract. The government had the right to withhold payment for noncompliance, and a Farfield executive had testified at trial that the company subjectively believed that compliance was a contractual requirement. Second, there was no evidence that government subjectively viewed compliance as immaterial and had ignored violations in other cases. Third, the court found that noncompliance was not trivial even if the monetary loss was small.

With regard to damages, the court applied the Fair Labor Standards Act's (FLSA) burden-shifting damages model for the first time in an FCA case. In the FLSA damages model, the plaintiff must show only a just and reasonable inference of the amount and extent of improperly compensated work, and the burden then shifts to the defendant to prove the amount of work performed or otherwise negate the plaintiff's reasonable inference. The Third Circuit found use of the FLSA model justified because the FLSA provided the substantive law to determine whether Farfield had violated the FCA. Further, the FCA required a similar level of proof on damages and, according to the court, placed the burden on the defendant to provide specific rebuttal evidence.

The Third Circuit also weighed in on a circuit split about the application of the Fraud Enforcement and Recovery Act of 2009 (FERA) amendments to the FCA. FERA retroactively applies to "all claims that are pending on or after" June 7, 2008. The Third Circuit — siding with decisions from the Second, Sixth, and Seventh circuits — held that "claims" in this context referred to any lawsuit pending on that date as opposed to a request for payment.

***Yates v. Pinellas Hematology & Oncology, P.A.*, No. 20-10276, 2021 WL 6133175 (11th Cir. Dec. 29, 2021)**

The Eleventh Circuit finds that awarding treble damages and $5,500 per claim penalties is not excessive because it is the lowest possible sanction under the FCA, but a two-judge concurrence questions the court's deference to Congress on the excessiveness of fines.

Pinellas Hematology & Oncology owned Park Place, a clinical laboratory that drew and processed blood samples for cancer patients. Such labs are required by the Clinical Laboratory Improvement Amendments (CLIA) of 1988 to have a CLIA certificate. Pinellas purchased a second laboratory named Bayfront. Though the prior owner had a CLIA certificate, the certificates are non-transferrable. Pinellas failed to apply for a new CLIA certificate under its new ownership. For a year, Pinellas performed tests at Bayfront without a CLIA certificate and submitted claims for payment to Medicare. When the claims were denied, Pinellas resubmitted them with Park Place's CLIA certificate number but Bayfront's address. Those claims were also denied. The government paid the Bayfront claims once Pinellas resubmitted them with Park Place's CLIA certificate number and address. Pinellas' billing manager, Michele Yates, filed the *qui tam* action, prevailed at trial, and was awarded $1,177,000. The district court called the award "quite harsh" because the total damages to the government were only $755.54.

On appeal, the Eleventh Circuit rejected Pinellas' arguments related to the measure of damages and the overall monetary award. The court held that the correct method for calculating damages is "the difference between what the government paid and what it would have paid had the claims been truthful." Pinellas argued the monetary award violated the Excessive Fines Clause, and the Eleventh Circuit joined the Ninth, Eighth, and Fourth circuits in holding that monetary awards under the FCA are fines for purposes of the Eighth Amendment Excessive Fines Clause because the government benefits from the awards and exercises ultimate control over their prosecution. Here, the court found the award was not excessive because Pinellas was fined "the lowest possible sanction under the FCA" — treble damages and $5,500 penalty per claim — and because the fine resulted from repeated fraud.

Judge Kevin Newsom wrote a concurrence, joined by the author of the opinion, to flag the issue of the Eleventh Circuit giving great deference to Congress's judgment about the excessiveness of the fines it levies, which he compared to "letting the driver set the speed limit." He suggests that the court refine its Excessive Fines Clause analysis to consider not only the relationship between the fine and the offense but also the impact of a fine on an offender's livelihood.

***U.S. ex rel. Jehl v. GGNSC Southaven, LLC*, No. 319CV00091MPMJMV, 2021 WL 2815974 (N.D. Miss. Jul. 6, 2021)**

The court questions whether the FCA's mandatory damages could offend fairness and due process in weak cases and provide an alternative reason for dismissal beyond materiality.

Relator Cameron Jehl sued nursing home operator GGNSC Southaven for allegedly claiming compliance with Medicare and Medicaid regulations even though GGNSC's nursing director did not qualify for a specific type of nursing license after changing her state of residency. In pretrial briefing, Jehl indicated that he would be seeking over $30 million in damages, almost $7 million of which would be mandatory civil penalties. The court expressed astonishment that a "minor licensing issue[]" that did not affect patient care could potentially result in such a huge award of damages.

While the court indicated that Jehl's flimsy factual allegations likely did not meet the materiality requirement after *Escobar*, it also identified the unfairness that would result from a finding of liability at trial due to the FCA's mandatory damages scheme as another potential basis for dismissal. As a result, the court postponed trial indefinitely and ordered Jehl to explain why the court should not dismiss his case, reasoning that "it appears that calculating damages unrelated to actual harm or injury may present a potential unfairness, or even absurdity, in the law," especially given that the nurse's "licensing status had no actual impact on patient care." The court further addressed what it viewed as unfair leverage that allowing such allegations to proceed would give to FCA plaintiffs, writing that "if FCA plaintiffs with even factually weak claims are able to threaten nursing homes with staggering sums in mandatory penalties in the event that liability is found by a jury, then this will give them great leverage to compel settlements on unjust terms."

ANTI-KICKBACK STATUTE

Pursuant to the Affordable Care Act and each appellate court to rule on the issue, a claim that includes items or services resulting from a violation of the Anti-Kickback Statute (AKS) constitutes a false claim for purposes of the FCA.

***U.S. ex rel. Lutz v. Mallory*, 988 F.3d 730 (4th Cir. Feb. 22, 2021)**

The Fourth Circuit finds that the AKS safe harbor for bona fide employees does not cover payments to independent contractors.

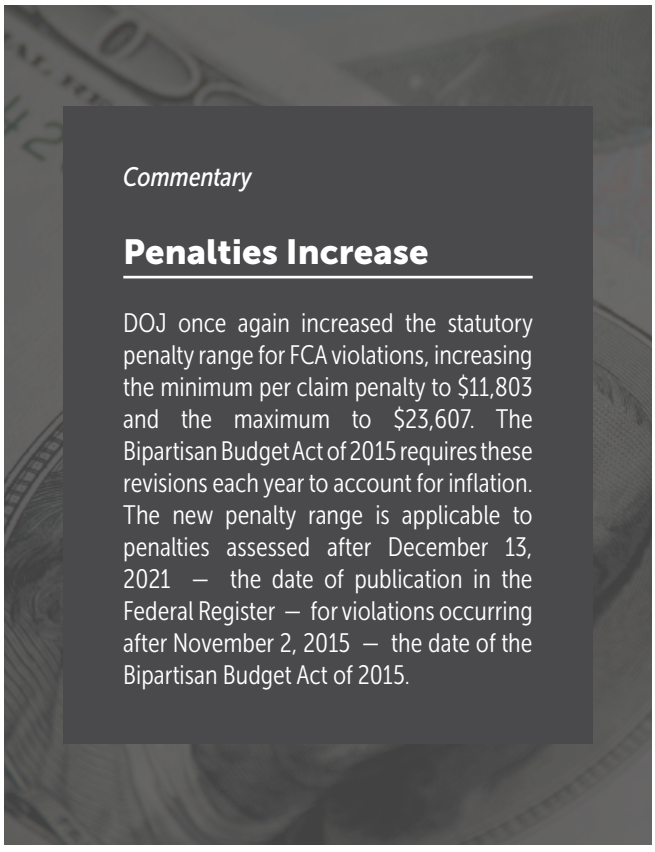
After a 12-day trial, the defendant-owner of blood testing facility Health Diagnostic Laboratory and the men who led its sales operation unsuccessfully appealed their adverse jury verdict to the Fourth Circuit. Relators alleged that Health Diagnostic Laboratory improperly compensated its independent contractor sales representatives in violation of the AKS when it paid commissions based on the volume of blood testing services utilized by the physicians they referred and that the claims submitted to the government as a result of the AKS-tainted referrals were false. Defendants appealed after the district court denied their post-trial motions.

Notably, on appeal to the Fourth Circuit, defendants argued that they were entitled to judgment as a matter of law because commission payments to salespeople cannot violate the AKS. The Fourth Circuit disagreed, noting that the safe harbor to the AKS that protects payments to bona

fide employees does not cover independent contractors. The court relied on a statement from the Department of Health and Human Services that "if employers 'desire to pay [] salesperson[s] on the basis of the amount of business they generate,' they 'should make these salespersons employees' to avoid 'civil or criminal prosecution.'"

Defendants also argued they were entitled to a new trial because of multiple legal errors in the jury instructions. In part, the defendants argued that the district court failed to properly instruct the jury that, under the FCA, a false claim must be material. The court found that the false and fraudulent claim element under the FCA is "necessarily satisfied" when it is determined that an AKS violation occurred because the Affordable Care Act amended the AKS to state "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim." In so ruling, the court seems incorrectly to have considered the element of materiality to be subsumed within the separate element of falsity.

The Fourth Circuit also applied the dominant "one purpose" test, rejecting the defendants' argument that the district court should have instructed the jury that it needed to find the "primary purpose" of the remuneration was to induce referrals. The court found it was proper for the district court to instruct the jury that it only needed to find "one purpose" of the remuneration was to induce referrals, noting that "every circuit to address the issue" has adopted the "one purpose" test.



Commentary

Penalties Increase

DOJ once again increased the statutory penalty range for FCA violations, increasing the minimum per claim penalty to $11,803 and the maximum to $23,607. The Bipartisan Budget Act of 2015 requires these revisions each year to account for inflation. The new penalty range is applicable to penalties assessed after December 13, 2021 — the date of publication in the Federal Register — for violations occurring after November 2, 2015 — the date of the Bipartisan Budget Act of 2015.

OVERPAYMENTS

In what is known as a "reverse false claim," the knowing concealment or knowing and improper avoidance and decrease of an obligation to pay money to the government constitutes a violation of the FCA. Medicare overpayments to healthcare providers may constitute such obligations if not returned within 60 days of identification.

***UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. Nov. 1, 2021)**

The D.C. Circuit reverses the lower court's invalidation of the overpayment rule for Medicare Parts C and D, except with regard to its definition of when an overpayment is "identified."

Medicare's overpayment rule, which was adopted as part of the Affordable Care Act, requires Medicare Advantage Organizations (MAOs) to report and return any overpayment within 60 days after the payment is "identified" (the "Overpayment Rule"). An overpayment is "identified" when the MAO "has determined, or should have determined through the exercise of reasonable diligence," that the MAO received an overpayment.

UnitedHealthcare argued that the Overpayment Rule violated the statutory requirement of "actuarial equivalence," which is meant to ensure that Medicare Advantage providers receive equivalent pay for services as compared to their traditional fee-for-service Medicare counterparts. According to UnitedHealthcare, Medicare Advantage payments were derived from unaudited Medicare fee-for-service claims and that such fee-for-service claims include both correct and incorrect codes. Medicare Advantage programs then are required to refund each individual payment that is not supported by the patient medical record. This results in Medicare paying more for fee-for-service beneficiaries than for Medicare Advantage beneficiaries in violation of actuarial equivalence. The district court agreed with UnitedHealthcare and invalidated the Overpayment Rule. The district court also found that the language "or should have determined through the exercise of reasonable diligence" in the Overpayment Rule establishes an apparent negligence standard that is inconsistent with the FCA's scienter requirements and had not been included in the proposed rule in violation of the Administrative Procedure Act.

On appeal, the D.C. Circuit reversed. Addressing the actuarial equivalence holding, the court found that the actuarial equivalence requirement in one section of the statute was inapplicable to the overpayment refund obligations in a completely separate section of the statute. Notably, CMS did not appeal the lower court's invalidation of the negligence standard in the Overpayment Rule, leaving the lower court's decision intact in that regard.

LOCAL COVERAGE DETERMINATIONS

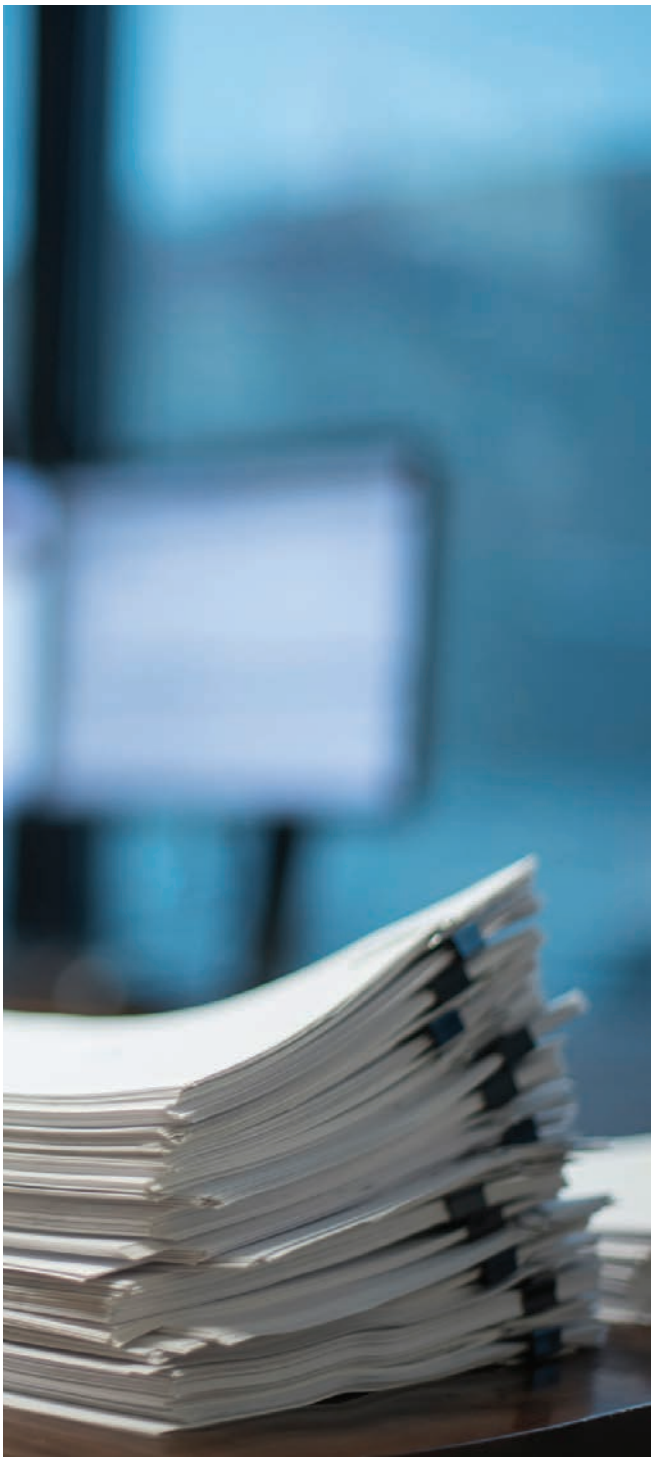
***Agendia, Inc. v. Becerra*, 4 F.4th 896 (9th Cir. July 16, 2021)**
The Ninth Circuit holds that a local coverage determination (LCD) is valid without going through the notice-and-comment process set forth in 42 U.S.C. § 1395hh, thereby reversing the lower court's ruling in favor of Agendia, Inc., which would have invalidated all LCDs.

While not directly related to the FCA, this decision concerns the validity of LCDs, which are often part of the government's theory in cases alleging false claims based on medically unnecessary care. The primary dispute before the Ninth Circuit in *Agendia* was whether the notice-and-comment process is required before a Medicare Administrative Contractor (MAC) can issue an LCD. Plaintiff Agendia, Inc. submitted claims for reimbursement of its diagnostic tests, which were denied based on an LCD. During the administrative appeal process and at the trial court level, Agendia challenged the denial of its claims on the ground that the LCD was issued without notice and opportunity for comment in violation of 42 U.S.C. § 1395hh of the Medicare Act. Agreeing with Agendia's statutory argument, the district court concluded that § 1395hh requires LCDs to undergo notice and comment. On appeal, a divided panel reversed the district court's ruling, finding that an LCD is valid without going through the notice-and-comment process prescribed in 42 U.S.C. § 1395hh.

Importantly, the Medicare Act requires the Secretary of Health and Human Services to follow a notice-and-comment process for any "rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing . . . the payment for services." The Ninth Circuit found that LCDs are not subject to the notice-and-comment process because such determinations do not establish or change the substantive legal standard — i.e., that "an item or service must be 'reasonable and necessary' for a provider to have a right to payment." In so ruling, the Ninth Circuit concluded that, although LCDs help adjudicators apply the reasonable and necessary standard to the facts of a claim, they do not establish or change the standard for reimbursement contained in the statute itself.

In a strongly worded dissent, Judge Frederic Block of the Eastern District of New York, sitting by designation, called the majority's opinion "a missed opportunity" to "define[] to the term 'substantive legal standard' in a realistic manner." Judge Block found that, because LCDs bind initial claim adjusters and significantly alter the nature of appellate review in Medicare cases, they establish a standard at the initial stage of review and change the standards applied on appellate review. According to Judge Block, LCDs should therefore be subject to notice and comment.

Both the majority and dissent, however, rejected Agendia's alternative theory that a MAC's ability to issue LCDs reflects an unconstitutional delegation of regulatory power to private entities. The Ninth Circuit instead found that, because MACs function subordinately to the secretary, the Constitution does not forbid them from carrying out the administrative function of issuing LCDs.



FRAUD ON THE FDA

***U.S. ex rel. The Dan Abrams Co. LLC v. Medtronic PLC*, 850 F. App'x. 508 (9th Cir., 2021)**

The Ninth Circuit allows a fraud-on-the-FDA theory to proceed where the devices in question could not actually be used for any indication approved by the FDA, but not where the device had other legitimate, approved uses.

The relator, the Dan Abrams Company LLC, appealed a district court's grant of Medtronic Inc.'s motion to dismiss FCA and AKS claims. Dan Abrams's claims were based on the theory that Medtronic defrauded FDA into approving several spinal fusion devices. Medtronic did not disclose that it intended to market the devices for off-label uses. Some of these devices (extra-use devices) could be used for other FDA-approved uses, whereas the remaining devices (contraindicated-use devices) could not actually be used for any FDA-approved uses.

The Ninth Circuit reversed the district court's dismissal of claims related to the contraindicated-use devices and allowed the fraud-on-the-FDA theory to proceed. The court found that Medtronic's failure to disclose that these devices could only be used for contraindicated purposes went to the essence of its bargain with the government.

The court affirmed the district court's dismissal of claims related to the extra-use devices, as well as claims that Medtronic violated the FCA by impermissibly marketing the devices for off-label uses. The court noted that the federal government has long recognized that doctors may use and be reimbursed for medical devices for off-label purposes so long as the device has FDA approval and the use is reasonable and necessary and not in violation of other applicable regulations.

FAILURE TO PLEAD WITH PARTICULARITY

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.

***Integra Med Analytics LLC v. Providence Health & Servs.*, 854 F. App'x 840 (9th Cir. March 31, 2021)**

The Ninth Circuit affirms dismissal of a data analytics-based complaint that failed to rule out obvious alternative explanations for the data.

Here, the Ninth Circuit gave the Clinical Documentation Integrity (CDI) industry a win and struck a blow to professional whistleblower Integra Med Analytics, LLC, a data analytics firm that has filed numerous *qui tam* actions across the country based on statistical analyses of publicly available Medicare data. In this case, Integra alleged that the defendants, various Providence Health entities and their CDI consultant, engaged in fraudulent practices to encourage physicians to falsely document language in medical records to justify upcoding the patient's condition and, resultingly, generate more Medicare reimbursement. The district court denied the defendants' collective motion to dismiss as to Integra's primary FCA claim but, at Providence Health's request, certified its order for interlocutory appeal.

On appeal, the Ninth Circuit reversed, finding that Integra failed to plausibly plead falsity to meet the pleading standards under Rule 8, much less the heightened standards under Rule 9(b). Integra's data-driven pleading failed to "rule out an obvious alternative explanation that Providence, with [Providence's CDI consultant's] assistance, was simply ahead of others in its industry" with respect to accurate coding. The court found that Integra's conclusion that the statistical trends were the result of fraud was insufficient and remanded with directions that the district court dismiss the complaint.

***U.S. ex rel. Sheoran v. Wal-Mart Stores East, LP*, 858 F. App'x. 876 (6th Cir. June 4, 2021)**

The Sixth Circuit affirms dismissal of a complaint that attached a summary of medical expenses but failed to indicate specifics of claims, which expenses were false, or defendant's knowledge.

Relator Ashwani Sheoran, a pharmacist for Walmart in Michigan, filed a *qui tam* suit under the FCA and the Michigan Medicaid FCA alleging that a doctor was writing improper prescriptions for high dosages of opiates and that Walmart was filling those prescriptions. The district court dismissed the complaint.

In affirming the district court's decision, the Sixth Circuit noted that in order to satisfy the particularity requirements of Rule 9(b) for an FCA claim, the plaintiff must "allege the time, place, and content of the alleged misrepresentation…[;] the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud."

The court determined that Sheoran had not satisfied the heightened pleading standard for any of the elements of an FCA claim. Although Sheoran relied on a medical expenses summary document, which showed one unidentified patient's prescriptions and expenses, there were no specific details within the document to indicate (1) when or how claims were actually presented to the government; (2) whether the information in the summary was false or fraudulent; and (3) whether Walmart knew the claims presented were false or fraudulent in some way. Finally, even if the court assumed all prior elements had been met, it determined that "the government's decision to pay those claims despite that knowledge 'is very strong evidence that those requirements are not material.'"

Because Sheoran's underlying FCA claims were dismissed, the court also dismissed the related conspiracy charges. Finally, although Sheoran's retaliation claims were not subject to Rule 9(b), the court dismissed those claims as well because he failed to adequately plead that Walmart knew he was pursuing an FCA action, not just that he had witnessed potentially illegal conduct.

***Estate of Debbie Helmy v. Bethany Hospice and Palliative Care of Coastal Georgia, LLC*, 853 F. App'x 496 (11th Cir. Apr. 26, 2021)**

The Eleventh Circuit affirms dismissal of a complaint that does not identify specific claims submitted.

The Eleventh Circuit affirmed its strict requirement that plaintiffs must identify specific false claims submitted to the government meet the Rule 9(b) pleading burden for an FCA violation. The court dismissed the relators' claims despite rather detailed allegations of AKS violations by the defendant. Relators alleged that kickbacks were provided through below-market-share investments in the company, which would pay huge returns based on the number of patients the doctors referred. The relators provided several examples of doctors who made such investments and saw such returns. Relators also alleged that, on occasion, the administrator at Bethany acknowledged that the compensation structure was so designed to avoid any scrutiny for an FCA violation. Without specific claims to

cite, the relators claimed that they saw records that showed almost all of these patients were covered by Medicare or Medicaid, and based on their own information, as well as confirmation from five other Bethany employees, Bethany submitted claims to Medicare and Medicaid for reimbursements for treating these patients. Relators also provided data purporting to show that Bethany derived all or nearly all of its revenue from Medicare or Medicaid claims.

The court affirmed the district court's dismissal noting the lack of specific claims in the relators' complaint. The court also noted that, while relators did have some inside knowledge of Bethany's operations, they failed to provide any specific details regarding either the dates on or the frequency with which the defendants submitted false claims, the amount of those claims, or the patients whose treatment served as the basis for the claims. Further, the relators never claimed they either witnessed false claims being submitted or submitted any false claims themselves. Additionally, the relators' evidence that Bethany doctors referred a high number of Medicare and Medicaid patients, that nearly all of Bethany's patients were Medicare and Medicaid recipients, and that Medicare and Medicaid data showed that Bethany billed the government for patients was not sufficient to satisfy Rule 9(b)'s pleading standard, given that a false claim could not be inferred from the circumstances.

***Thayer v. Planned Parenthood of the Heartland, Inc.*, 11 F.4th 934 (8th Cir. Sept. 3, 2021)**

Where the relator's theory of the case changed, the Eighth Circuit affirms summary judgment for failure to plead the new theory with particularity.

Relator Susan Thayer, a former center manager for a Planned Parenthood clinic in Iowa, brought an FCA case against the clinic alleging that it engaged in two separate schemes in violation of the FCA. First, Thayer claimed that Planned Parenthood dispensed extra cycles of oral contraceptives without a physician's approval, in violation of Iowa law. Second, Thayer contended that Planned Parenthood illegally billed Iowa Medicaid Enterprise (IME) for post-abortion procedures. The government declined to intervene. The district court granted summary judgment for Planned Parenthood, finding that Thayer failed to allege a fraudulent scheme with particularity.

On appeal, the Eighth Circuit affirmed, agreeing that Thayer had failed to satisfy the pleading standards in Rule 9(b). Addressing Thayer's claim about dispensing medication without a physician's approval, the court noted that Thayer's theory of liability asserted in response to the motion for summary judgment had changed from the theory she pleaded in the complaint. The complaint alleged that Planned Parenthood distributed contraceptives without physician approval. However, in response to the motion for summary judgment, Thayer argued that Planned Parenthood dispensed extra cycles for some patients and changed prescription brands for others without physician sign-off. The court affirmed dismissal because she "failed to sufficiently plead the claim she presses now."

In analyzing Thayer's second claim — that Planned Parenthood intentionally miscoded abortion-related services in order to "financially subsidize abortions" — the court held that Thayer failed to show that there was a genuine issue of material fact over whether the claims were knowingly false. The alleged false codes resulted in a one-level difference in billing, resulting in less than a $12 reimbursement difference. Affirming the district court's grant of summary judgment, the court found that the facts of the case at most evidenced an innocent mistake or negligence, not intentional falsity.

***U.S. ex rel. Owsley v. Fazzi Assocs., Inc.*, 16 F.4th 192 (6th Cir. Oct. 13, 2021)**

The Sixth Circuit affirms dismissal of a complaint with "considerable detail" that does not identify specific claims submitted.

Relator Cathy Owsley, a former quality assurance nurse for home-health agency Care Connection of Cincinnati (CC), filed a *qui tam* suit against CC, other home-health providers, and CC's coding contractor. In her complaint, Owsley claimed that CC and its contractor violated the FCA and state law by fraudulently "upcoding" to enhance existing codes and adding new codes not supported by medical documentation. Owsley contended that the defendants engaged in this scheme in order to submit inflated claims for reimbursement to the federal and Indiana governments. The government declined to intervene, and the district court granted the defendants' motion to dismiss under Rule 9(b).

On appeal, the Sixth Circuit affirmed the district court's dismissal, holding that despite the "considerable detail" of the fraudulent scheme in Owsley's complaint, she failed to identify any specific claim that CC submitted pursuant to that scheme. In analyzing the complaint, the court noted that all of Owsley's claims under the FCA and Indiana law attach liability to the claim for payment, not the underlying fraudulent scheme or the government's payment. Courts within the Sixth Circuit have imposed a "clear and unequivocal" requirement that a relator allege specific false claims when pleading a violation of the FCA, and the identification of at least one false claim with specificity is an "indispensable element" needed to satisfy Rule 9(b).

***U.S. ex rel. Mamalakis v. Anesthetix Management LLC*, 20 F.4th 295 (7th Cir. Dec. 8, 2021)**

Ten examples of fraud alleged in a relator's amended complaint were sufficient to satisfy Rule 9(b), where the relator had personal knowledge and provided details about the people involved in each example and why billing was improper.

Relator John Mamalakis, a Wisconsin anesthesiologist, brought this *qui tam* suit against his previous employer, Anesthetix Management, LLC, alleging that Anesthetix billed Medicare and Medicaid for services performed by its anesthesiologists as "medically directed" services when the services only qualified for payment at the lower rate for "medically supervised" services.

Commentary

Telehealth

Telehealth has been a growing area for several years but took off amid the global pandemic. Widespread changes in federal and state reimbursement rules and skyrocketing use have led to predictable growing pains as providers, patients, and payors navigate the new normal.

Regulators and enforcement agencies have, of course, taken notice too. In recent years, most enforcement has focused on telemarketing schemes usually involving durable medical equipment or various types of laboratory testing, such as cancer genomic testing. Both DOJ and HHS-OIG have trumpeted large-scale enforcement efforts such as 2019's "Operation Brace Yourself," the November 2020 national healthcare takedown, and a September 2021 national enforcement action. Most of the resulting cases were charged criminally, and most involved the aforementioned telemarketing schemes in which telehealth consultations were used to facilitate fraud.

While the FCA has been used less often to date, civil enforcement related to telehealth continues to grow. In February 2021, Assistant Attorney General Brian Boynton included telehealth in his remarks at a Federal Bar Association conference, highlighting it as an area of focus and noting a recent FCA settlement. Later that same month, HHS-OIG Principal Deputy Inspector General Christi A. Grimm issued a statement on telehealth, noting the importance it played through the pandemic and evolving enforcement efforts. In particular, Grimm distinguished between "telefraud," the telemarking-style schemes that may utilize telemedicine, and "telehealth fraud," which involves more traditional concepts associated with fraudulent healthcare billing.

Mamalakis's complaint was dismissed by the district court because it failed to plead fraud with particularity as required under Rule 9(b). To cure the deficiencies identified by the district court, Mamalakis filed an amended complaint adding 10 specific examples of fraud. The district court found, however, that only one of the 10 examples provided adequate particularized factual support for his allegations of fraud and held that a single example was not enough to survive a motion to dismiss.

On appeal, the Seventh Circuit reversed and remanded the case back to the district court for further proceedings. The Seventh Circuit found that six of the 10 examples alleged in the amended complaint provided sufficient detail to support Mamalakis's allegations of fraud, noting that Mamalakis had personal knowledge regarding these specific examples and identified specific doctors, identified specific procedures, identified that the patient was receiving services that were billed to Medicare or Medicaid, and described why the procedure was billed improperly. While the Seventh Circuit acknowledged that the remaining four examples did not contain as much detail, it concluded that, together, with the other more-detailed examples, Mamalakis satisfied Rule 9(b) and should be allowed to proceed with his case.

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. Rahimi v. Rite Aid Corp.*, 3 F.4th 813 (6th Cir. June 29, 2021)**

Connecticut's state attorney general's announcement of investigation regarding similar facts was sufficient public disclosure to bar the relator's nationwide claim.

This case centered around Rite Aid's "Rx Savings Program," whereby Rite Aid provided generic prescription drugs at a reduced price. The program excluded customers whose prescriptions were paid, at least in part, by publicly funded healthcare programs. Federal regulations prohibit pharmacies, such as Rite Aid, from charging the government more for prescriptions than the usual and customary cash price (the "U&C rate") offered to the public at large. Azam Rahimi alleged that

Rite Aid submitted false claims to the government by failing to charge its public program customers the true U&C rate offered under the Rx Savings Program. The alleged fraud took place both before and after the 2010 amendment to the FCA. Applying a three-part test under both versions of the FCA, the Sixth Circuit determined that Rahimi's complaint was rightly dismissed by the district court due to the FCA's public disclosure bar.

First, the court determined that, before Rahimi filed his claim, there had been public disclosures from which the alleged fraud might be inferred. Rahimi first reported the alleged fraud to the government in May 2011. Almost 10 months prior, the Connecticut Attorney General's Office issued a press release announcing an investigation into Rite Aid's claim that it was forced to increase the prices under its Rx Savings Program because of a recent Connecticut law. The court found that this press release disclosed the key facts from which the fraud could be inferred, namely that Rite Aid excluded public health insurance beneficiaries from participating in the Rx Savings Program, that Connecticut believed that its pre-existing rules required pharmacies to bill its public health insurance program the lowest drug price offered to customers and passed a new law to that effect, and that Rite Aid in response raised its Rx Savings Program rate in Connecticut. This revealed both the alleged mispresented fact (that Rite Aid was billing the government the true U&C rate) and the true fact (that Rite Aid was charging less for the same drugs sold to Rx Savings Program customers).

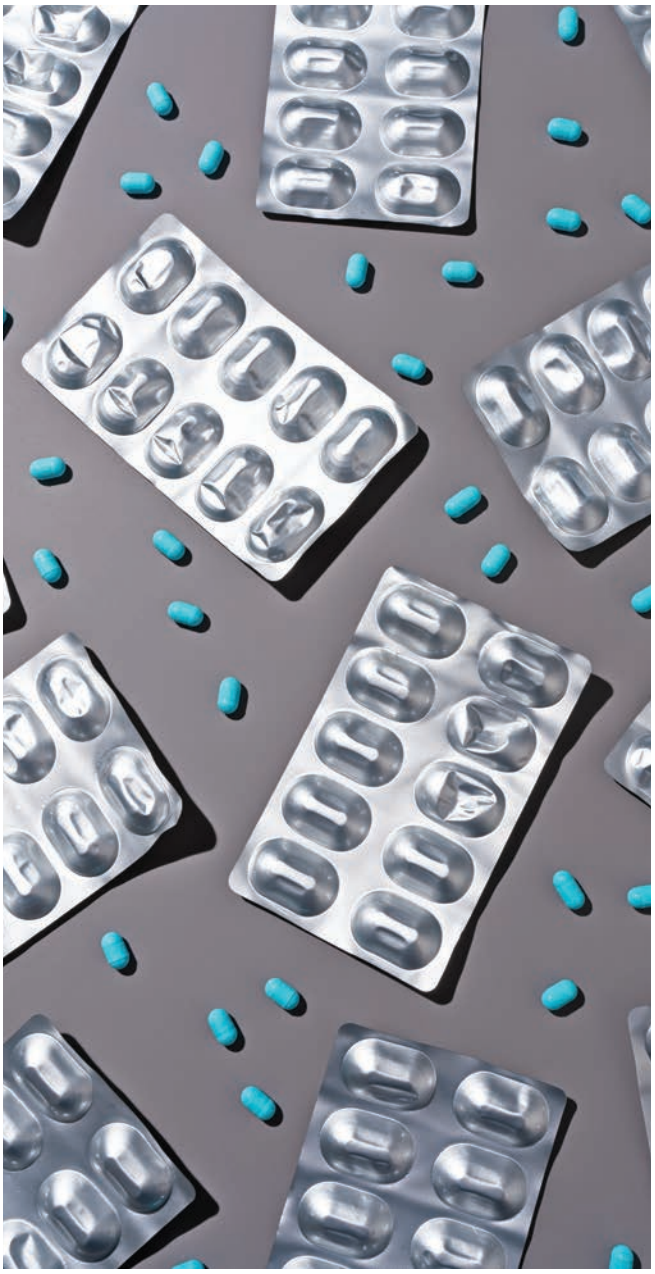
Second, the court determined that the public disclosures were sufficiently related to the allegations of fraud contained in Rahimi's complaint under either version of the FCA. Rahimi argued that the Connecticut disclosure only concerned the disclosure of a single fraud in a single state. However, the court rejected this argument because Rahimi's claims simply added new details to substantially the same scheme by the same corporate actor.

Finally, the court determined that Rahimi was not an "original source" under either version of the FCA. Under the pre-2010 FCA, he did not have direct knowledge of the information underlying his allegations. Under the current version of the FCA, Rahimi was not an original source because the scheme in his complaint was easily inferred from publicly available information, and his new allegations did not add materially to the public disclosures.

***U.S. ex rel. Solis v. Millennium Pharm., Inc.*, 852 F. App'x. 298 (9th Cir. July 9, 2021)**

Applying the pre-2010 standard, the Ninth Circuit finds a relator is not an original source because he lacks direct knowledge.

On July 9, 2021, the Ninth Circuit affirmed the dismissal of relator Frank Solis's 12-year-old allegations that Millennium Pharmaceuticals, Inc., Schering-Plough Corp., and Merck & Co. violated the FCA by offering doctors kickbacks to prescribe their blood-thinning drugs.



After previously determining that a public disclosure occurred regarding Solis's allegations, the Ninth Circuit focused its analysis on whether Solis had "direct and independent knowledge" of the information underlying his FCA claim to determine if he might be an "original source" pursuant to the public-disclosure bar. It found that he was not. Solis's allegations of FCA violations were "purely speculative," and his "inability to identify any instances of false claims for reimbursement [made] his allegations inadequate to show direct knowledge." Importantly, this case applied the pre-2010 standard requiring firsthand and independent knowledge of the facts underpinning his claims in order to be an original source.

Commentary

Medicare Advantage Enforcement

Government enforcement efforts in the Medicare Advantage program have focused on the alleged manipulation of diagnosis codes to obtain higher payments under CMS's risk adjustment process. In Medicare Advantage, an insurer is paid a certain amount for each covered life in a "capitated payment" that is subject to adjustment. Simplifying a very complex process, a Medicare Advantage Plan can obtain additional payments from CMS for a covered beneficiary by adding diagnoses of certain conditions that make it more expensive to care for the individual. Medicare Advantage Plans may share their payments from CMS with downstream providers through contractual arrangements. These arrangements can give providers and plans incentives to add inappropriate diagnosis codes to increase payments.

In 2021, there were several significant FCA enforcement actions involving Medicare Advantage. For example:

U. S. ex rel. Osinek v. Kaiser Permanente, et al.

In *Osinek*, the government intervened in six *qui tam* lawsuits filed against Kaiser Permanente Medicare Advantage Plan and affiliated physician practice groups. The government's core allegation is that Kaiser orchestrated a scheme to inflate diagnosis codes to obtain higher payments from CMS — a scheme aided by Kaiser's exclusive contracts and highly integrated structure. In particular, the government alleges that Kaiser systematically added diagnosis codes to patient records after patient visits; mined patient charts for old or undocumented diagnoses; pressured physicians to add these diagnoses to patient records in violation of Medicare Advantage regulations; and knowingly engaged in these practices to increase revenue. The government has sued both the Medicare Advantage Plan and the downstream healthcare providers (all under the Kaiser umbrella) for their participation in the alleged scheme.

U. S. ex rel. Ormsby v. Sutter Health, et al.

In late August, the government announced a $90 million settlement with Sutter Health and Palo Alto Medical Foundation (PAMF). The $90 million settlement came in two parts. The matter was partially resolved in April 2019, shortly after the government intervened, for $30 million. Under a follow-on agreement in August 2021, Sutter Health agreed to pay an additional $60 million to fully resolve the matter.

Like *Osinek* noted above, *Sutter Health* involved allegations of a scheme to assign false diagnosis codes to obtain higher payments. Specifically, the government alleged the scheme included (1) physician champions who would convince other doctors to add diagnosis codes; (2) medical wellness exams for the purpose of capturing additional diagnosis codes; (3) distribution of cheat sheets with common diagnoses to increase payments; and (4) pressure for physicians to add diagnoses on a specific problem list.

United States v. Anthem, Inc.

Although filed in 2020, *United States vs. Anthem, Inc.* remains active with motions to dismiss and to transfer venue pending in the Southern District of New York. This case is notable because it is not the result of a *qui tam* complaint, indicating that the government is actively investigating and developing cases against Medicare Advantage Plans on its own. In *Anthem*, the government is pursuing the Medicare Advantage Plan under the theory that it was responsible for identifying incorrect diagnosis codes in the data it submitted to CMS.

Final thoughts

Many of the practices targeted by the government in these cases will be familiar to those who work with Medicare Advantage Plans. And none of those practices is inherently improper. Indeed, physician champions, queries, chart reviews, and similar efforts to ensure accurate diagnosis codes are necessary for both patient care and appropriate payments. But these cases serve as a warning that even standard business practices must be monitored to ensure compliance and avoid the kinds of activity that the government believes will result in false claims.

STANDARD FOR DISMISSAL BY GOVERNMENT

***United States v. Eli Lilly & Co., Inc.*, 4 F.4th 255 (5th Cir. July 7, 2021)**

Finding both standards satisfied, the Fifth Circuit declines to pick a side in the circuit split over the standard for government motions to dismiss a relator's claims.

In *Eli Lilly*, the Fifth Circuit addressed, but declined to take a side in, the circuit split between the unfettered discretionary standard for government requests to dismiss FCA litigation established by the D.C. Circuit in *Swift v. United States* and the more burdensome *Sequoia Orange Co. v. Baird-Neece Packaging Corp.* Ninth Circuit standard.

Across the country, corporate relators Health Choice Alliance and affiliates, formed for the sole purpose of filing *qui tam* actions, filed 11 suits under the FCA against a total of 38 defendants, alleging similar violations of the AKS. Two of the cases were filed in the Eastern District of Texas alleging that the pharmaceutical manufacturing defendants illegally provided remuneration in the form of patient-education services to providers to encourage prescriptions.

Upon the government's strongly worded request for dismissal claiming that "the allegations … lack sufficient merit to justify the cost of investigation and prosecution" and "further litigation … will undermine practices that benefit federal healthcare programs by providing patients with greater access to product education and support," and after a hearing before the magistrate judge, the district court adopted the magistrate judge's recommendation to dismiss the case. Assuming *Sequoia Orange's* valid purpose/rational relation test applied, the district court found that the government's reasons for dismissal satisfied the inquiry. Health Choice Alliance appealed.

The Fifth Circuit affirmed, but declined to decide which standard applied. Instead, because the government satisfied the more burdensome *Sequoia Orange* standard, the Fifth Circuit determined that it need take no position on the circuit split.

***Polansky v. Executive Health Resources*, 17 F.4th 376 (3d Cir. Oct. 28, 2021)**

The Third Circuit requires the government to intervene before moving to dismiss and finds that Rule 41(a) governs such motions.

In 2012, relator Jesse Polansky filed an FCA lawsuit alleging that EHR improperly billed for inpatient services that should have been provided on an outpatient basis. After investigating for two years, the government declined to intervene. Polansky thereafter proceeded with the lawsuit, which remained in litigation for several more years. In 2019, the government moved to dismiss under § 3730(c)(2)(A), and the district court granted the motion.

On appeal, the Third Circuit addressed two issues: (1) whether the government could move to dismiss without first intervening and (2) the proper standard for such a motion to be granted.

On the first issue, the court joined the Sixth and Seventh circuits in holding that the government must intervene before it can move to dismiss, finding that reading of § 3730(c) to best reflect its text and the overall statutory structure. In doing so, the court rejected the opposing view, adopted by the D.C., Ninth, and Tenth circuits — and pressed here by the government — that intervention was not necessary.

On the second issue, the court navigated a three-way circuit split, ultimately agreeing with the Seventh Circuit that the government's motion to dismiss, like any party's similar motion, was governed by Fed. R. Civ. P. 41(a)'s requirements for voluntary dismissal. Prior to this case, the Seventh Circuit had been the only circuit to follow this approach, with the D.C. Circuit (in *Swift*) taking the most deferential view that the government had an unfettered right to dismiss, and the Ninth and Tenth circuits requiring the government to show a "rational relation" to a valid purpose for dismissal as first announced in *Sequoia Orange*.

Applying the above holdings, the Third Circuit construed the government's motion to dismiss as including a motion to intervene, found legally sufficient bases for the intervention, and then determined that the district court had not abused its discretion in granting dismissal under Rule 41(a)'s standards.

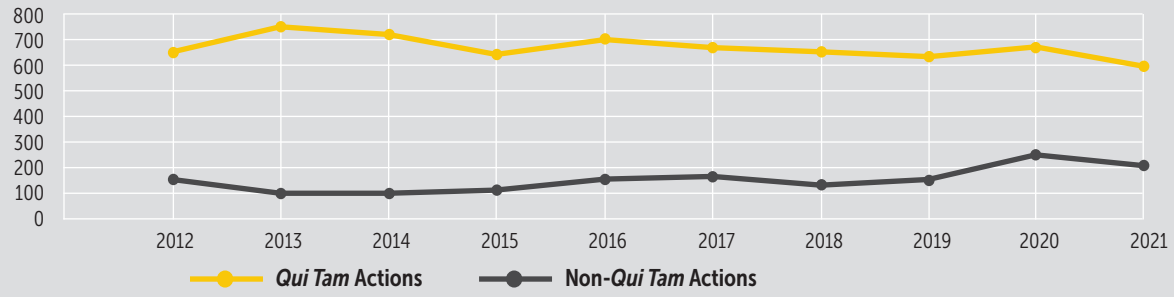
BELATED GOVERNMENT INTERVENTION

***U.S. ex rel. Odom v. Southeast Eye Specialists, PLLC*, No. 3:17-CV-00689, 2021 WL 790889 (M.D. Tenn. Feb. 24, 2021)**
Finding that the government failed to demonstrate good cause, a district court denies its motion to intervene filed six months after it originally declined to intervene.

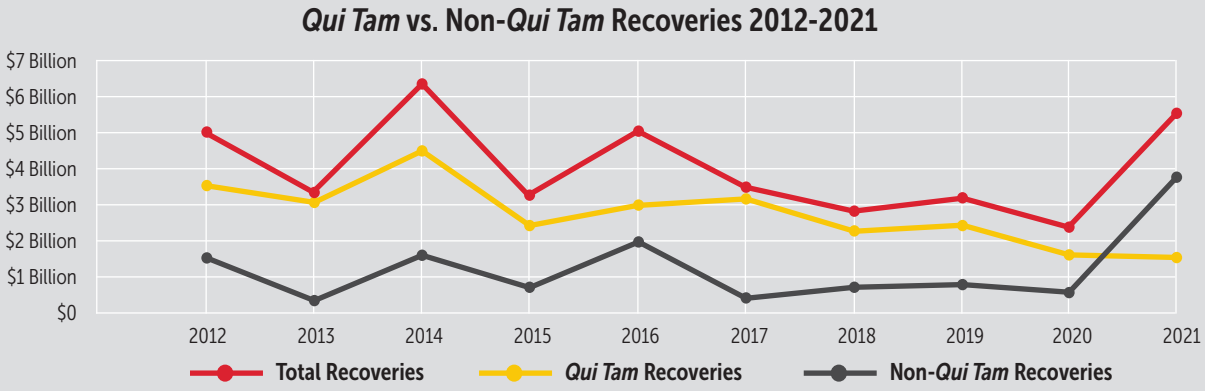
On February 24, 2021, the Middle District of Tennessee issued an order denying the government's motion to intervene and add new defendants in a pending *qui tam* FCA case after the government had previously declined to intervene. The underlying complaint alleged that the defendant, Southeast Eye Specialists, PLLC, had submitted false claims by paying kickbacks for patient referrals. After taking 28 months to investigate after the *qui tam* action was filed, the government made its declination decision in August 2019. As part of its declination, the government stated that it was reserving its right to intervene "for good cause" at a later time.

In February 2020, the government sought to intervene and add two new defendants after investigating further and discovering new evidence. The defendants argued that the motion should be denied because the government failed to provide sufficient detail to demonstrate that new facts or evidence were discovered and failed to demonstrate good cause for the belated intervention that would prejudice the defendants.

The court ordered the government to submit affidavits or declarations describing the investigation the government had undertaken and details about specific topics identified by the court. After reviewing the submitted affidavits and holding a hearing, the court denied the government's belated motion to intervene. The court noted that the government failed to show that its decision to intervene was based on any truly new information developed after its earlier declination.



The majority of FCA matters continue to be initiated by *qui tam* whistleblowers, though the DOJ significantly increased the number of actions it initiated in recent years.



Due to large settlements in opioid-related cases, recoveries from DOJ-originated suits exceeded recoveries in whistleblower suits for the first time since 2006.

Commentary

Private Equity

Private equity investment in the healthcare industry has increased significantly over the past several years. These entities (and especially their deep pockets) have not gone unnoticed by enforcement authorities or whistleblowers' counsel. Unsurprisingly, private equity investors now find themselves the targets of FCA cases. This past year saw several notable cases, including:

U.S. ex rel. Martino-Fleming v. South Bay Mental Health Center, Inc.

In *Martino-Fleming*, the relator accused a mental health provider, South Bay Mental Health Center, of providing services by unlicensed, unqualified and unsupervised employees rendering the claims for the services not payable. Significantly here, the relator also sued the private equity owner of South Bay — H.I.G. Capital, LLC — alleging that it caused the false claims by failing to prevent South Bay from submitting those false claims.

Plaintiffs' survived a motion to dismiss and proceeded through discovery, after which H.I.G. moved for summary judgment. But the court denied that motion too. The court held there was sufficient evidence of H.I.G.'s knowledge, because H.I.G. knew that South Bay's revenues were tied to Medicaid; Medicaid had terms and conditions of payment; H.I.G. members were aware that MassHealth (Massachusetts Medicaid) regulations required certain forms of supervision; and an H.I.G. employee testified that he knew that MassHealth had certain requirements in terms of licensure and qualifications. The court likewise found sufficient evidence of causation based on H.I.G.'s rejection of policies designed to stop submission of false claims.

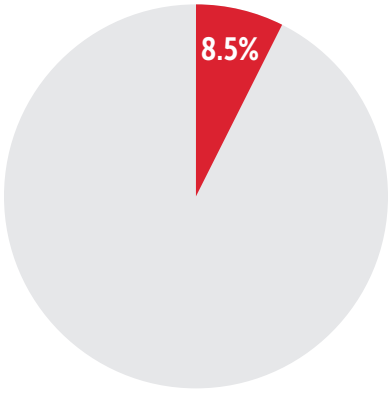
Alliance Family of Companies

In July 2021, the United States entered a settlement agreement with a private equity investor. The Alliance Family of Companies paid kickbacks to referring physicians for electroencephalography (EEG) tests. Ancor Holdings LP invested in Alliance after the fraud had started. The United States obtained a settlement from Ancor for over $1.8 million for Alliance's activities after Ancor invested in Alliance. The government's theory of liability for Ancor was that it learned of the fraudulent activity during due diligence prior to investing in Alliance and then caused the false claims to be submitted because it allowed the conduct to continue once it entered into an agreement to manage Alliance.

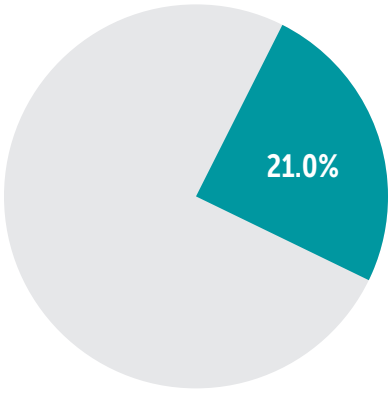
The settlement with Alliance and Ancor resolved six *qui tam* actions separately filed in the Southern District of Texas.

Final thoughts

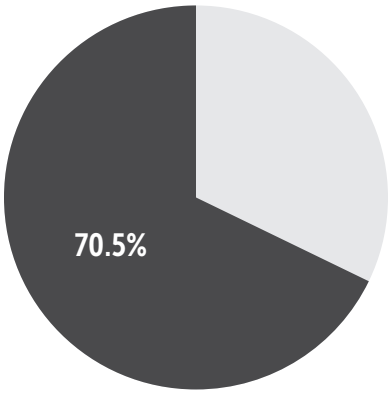
Private equity firms investing in healthcare companies have become attractive FCA enforcement targets. First and foremost, that's because they have deep pockets to pay damages and penalties. Second, DOJ takes the view that such firms have a duty to enforce compliance norms and correct otherwise non-compliant activity. Coupled with DOJ's emphasis on holding all culpable parties responsible as a means of deterring future bad conduct, that view invites scrutiny of private equity firms.



Percentage of total FCA recoveries from *qui tam* suits where DOJ declined intervention



Percentage of total FCA recoveries from *qui tam* suits where DOJ intervened



Percentage of total FCA recoveries from non-*qui tam* actions

ALTERNATE REMEDIES

Under 31 U.S.C. § 3730(c)(5), an alternate remedy is a remedy pursued by the government in another proceeding separate from the relator's *qui tam* suit, including administrative proceedings. If an alternate remedy is pursed in another proceeding, a whistleblower has the same rights in that proceeding as it would in an FCA *qui tam* claim.

***Guardiola ex rel. U.S. v. United States*, 845 F. App'x 707 (9th Cir. Apr. 30, 2021)**
RAC audits predating the filing of a *qui tam* suit are not alternative remedies to which the relator is entitled a share.

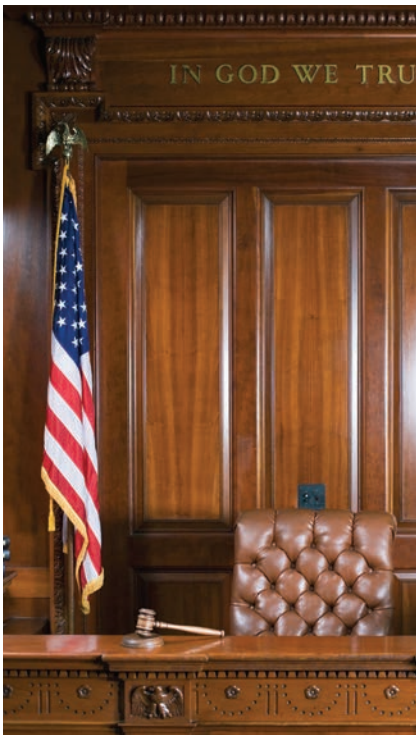
The government appealed a district court's order granting relator Cecilia Guardiola a 29% share of the $3,522,236.27 that the government's recovery audit contractor (RAC) recouped while auditing Guardiola's former employer, Renown Health. At the district court level, the government argued that these proceeds were not an alternate remedy under the FCA because the RAC audits began in 2010, two years before Guardiola brought her *qui tam* suit, and because the government's recovery did not entirely moot or preclude Guardiola's *qui tam* suit. On appeal, the Ninth Circuit agreed the RAC audits were not an alternate remedy under the FCA and reversed the district court's award. It found that if the government chooses to recoup lost dollars in a proceeding before the relator files her *qui tam* complaint, that proceeding does not constitute an alternate remedy under § 3730(c)(5).

***U.S. ex rel. Kennedy v. Novo A/S*, 5 F.4th 47 (D.C. Cir. Jul. 20, 2021)**
A private plaintiff who filed an FCA case is not entitled to a share of the monetary relief obtained by the government in its own separate enforcement action just because the underlying facts are similar to the earlier filed FCA lawsuit.

Relator Elizabeth Kennedy, a pharmaceutical sales rep for Novo Nordisk, brought a *qui tam* action against the company for violating the FCA by marketing a new diabetes drug in ways that ran afoul of the FDA's limitations for that drug. Eventually, the government, Novo Nordisk, and Kennedy reached a settlement where Novo Nordisk agreed to pay $46.5 million to resolve the FCA matter. Four days later, the government filed a separate complaint against Novo Nordisk under the Food, Drug and Cosmetic Act (FDCA) alleging the misbranding of the same drug. At the time it filed the complaint, the government disclosed that it had already settled the FDCA claims with Novo Nordisk. Kennedy was not a party to the FDCA lawsuit or the settlement. Subsequently, Kennedy moved for the district court to award her a share of the FDCA settlement as an "alternative remedy" under section 3730(c)(5) of the FCA. The district court denied her motion, and Kennedy appealed.

The D.C. Circuit affirmed the decision of the district court, denying Kennedy a share in the FDCA settlement. The court rejected Kennedy's argument that she was entitled to recover under § 3730(c)(5) because the FDCA claim arose from the same underlying facts identified in her *qui tam* lawsuit. Rather, the court found that the relevant inquiry was the nature of the legal claim — the fraudulent or false deprivation of a monetary or property interest, not a commonality of facts — which determined a relator's right to a share in an alternative recovery under the FCA. Specifically, the court noted that the FCA's alternative remedy provision confines a *qui tam* relator to recoveries arising from the type of fraud claims that could have been brought in an action under the FCA. Here, because the FDCA lawsuit was based on a misbranding claim that sought to protect the public from being misled by marketing tactics, not to recover damages for any use of falsity or fraud to deprive the government of its money or property, Kennedy had no right to a share in the FDCA lawsuit.

EQUITABLE ADJUSTMENT FOR DEFENSE COSTS



***Tolliver Group, Inc. v. United States*, 20 F.4th 771 (Fed. Cir. Dec. 13, 2021)**
Defendant seeks equitable adjustment under government contract for its *qui tam* defense costs but is denied on jurisdictional grounds.

After successfully defending itself against a *qui tam* action in which the government had declined intervention, plaintiff The Tolliver Group sought reimbursement of its attorneys' fees as an equitable adjustment from its government contracting officer under the subject contract, claiming that Federal Acquisition Regulations (FAR) entitled it to reimbursement. The contracting officer denied the claim, and Tolliver filed this action. The Court of Federal Claims granted Tolliver's request after determining that the government had breached an implied contractual warranty.

The Federal Circuit reversed and dismissed Tolliver's suit for lack of jurisdiction. It held that the breach of implied warranty claim was materially different from the FAR-based breach of contract claim Tolliver presented to the contracting officer. Tolliver had therefore not presented its claim to the contracting officer – a prerequisite to jurisdiction. While the court did not address the merits of the lower court's decision, it expressed skepticism on this point as well. Significantly, however, the court left open the question of whether a government contractor could, in an appropriate case, obtain reimbursement of its attorneys' fees from the government after successfully defending an FCA suit arising out of a government contract based on a breach of implied warranty claim or some other theory of recovery.

AREAS TO WATCH IN 2022

CYBERSECURITY

In October 2021, the DOJ announced the formation of the Civil Cyber-Fraud Initiative to utilize the FCA to pursue cybersecurity-related fraud by government contractors and grant recipients. DOJ plans to focus on entities that knowingly misrepresent their cybersecurity practices or protocols, knowingly violate obligations to monitor and report cybersecurity incidents and breaches, or knowingly provide deficient cybersecurity products or services. Such deficiencies could include failure to meet specific contract terms such as requirements to take measures to protect government data, to restrict non-U.S. citizen employees from accessing systems, or to avoid using components from certain foreign countries.

DOJ has already begun encouraging whistleblowers to bring cybersecurity-related FCA cases. Contractors and grant recipients would be wise to review the cybersecurity requirements in their contracts, grants, and licenses to ensure compliance and avoid being the subject of action by this new DOJ initiative.

CARES ACT

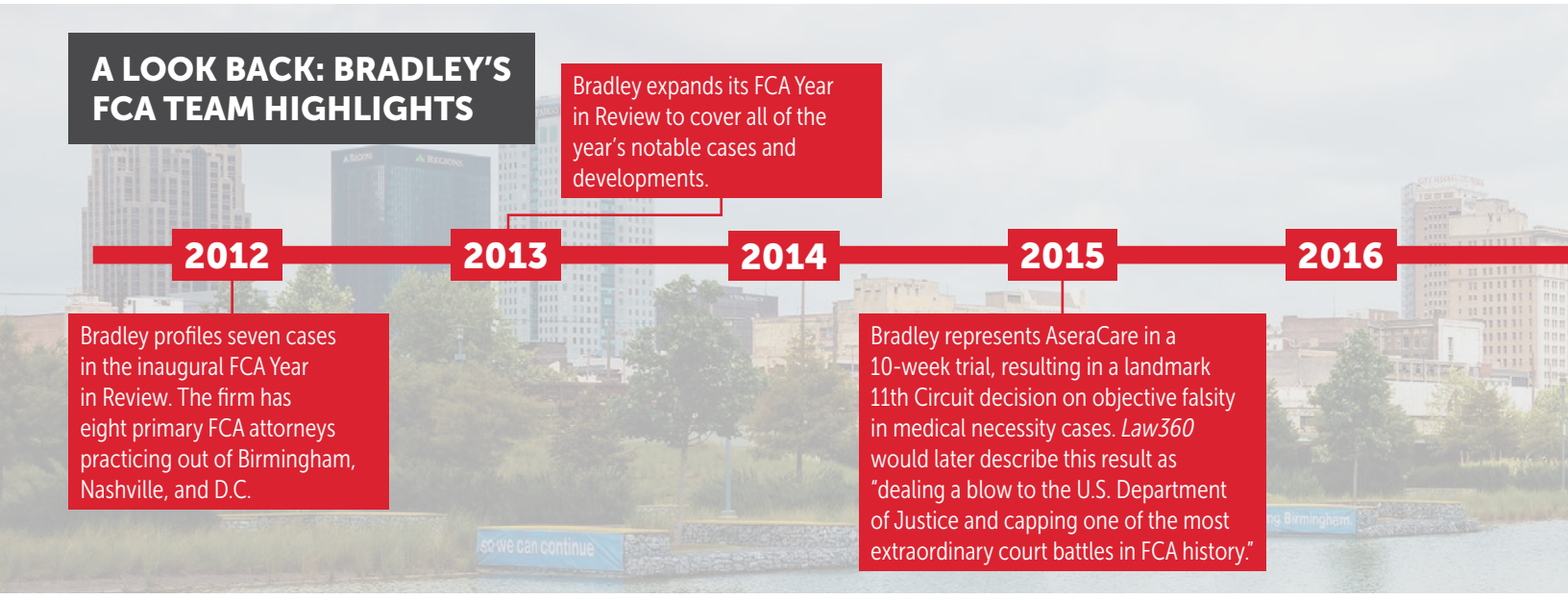
The United States has been actively involved in CARES Act enforcement matters. To date, the vast majority of cases have involved criminal prosecutions as opposed to civil enforcement through the False Claims Act and other civil enforcement tools. FCA practitioners generally expect significant civil enforcement activity in the near future.

The United States has made CARES Act enforcement a priority at DOJ and the many federal agencies that are stewards of CARES Act funds. On May 17, 2021, Attorney General Merrick Garland directed the establishment of the COVID-19 Fraud Enforcement Task Force stating "[t]he Department of Justice will use every available tool – including criminal, civil, and administrative actions – to combat and prevent COVID-19 related fraud." Similarly, on February 17, 2021, Assistant Attorney General Brian Boynton listed pandemic-related fraud as the first of the Civil Division's enforcement priorities stating "It is clear to me and my colleagues in the Civil Division…that the False Claims Act will play a significant role in the coming years as the government grapples with the consequences of this pandemic." Boynton added that the "Civil Division is working closely with various Inspector General and other agency stakeholders to identify, monitor, and investigate the misuse of critical pandemic relief monies, and we expect this collaborative effort to translate into significant cases and recoveries."

We expect two key programs to be the subject of FCA activity in 2022 and beyond. First, the Small Business Administration's Paycheck Protection Program, which provided over 11.45 million loans in the aggregate amount of over $791 billion, is at the top of most enforcement priority lists. The SBA Office of Inspector General (OIG) listed fraud in the PPP and other SBA programs as its No. 1 challenge in its "Top Management and Performance Challenges Facing the SBA in Fiscal Year 2022" report. Released on October 15, 2021, the report notes several key indicators of the scope of future enforcement activity in the PPP:

- There were 40,000 hotline tips on fraudulent activity.
- Through its own analysis the SBA identified over 70,000 loans that were potentially fraudulent based on certain indicators, including duplicative loans; businesses created after February 2015; and entities receiving loans that are on the Department of Treasury's "Do Not Pay" list.
- There were thousands of loans to potentially ineligible borrowers.

The PPP is well suited to FCA enforcement for a variety of reasons. It is subject to extensive rules and regulations regarding a borrower's eligibility. Companies were also required to submit documents supporting their loan applications. Additionally, the PPP has a separate application for forgiveness of the loan. Borrowers must submit additional representations about the use of the loan proceeds in supporting documentation related to those applications. Misstatements, whether intentional or mistaken, on any of these documents can result in investigation and potential FCA liability.

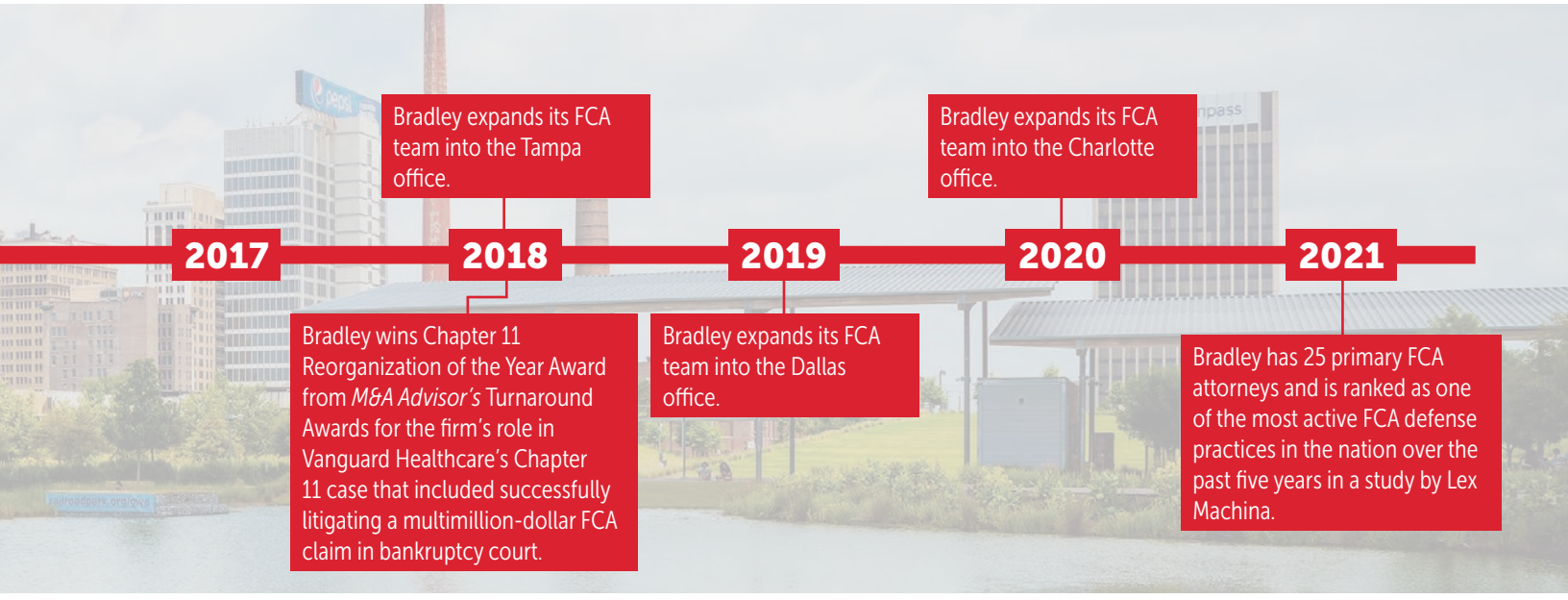


Currently, DOJ has pursued hundreds of criminal PPP cases dealing with egregious fraud, including the establishment of fake companies and ghost employees, misuse of proceeds to purchase luxury automobiles and other personal items, and grossly misstating payroll costs. As a general matter, it appears that enforcement authorities have focused their efforts on the most egregious cases. To date only a handful of FCA cases have been publicly reported with respect to the PPP program, and only one involved a *qui tam* complaint by a whistleblower. We expect, however, that whistleblower activity in these matters will increase as businesses obtain the loans and employees — sometime disgruntled employees — witness the use of the funds by their employers. As enforcement authorities investigate the many thousands of potentially fraudulent loans already identified by OIG, and those that are later reported by whistleblowers, we expect the "reckless disregard" scienter standard and preponderance of the evidence burden of proof applicable in civil cases will make the FCA an extremely attractive enforcement tool.

The second CARES Act program where we expect to see additional enforcement activity is the Department of Health and Human Services (HHS) Provider Relief Fund (PRF). The PRF allocated $178 billion to HHS to assist healthcare providers during the pandemic. Funds have been distributed in four phases, beginning with Phase One in late March 2021 when many of the nation's healthcare providers found vast sums of money directly deposited into their bank accounts by HHS without notice. Multiple other general and targeted distributions of funds have occurred up until the present. Acceptance and use of the PRF funds by healthcare providers are subject to numerous rules and regulations, including shifting guidance from HHS distributed in the form of Frequently Asked Questions (FAQs) posted to HHS's website. Recipients of PRF funds are also subject to detailed reporting requirements to validate the amount of funds they received and account for the use of the funds.

In addition to previously described enforcement priorities for pandemic-related fraud at the DOJ, the importance of PRF compliance and enforcement is underscored by HHS-OIG's inclusion of the audit of the PRF in its 2022 work plan. In late 2021, OIG began reaching out to recipients in preparation for upcoming audits of PRF funds.

To date, there have been only a handful of PRF enforcement cases, all of which are criminal in nature. Each generally deals with the flagrant misappropriation of PRF funds for personal use. The FCA, however, is very likely to be a more potent weapon in PRF enforcement in future cases. First, PRF funds are subject to an intricate web of rules for how the money can be used and how it can be accounted for. Violation of such rules is often the grist of whistleblower complaints and government FCA enforcement. Additionally, billions of dollars are at issue, with many sophisticated companies as recipients of many millions of dollars. Use of the PRF funds will in many cases involve complex accounting and regulatory interpretation. Under such circumstances, it is very likely that criminal intent will be lacking in all but the most egregious cases. FCA cases for PRF funds may be based on false statements in multiple different reports that recipients of PRF funds must file. Given the sophistication of many of the players in this area, the United States will expect a high degree of diligence in following the rules and accurately reporting information. Thus, the FCA's reckless disregard scienter standard and preponderance of evidence burden of proof are likely to make it the preferred enforcement tool in large PRF enforcement actions. With PRF reporting deadlines coming up only recently and extending as far forward as late 2023, we can expect FCA cases in this area for years to come.



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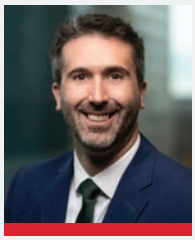

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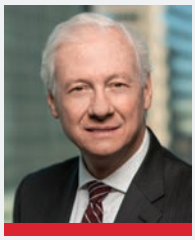

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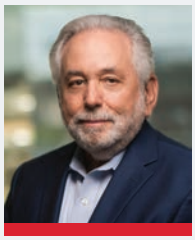

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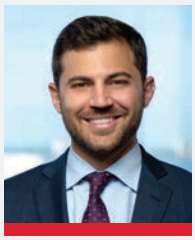

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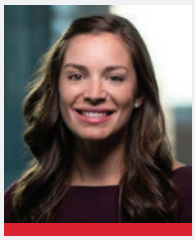

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