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FALSE CLAIMS ACT
2024 YEAR IN REVIEW

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The year 2024 marks another notable year for False Claims Act jurisprudence and related developments. According to the recently released Department of Justice statistics, the government collected over $2.9 billion in judgments and recoveries in the last fiscal year. But the source of those recoveries differed from recent years past. While healthcare still led the way — accounting for 57% of all recoveries — that percentage is down significantly from last year (67%). Defense-spending cases occupied the second spot (3%) and the remaining 40% of recoveries was spread across industries.

By any metric, FCA enforcement remains robust. More cases were brought in 2024 than ever before (1,402), and more than ever before were brought by relators (979). The government still did its part, initiating 423 FCA cases. Among the cases highlighted by the government were FCA matters involving opioids, substandard care, Medicare Advantage, and kickbacks.

In the courts, 2024 lacked a blockbuster FCA decision but still included several significant holdings addressing materiality, AKS causation and willfulness standards, and fraudulent inducement, among others. Perhaps most notably — at least for now — one court found the *qui tam* provisions of the FCA unconstitutional. After Justice Clarence Thomas' dissent in last year's *Polansky* case, in which he questioned the FCA's relator provisions based on Article II concerns, it was only a matter of time until the issue was raised anew in the lower courts. And in September, Judge Kathryn Kimball Mizelle for the United States District Court for the Middle District of Florida did just that, dismissing an FCA case on constitutional grounds after the defendant raised the issue post-*Polansky*. A full discussion of that case – *U.S. ex rel. Zafirov v. Fla. Med. Assocs., LLC.*, No. 8:19-CV-01236, 2024 WL 4349242 at *1 (M.D. Fla. Sept. 30, 2024) – and many more follow.

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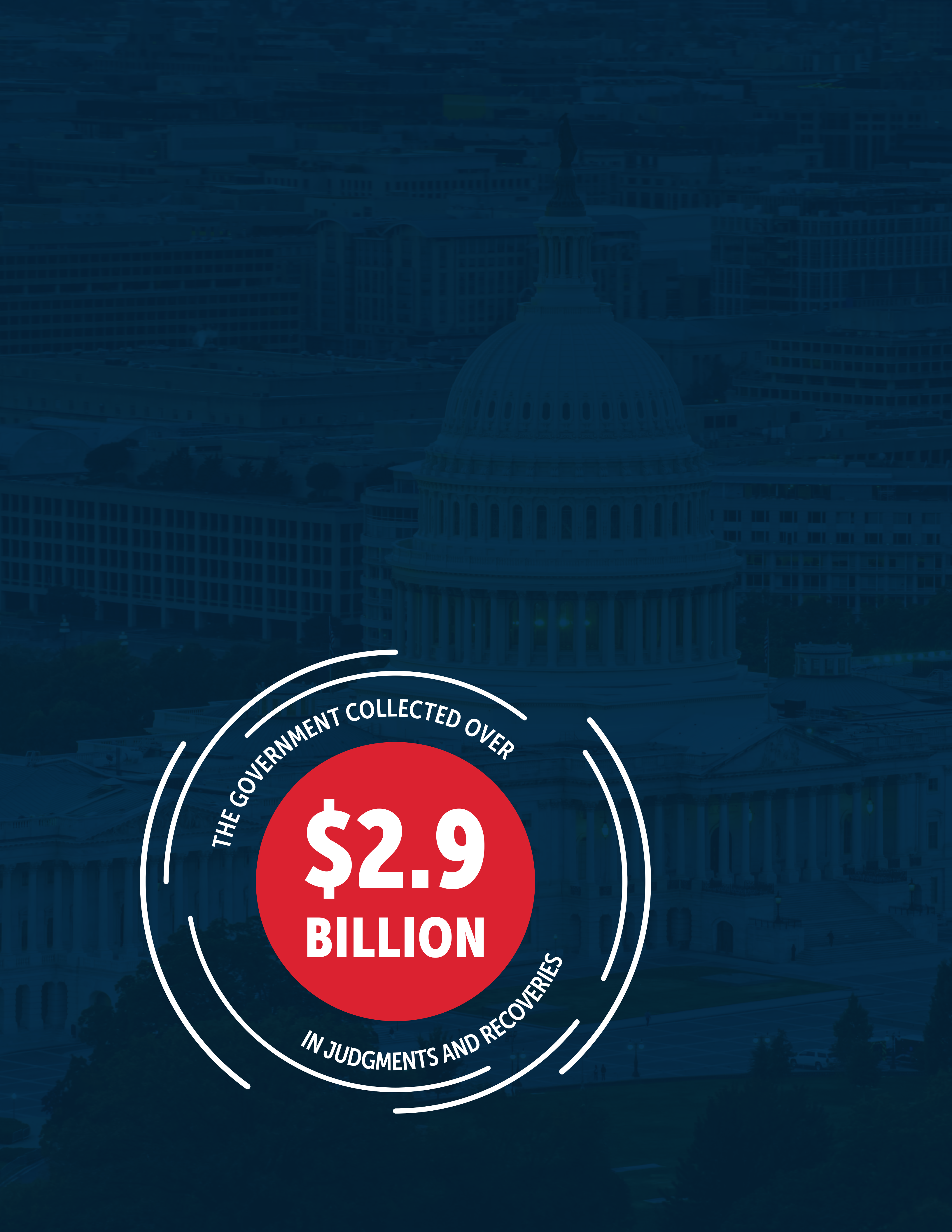
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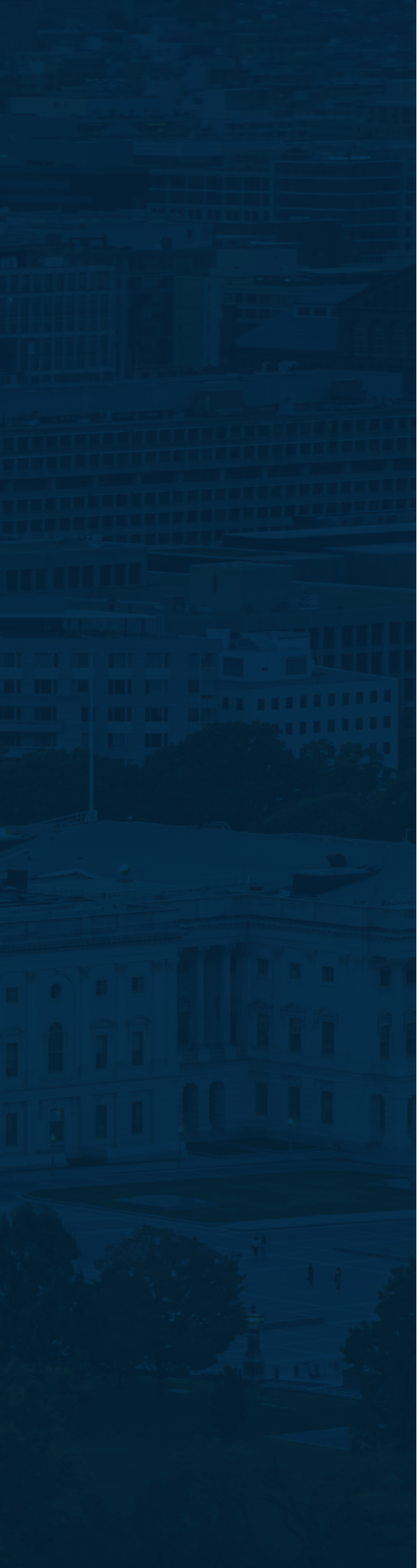
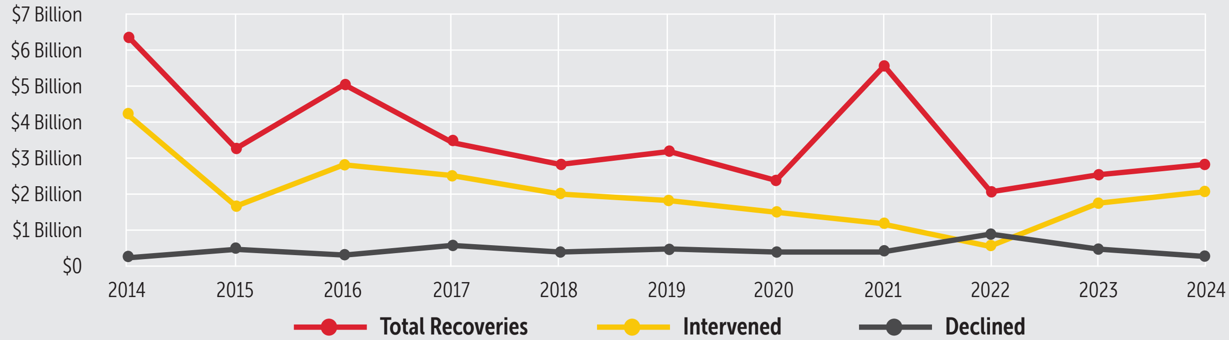


TABLE OF CONTENTS

DOJ YEAR-END STATS

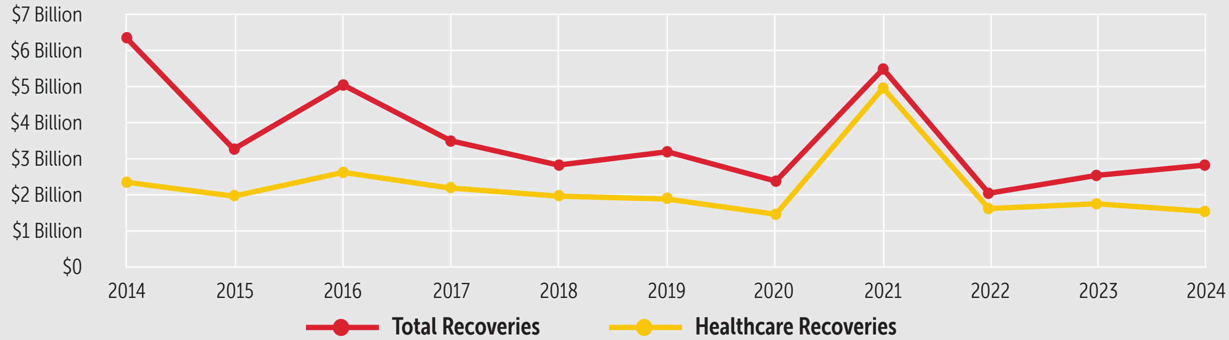
In fiscal year 2024, FCA recoveries topped $2.92 billion. The charts below and throughout the *FCA Year in Review* track notable trends in recoveries and other key metrics over the last decade.

Total FCA Recoveries 2014-2024

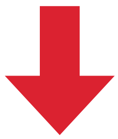


Recoveries were up slightly in 2024. Intervened cases accounted for over 10 times the amount of recoveries than non-intervened cases.

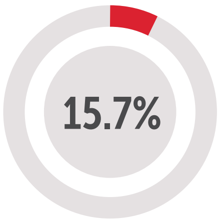
Healthcare Recoveries vs. Total Recoveries 2014-2024



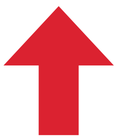
Though at a 10-year low, FCA recoveries from the healthcare industry continue to make up the largest portion of FCA recoveries.



3%
Defense spending cases constituted only 3% of total recoveries in 2024



Where DOJ intervened, it shared only 15.7% of total recoveries with relators.



46%
Percentage increase in new FCA matters from 2022 to 2024.

KEY DECISIONS & DEVELOPMENTS

MATERIALITY

***U.S. ex rel. Zotos v. Town of Hingham,* 98 F.4th 339 (1st Cir. Apr. 8, 2024)**

To assess allegations of materiality, the First Circuit considers whether the government expressly identified compliance as a condition of payment, whether the government paid a particular type of claim in full despite knowledge that requirements were violated, and whether the noncompliance goes to the "essence of the bargain."

Relator Frederic P. Zotos filed a *qui tam* complaint against the Town of Hingham, Massachusetts, alleging that the town's speed limit signs and advisory speed plaques did not comply with federal and state regulations and that, by receiving reimbursements for the signage, the town caused the Massachusetts Department of Transportation to present false claims to the federal government. The district court dismissed Zotos' complaint for failure to state a claim, finding that it failed to plead that the alleged misrepresentations were material under the standard in *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176 (2016).

Zotos appealed, and the First Circuit affirmed, finding that the alleged misrepresentations were not material for either the projects administered under the Federal Aid Highway Program or under Chapter 90 of Massachusetts General Laws. The court considered three non-dispositive factors in its analysis, including whether the government expressly identified compliance with a particular provision as a condition of payment, whether the government paid a particular type of claim in full despite knowledge that certain requirements were violated, and whether the noncompliance goes to the "essence of the bargain" or is merely insubstantial. Applying those factors, the court explained that Zotos failed to sufficiently plead materiality because there was no express indication on the relevant reimbursement form stating that compliance with certain regulations was necessary for federal funding; Zotos had already told the city his belief that the signage violated the law; and the alleged violations were ancillary to the federal and state projects at issue.

***U.S. ex rel. Holt v. Medicare Medicaid Advisors, Inc.*, 115 F.4th 908 (8th Cir. Sept. 13, 2024)**

The Eighth Circuit provides a framework for analyzing materiality in Medicare Advantage cases, establishing that minor or unsubstantial regulatory violations cannot serve as a basis for FCA liability when the government continues to make payments despite such violations.

Relator Elizabeth Holt, a former insurance agent, filed a *qui tam* suit against Medicare Medicaid Advisors, Inc. (MMA), an insurance brokerage firm, and other insurance carriers alleging they violated the FCA through unlawful marketing practices, falsified agent certifications, and manipulated star ratings to minimize complaints. The district court dismissed Holt's complaint, finding that no claims were submitted to the government, that the alleged regulatory violations were material to CMS's decision to pay, and that the complaint failed to meet Rule 9(b) particularity standards.

The Eighth Circuit affirmed. The court's decision centered on the materiality standard established in *Universal Health Servs., Inc. v. United States ex rel. Escobar*, examining three key factors: (1) whether the requirement was an express condition of payment, (2) whether the violation went to the essence of the government contract, and (3) whether the government continued payments despite knowledge of violations. In analyzing these factors, the court emphasized that the essence of CMS's contracts with carriers is fundamentally about providing healthcare services to qualified individuals.

For all three alleged schemes, the court found the violations were not material to CMS's payment decisions. Regarding the marketing violations, the court noted that CMS has discretionary authority to sanction carriers rather than mandatory requirements. For the false certification scheme, the court found that while carriers must withhold payment to brokers using uncertified agents, CMS still pays carriers despite such violations. The star-rating scheme was similarly deemed immaterial as it didn't affect the fundamental purpose of providing healthcare services to patients.

FAILURE TO PLEAD WITH PARTICULARITY RULE 9(b)

Federal Rule of Civil Procedure 9(b) continues to be a fertile source of FCA litigation and a point of contention in nearly every motion to dismiss. Because FCA claims allege fraud, they must meet heightened pleading standards beyond those that apply in ordinary civil actions. Specifically, Rule 9(b) requires plaintiffs to state with particularity the circumstances constituting the fraud, a showing that generally requires details about the time, place, and content of the misrepresentations; the fraudulent scheme; the defendants' fraudulent intent; and the injury resulting from the fraud.

***Pilat v. Amedisys, Inc.*, No. 23-566, 2024 WL 177990 (2d Cir. Jan. 17, 2024)**

The Second Circuit holds that while relators failed to adequately plead that billing information was peculiarly within defendant's knowledge, they should be granted leave to amend their complaint to address pleading deficiencies in their FCA claims.

Relators Michael Pilat and Philip Maniscalco alleged that their former employer Amedisys submitted false claims to Medicare by falsely certifying unqualified patients, providing unnecessary treatments, and falsifying records. After the district court dismissed their third amended complaint and denied leave to amend, Pilat and Maniscalco appealed. Though their complaint adequately pleaded a strong inference of false claims submission, it did not plead specific false claims, and the district court found that they failed to show billing information was peculiarly within Amedisys' knowledge since Pilat and Maniscalco had some access to billing records.

The Second Circuit vacated in part, holding that while the complaint as written failed to plead with particularity, the district court abused its discretion in denying leave to amend. The court found Pilat and Maniscalco should have an opportunity to clarify the relationship between the treatment forms that they could access and actual billing records, as well as explain the nature of their access to the billing department, especially since Amedisys only raised the decisive argument about the relators' access to records after they filed their third amended complaint.

***Olhausen v. Arriva Med., LLC,* 124 F.4th 851 (11th Cir. Dec. 20, 2024)**

The Eleventh Circuit provides a roadmap for satisfying Rule 9(b) in FCA cases, holding that detailed allegations about internal audits coupled with insider knowledge can provide sufficient "indicia of reliability" to survive dismissal, even without direct evidence of claim submission.

The Supreme Court ordered the Eleventh Circuit to reconsider its prior dismissal of Troy Olhausen's False Claims Act case against Arriva Medical, LLC, and its parent companies. Olhausen alleged that the defendants submitted fraudulent Medicare claims without obtaining required assignment-of-benefits signatures from beneficiaries and failed to disclose certain call center locations that processed claims.

The Eleventh Circuit had previously affirmed dismissal based on insufficient allegations of scienter. However, after the Supreme Court's intervening decision in *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739 (2023), which held that a defendant's subjective beliefs about compliance are relevant to FCA liability, the Supreme Court vacated and remanded. On remand, the Eleventh Circuit focused solely on whether Olhausen adequately alleged submission of false claims with sufficient particularity under Rule 9(b), finding he had done so for his assignment-of-benefits theory but not for his undisclosed call center locations theory.

The court concluded that Olhausen's allegations regarding internal audits showing assignment-of-benefits documentation deficiencies in specific quarters sufficiently alleged actual submission of false claims, particularly given his insider position providing direct knowledge. However, the court found his allegations about undisclosed call center locations processing claims too general and speculative to satisfy Rule 9(b). The Eleventh Circuit remanded for the district court to consider other elements such as falsity and materiality in the first instance, with instructions to have the parties brief scienter under the *Schutte* framework.

REVERSE FALSE CLAIMS

Miller v. U.S. ex rel. Miller, **110 F.4th 533 (2d Cir. Aug. 6, 2024)**
The Second Circuit joins other circuits in ruling that to adequately plead an "obligation" under the reverse false claim provisions of the FCA, a relator must show that there was an immediate and self-executing duty to pay, not just the mere possibility of a civil penalty at the government's discretion.

Relator Tamika Miller, a vice president at Citibank, filed a *qui tam* complaint alleging that the company violated the FCA's reverse false claim provision through its auditing system for third-party vendors.

The purpose of the auditing system was to assist in the oversight of Citibank's third-party vendors' compliance with applicable laws, regulations, and consent orders. However, Miller claimed that Citibank manipulated the system to suppress reporting of third-party compliance violations and avoid mandatory government reporting, permitting the bank to avoid paying the government millions in fines. After reporting her concerns to the Office of the Comptroller of the Currency (OCC), Miller filed her *qui tam* complaint alleging reverse false claims, and the government declined intervention in June 2020. In October 2020, Citibank entered into a consent order with the OCC and agreed to pay a fine related to its risk management programs. However, this consent order did not reference Miller's concerns about third-party vendor oversight.

Miller moved for a share of the fine, asserting that her report to the OCC formed the basis of the subsequent consent order, and Citibank filed a motion to dismiss her *qui tam* complaint. The district court denied relator's motion for a share of the OCC fine because her complaint failed to adequately plead a reverse false claim and granted Citibank's motion to dismiss.

The Second Circuit affirmed the dismissal on multiple grounds. First, the court found that Miller failed to meet the particularity requirement under Rule 9(b), as she neither identified specific fraudulent statements nor described the alleged compliance failures. Second, the court determined that any potential civil fines resulting from the alleged conduct would have been implemented at the government's discretion, rather than mandatorily. Finally, the court affirmed the denial of Miller's motion for a share of the OCC fine, joining the Third, Sixth, Eighth, and Ninth circuits to hold that, under the FCA's "alternate remedy" provision at 31 U.S.C. § 3730(c)(5), relators can only receive a share of the government's recovery if they have pleaded a valid FCA cause of action.

Commentary

POST-*POLANSKY* DISSENT, DISTRICT COURT DECLARES *QUI TAM* PROVISIONS UNCONSTITUTIONAL

On June 16, 2023, the Supreme Court issued its *Polansky* opinion focused on governmental jurisdiction to dismiss a case after initially declining to intervene (*U.S. ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419 (2023)). In short, the Supreme Court decided two issues: (1) whether the government must intervene to dismiss an FCA case, and (2) against what standard the government's request for dismissal should be assessed.

In dissent, however, Justice Clarence Thomas raised an entirely different question: Is there good reason "to suspect that Article II does not permit private relators to represent the United States' interests in FCA suits" (*Id.* at 451)? Justices Brett Kavanaugh and Amy Coney Barrett concurred in the majority's holdings but acknowledged that the FCA's constitutionality should be considered "in an appropriate case" (*Id.* at 442). Since that time, the Thomas dissent has made more waves than the majority's findings.

Historically, before *Polansky*, challenges to the constitutionality of the FCA's *qui tam* provision have failed, with all courts, including four circuits, concluding that the Appointments Clause does not apply to relators. *See, e.g., U.S. ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 757–59 (9th Cir. 1993); *U.S. ex rel. Taxpayers Against Fraud v. Gen. Elec. Co.*, 41 F.3d 1032, 1040 (6th Cir. 1994); *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749, 757 (5th Cir. 2001); *U.S. ex rel. Stone v. Rockwell Int'l Corp.*, 282 F.3d 787, 805 (10th Cir. 2002).

In the months immediately after *Polansky*, courts remained unwilling to find *qui tams* unconstitutional, but judicial hesitancy to change course ended on September 30, 2024, when Judge Kathryn Kimball Mizelle for the United States District Court for the Middle District of Florida dismissed *U.S. ex rel. Zafirov v. Fla. Med. Assocs., LLC*, No. 8:19-CV-01236, 2024 WL 4349242 at *1 (M.D. Fla. Sept. 30, 2024). In *Zafirov*, after the government declined to intervene, a relator proceeded with FCA claims alleging that the defendants falsely billed Medicare for medically unnecessary services. The defendants initially filed motions to dismiss that did not mention constitutional arguments, with the court granting dismissal on Rule 9(b) and public disclosure grounds in 2021 but allowing the relator to amend. In 2022, the court denied a second round of similarly based motions to dismiss the amended complaint, allowing the relator to proceed.

After the Supreme Court issued *Polansky* in June 2023, however, the *Zafirov* defendants filed a novel motion for judgment on the pleadings based on the Thomas dissent, arguing that the FCA's *qui tam* provision violates (1) the Take Care Clause and the Vesting Clause of Article II by denying the president removal authority and sufficient supervisory control over a relator; and (2) the Appointments Clause (also Article II) because a relator is not a properly appointed officer of the United States. The government did not intervene, but instead filed a Statement of Interest in support of the FCA's continued constitutionality based primarily on the historic circuit court opinions mentioned above. DOJ did not address Thomas' dissent (No. 8:19-CV-01236 (M.D. Fla., Dkt. No 217)).

In granting the defendants' motion and dismissing *Zafirov*, the court overruled the relator's objection that the defendants had waived constitutional arguments by failing to make the points in their initial motions, finding that, although the arguments were not jurisdictional, and thus, typically should be raised in an initial pleading, the defendants' delay was excusable, since the relator was not prejudiced, receiving notice well before trial, and because it was not too late for the defendants to amend their initial pleadings (2024 WL 4349242 at *5). Turning to the merits of the defendants' argument, the court focused on the Appointments Clause, concluding that the relator "arrangement [created by the FCA] directly defies the Appointments Clause by permitting unaccountable, unsworn, private actors to exercise core executive power with substantial consequences to members of the public" (*Id.* at *19). The court did not address other constitutional grounds for dismissal. DOJ and the relator have both appealed to the Eleventh Circuit.

On January 6, 2025, DOJ filed its appellant brief in *Zafirov*, largely focusing on Mizelle's disregard for precedent and purportedly mistaken application of the Appointments Clause, which government attorneys argue is inapplicable because a relator is not part of the government workforce, the government exercises sufficient control over the suit even if it is relator driven, and a relator has a limited, non-continuous, personal interest in a *qui tam*. With respect to precedent, in addition to citing the routinely referenced circuit opinions mentioned above, DOJ relied heavily on *Vermont Agency of Natural Resources v. U.S. ex rel. Stevens*, 529 U.S. 765 (2000). The Supreme Court in Stevens addressed the constitutionality of *qui tam* claims under Article III, but the government contends that the Court's findings, particularly with respect to relators having personal standing and not acting solely as agents of the government, are grounds upon which the district court should have rejected the defendants' Article II-based constitutional challenge in *Zafirov*.

Although no circuit court has addressed the *qui tam* provision's constitutionality since *Polansky* and no other district courts have followed *Zafirov* yet – with some courts directly rejecting the holding *(see United States v. Chattanooga Hamilton Cnty. Hosp. Auth.*, No. 1:21-CV-84, 2024 WL 4784372, at *3 (E.D. Tenn. Nov. 7, 2024) – the resurgence of these constitutional questions has spurred a response by DOJ in other cases where defendants have raised the issue. In the Northern District of Illinois, on December 4, 2024, the government filed a Statement of Interest to address constitutional arguments in a motion for judgment on the pleadings similar to that filed in *Zafirov* (*see U.S. ex rel. Muhawi v. Pangea Equity Partners, et al.*, No. 1:18-cv-02022 (N.D. Ill., Dkt. No. 131)). In *Muhawi*, DOJ has taken the position that relators are not agents of the United States, but rather private litigants with private interests resulting from the FCA's statutory award of a portion of the government's damages to relators. Also, in the Northern District of Illinois, DOJ, akin to its conduct in *Zafirov*, intervened in limited fashion for the sole purpose of defending the FCA's constitutionality (*U.S. ex rel. Gill v. CVS Health Corp., et al.*, No. 18-cv-6494 (N.D. Ill., Dkt. No. 386)).

In the Middle District of Florida, on December 17, 2024, DOJ filed a Statement of Interest after the defendants moved to dismiss an amended complaint in *U.S. ex rel. Omni Healthcare Inc. v. N. Brevard Cnty. Hosp. Dist., et al.*, in part on constitutional grounds (No. 6:22-cv-696 (M.D. Fla. Dkt. No. 90)). The arguments set forth in this Statement of Interest are substantively identical to DOJ's position in *Muhawi*. Other judges within the Eleventh Circuit with pending constitutional motions to dismiss have directed DOJ to intervene to make its arguments known (*see, e.g., U.S. ex rel. Boger v. Select Rehabilitation, LLC, et al.*, No. 3:24-cv-00893 (M.D. Fla., Dkt. No. 157). In *Boger* and *Omni*, both the courts could dismiss the complaints on grounds other than constitutionality (there are motions to dismiss for other reasons pending), thereby avoiding the issue entirely.

Unless courts reject the constitutional challenges, however, DOJ's submission of a Statement of Interest will not be enough — courts willing to hear defendants out will require DOJ to intervene to be heard. It also remains to be seen what impact a "limited" intervention, like DOJ submitted in *Gill*, may have on a defendant's ability to obtain discovery from the United States.

Historically, so long as DOJ has not intervened, the only way defendants could obtain discovery and depositions directly from the government in FCA cases is through the *Touhy* process; the ability to treat the DOJ as a party for routine discovery even when relators are running the show would be a boon to defendants, who often find themselves tied up in governmental agency red tape under *Touhy*.

Given conflict between *Zafirov*, other district court opinions, and DOJ, we expect a circuit court to weigh in sooner rather than later. The Eleventh Circuit, with the *Zafirov* appeal pending, is most likely to make the first move. Stay tuned in 2025, however, for the possibility of a circuit split depending on where the Eleventh Circuit lands and the outcome of the Northern District of Illinois (Seventh Circuit) cases.

**Bradley Arant Boult Cummings LLP, among others, represents defendants in the Zafirov matter.*

FRAUDULENT INDUCEMENT

***Gose v. Native Am. Servs. Corp.*, 109 F.4th 1297 (11th Cir. July 25, 2024)**

In a matter of first impression, the Eleventh Circuit holds that a graduate of the SBA 8(a) program that continues to perform government contracts exclusively set aside under 8(a) is still a program "participant" subject to the program's notice rules.

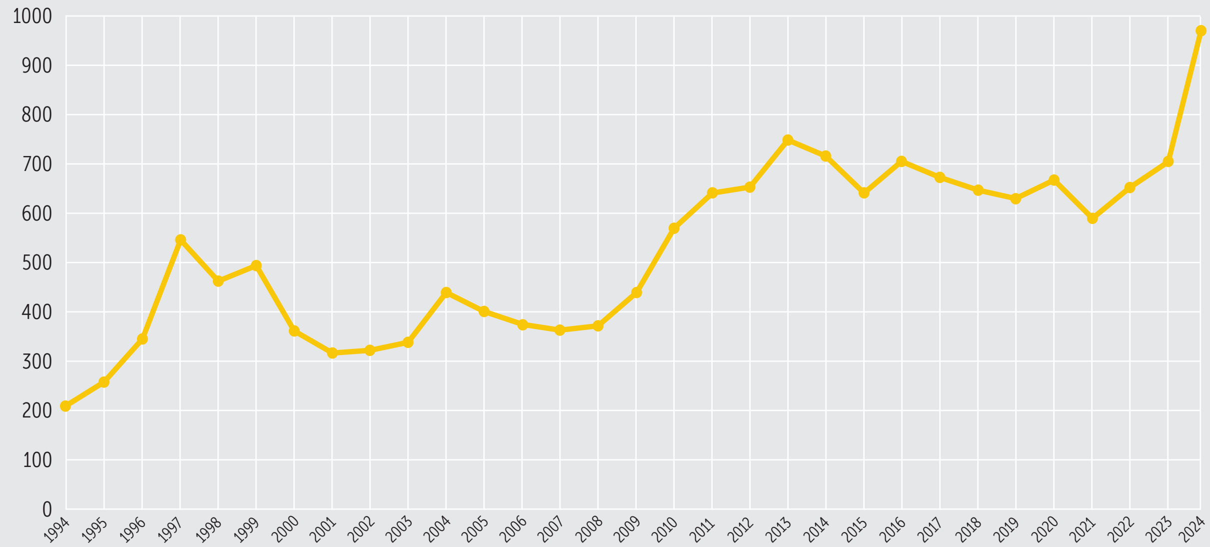
Relators Dennie Gose and Brent Berry were owners of DWG & Associates, Inc., an architecture and construction firm, which was awarded several contracts under the Small Business Administration's (SBA) 8(a) program. The 8(a) program obligates "participants" to advise the SBA of any change of ownership that would make it ineligible for the SBA 8(a) program. DWG graduated from the 8(a) program, due to its size, but continued fulfilling orders on previously awarded 8(a) contracts.

While DWG was in financial peril, defendants Great American Insurance Company (GAIC) and Native American Services Corp. (NASCO) allegedly obtained controlling ownership interest of DWG. Relators alleged that despite the change in ownership, DWG continued bidding on jobs and submitting claims under the 8(a) contracts. By doing so, relators alleged that GAIC and NASCO used DWG to present false claims to the SBA. Defendants moved to dismiss.

The district court granted the defendants' motion to dismiss under Rule 12(b)(6). In doing so, it found that as a "graduate" of the 8(a) program, DWG was no longer an 8(a) program "participant" subject to the SBA's 8(a)-related ownership and control regulations. Relators appealed.

The Eleventh Circuit reversed. The court held that under the SBA 8(a) program, a "graduate" of the program that was still bidding or performing work on 8(a) contracts remained a "participant" and subject to SBA's 8(a)-related ownership notification regulations. The court held relators had adequately pled a change in ownership that required DWG to provide notice to the SBA and seek a waiver to continue to bid on jobs under its existing 8(a) contracts. The Eleventh Circuit reaffirmed that fraudulent inducement is a valid liability theory under the FCA based on claims submitted for fraudulently obtained contracts.

***Qui Tam* Actions Filed 1994-2024**



Driven by a large increase in non-healthcare and non-DOD cases, relators brought more actions in 2024 than ever before.

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.

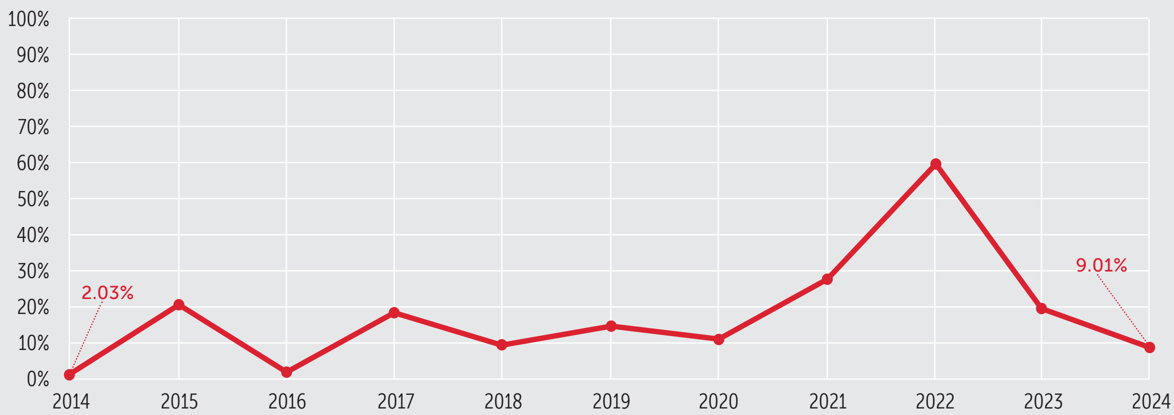
***Stop Illinois Health Care Fraud, LLC v. Sayeed*, 100 F.4th 899 (7th Cir. May 2, 2024)**

The Seventh Circuit affirms liability but remands for recalculation of damages to exclude Medicare claims that did not "result from" defendants' kickbacks.

Relator Stop Illinois Health Care Fraud, LLC, sued Asif Sayeed and his healthcare companies, alleging they violated the Anti-Kickback Statute (AKS) and FCA by paying a healthcare consortium $90,000 over 18 months in exchange for access to patient data that defendants used to directly solicit Medicare-eligible seniors. After the district court found defendants liable and awarded nearly $6 million in damages based on all Medicare claims submitted during the relevant period, defendants appealed.

The Seventh Circuit affirmed the liability finding, rejecting defendants' arguments that they lacked the requisite AKS scienter and that their conduct fell within the regulatory safe harbor for personal services agreements. However, the court vacated the damages award, finding the district court incorrectly assumed that every Medicare claim submitted after defendants began the kickback scheme was false, regardless of whether the claim resulted from improper data mining or legitimate referrals through the consortium's standard rotational system. The court held that under the FCA's requirement that false claims must "result[] from" an unlawful kickback, only claims for services provided to patients identified through defendants' improper data mining should be included in the damages calculation. Claims for patients referred through the consortium's legitimate referral process must be excluded, even if submitted after the kickback scheme began. The court remanded for the district court to determine which claims actually resulted from the illegal scheme.

Percentage of Total *Qui Tam* Recoveries from Declined Cases 2014-2024



The percentage of total *qui tam* recoveries from *qui tam* cases where the DOJ declined to intervene fell sharply in 2024.

Commentary

CAUSATION STANDARD IN AKS-BASED FCA CASES CONTINUES TO DEVELOP

2024 saw further developments in an issue we highlighted in our *2023 FCA Year in Review*: the circuit split regarding the proper causation standard in FCA cases based on Anti-Kickback Statute (AKS) violations. At issue is language in the AKS added by the Affordable Care Act in 2010 that states that "a claim that includes items or services *resulting from* a violation of the [AKS] constitutes false or fraudulent claims for purposes of" the FCA. Courts have had varying interpretations of what the government (or a relator) needs to prove to show that a claim "resulted from" a violation of the AKS.

The Seventh Circuit weighed into the debate this year, requiring a causal link between the AKS violation and claims submitted to a government program. Unlike the Sixth and Eighth circuits, which adopted a defendant-friendly and more easily applied "but for" causation standard, the Seventh Circuit declined to specifically address the question. Instead, it issued a limited opinion that a number of claims clearly had no causal connection with the AKS violation and thus were not false under the FCA. It is unclear if the Seventh Circuit would join the Third Circuit, which is currently the only circuit court that favors a less stringent (and somewhat ill-defined) causation standard. The First Circuit heard oral arguments on this issue in mid-2024, so it should decide on which side of the split it falls sometime in 2025.

Third, Sixth, and Eighth Circuits Create the Split

In 2018, the Third Circuit was the first appeals court to interpret this language i*n United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89 (3d Cir. Jan. 19, 2018). There, the Third Circuit adopted the more plaintiff-friendly standard that "resulting from" only requires a sufficient causal link that is less than but-for causation. Such a link requires only that "a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient" — whether or not the provider would have submitted a claim for the patient absent the illegal kickback. Relying primarily on the provision's legislative history, the Third Circuit concluded that a narrow reading of "resulting from" was at odds with the drafters' intent to strengthen the government's capability to punish Medicare and Medicaid fraud.

The next two circuit courts that weighed in adopted a more stringent but-for standard: The plaintiff must show that the claims would not have been submitted in the absence of the illegal kickback. First came the Eighth Circuit in its 2022 decision in *United States ex rel. Cairns v. D.S. Med., LLC*, 42 F.4th 828 (8th Cir. July 26, 2022). The Eighth Circuit credited an argument that the Third Circuit explicitly rejected: that the Supreme Court had interpreted the same and similar language in other statutes (such as the Controlled Substances Act) to require but-for causation. The following year, the Sixth Circuit followed suit in *United States ex. rel. Martin v. Hathaway*, 63 F.4th 1043 (6th Cir. Mar. 28, 2023), finding that the ordinary meaning of "resulting from" meant but-for causation.

Seventh Circuit Deepens the Split

In *Stop Illinois Health Care Fraud, LLC v. Sayeed*, 100 F.4th 899 (7th Cir. May 2, 2024), the Seventh Circuit declined to directly address the question, instead providing at least one example of the kind of case where a court will find no causal link between the AKS violation and the claim. The case arose from allegations of illegal referrals where one of the defendants entered a management services contract with a non-governmental organization that referred low-income seniors for home-based medical services. The NGO kept a list of home healthcare providers, which included the defendants, and rotated through that list when it made referrals. The defendants also paid the NGO to provide full access to the NGO's clients' healthcare data. The defendants then mined that information to identify and solicit Medicare-eligible seniors for additional healthcare services. After finding the defendants liable, the district court calculated damages based on all Medicare claims submitted by the defendants after the alleged illegal kickback scheme commenced because the "[defendant] had a unique relationship with [the NGO] that pervaded every referral sent." Defendants appealed, arguing, among other things, that the district court's damages calculation was too expansive and included claims for patients who were lawfully referred.

The Seventh Circuit agreed and remanded for a new damages assessment. In doing so, the Seventh Circuit acknowledged the circuit split but also noted that the case "does not require us to determine whether [the Anti-Kickback Statute] requires a showing of but-for causality or something less." Instead, the Seventh Circuit divided the claims into two buckets: claims resulting from the defendants' data-mining operation and claims resulting from patients on the rotation list. The former had a causal connection to the AKS violations because "without mining [the NGO's] data, the defendants could not have provided services to those patients." The latter did not because it had no causal connection to the data-mining scheme. The court concluded that the "broad suggestion—that every claim for payment following an anti-kickback violation is automatically false regardless of its origin—is inconsistent with [the Anti-Kickback Statute]'s directive that a false claim must 'result[] from an unlawful kickback."

First Circuit to Enter the Fray

The First Circuit will likely be the next to weigh in on the issue. In July 2024, it heard oral arguments in the appeal of a district court case, *United States v. Regeneron Pharmaceuticals, Inc.*, No. 20-11217-FDS, 2023 WL 6296393 (D. Mass. Sept. 27, 2023), that adopted the but-for standard. There, the district court granted partial summary judgment to the defendant because the government failed to show a but-for connection between an AKS violation and an allegedly false claim. The court rejected the government's argument that all claims submitted within the relevant period were "exposed" to the AKS violation and therefore were false. Perhaps acknowledging the circuit split and the First Circuit's silence on the issue, the district court judge also certified his ruling for interlocutory appeal, asking the First Circuit to resolve the level of causation needed in these cases. At that time, there was a conflicting district court decision, *United States v. Teva Pharmaceuticals USA, Inc.*, that was teed up for oral argument but was ultimately settled for $450 million in late 2024. The *Regeneron* decision will either finally provide a companion to the Third Circuit's standard or cast that standard increasingly as an outlier.

Supreme Court Intervention More Likely?

The Supreme Court declined to settle the growing circuit divide in 2024 when it denied a petition for certiorari in the Sixth Circuit's *Hathaway* case, but it may eventually feel compelled to do so. The First Circuit's *Regeneron* decision will likely increase interest in the issue. In addition, there are some district courts in circuits whose appeals courts have yet to weigh in that have issued decisions in 2024. For example, a Maryland district court adopted the less stringent causation standard in *United States v. Allergan, Inc.*, No. 1:17-cv-00668, 2024 WL 3015364 (D. Md. June 3, 2024). A few months later, a Northern California district court followed suit in *United States v. Sutter Health*, No. 14-cv-04100-KAW, 2024 WL 4112315 (N.D. Cal. Sept. 6, 2024). Though neither of these cases have been teed up for appeal, these decisions show the growing divide among the courts.

Commentary

SECOND CIRCUIT EMPHASIZES WILLFULNESS ELEMENT OF AKS-BASED FCA CLAIMS

Will 2024 be remembered as the year courts finally started requiring a true showing of willfulness for AKS-based FCA actions? A violation of the AKS requires a defendant to "knowingly *and willfully*" solicit or receive remuneration to induce referrals for items or services reimbursable under a federal healthcare program (42 U.S.C. § 1320a-7b(b)). In 2010, Congress amended the AKS to specifically provide that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim" under the FCA. 42 U.S.C. § 1320a-7b(g). That means that each element of an AKS violation must be satisfied to satisfy the falsity element of an FCA violation. Therefore, FCA plaintiffs must not only meet FCA scienter requirements with regards to the claim submission, but in order to establish falsity, they must also meet the higher criminal scienter standard of willfulness with regard to the kickback. Establishing willfulness requires more than the mere reckless disregard or deliberate ignorance required by the FCA. Willfulness generally means that the defendant acted with the intent to do something that the law forbids — to disobey or disregard the law. *See United States v. Vernon*, 723 F.3d 1234, 1256 (11th Cir. 2013).

To date, only a handful of courts have focused on this distinction. *See, e.g., U.S. ex rel. Patel v. Cath. Health Initiatives*, 312 F. Supp. 3d 584, 594 (S.D. Tex. 2018) (dismissing complaint where relators did not plausibly plead that defendants had specific intent to do what the law forbids), *aff'd*, 792 F. App'x 296 (5th Cir. 2019); *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 677–78 (N.D. Ill. 2006) (granting summary judgment for defendants because relators failed to show evidence that defendants' intent met the heightened "knowingly and willfully" requirement of the AKS).

But this year, the Second Circuit weighed in to explain how important it is that relators meet this high bar, as "defining 'willfully' to require that a defendant act knowing that her conduct is in some way unlawful avoids sweeping in [] innocent conduct." *U.S. ex rel. Hart v. McKesson Corp.*, 96 F.4th 145, 156, 159 (2d Cir. 2024), *cert. denied* 2024 WL 4426646 (U.S. Oct. 7, 2024).

Relator Adam Hart brought a *qui tam* action against McKesson, a pharmaceutical distributor, alleging that McKesson offered its customers free access to valuable business management tools to induce them to purchase drugs from McKesson. Hart claimed that this practice violated the AKS and that any claims for reimbursement submitted to the United States by McKesson's customers were false and fraudulent because they were tainted by the alleged kickback. The district court dismissed Hart's FCA claim, concluding that he failed to allege that McKesson acted willfully as required to establish the predicate AKS violation.

The Second Circuit affirmed the district court's dismissal of Hart's FCA claim. The court analyzed the AKS's *mens rea* requirement and concluded that a defendant who violates the AKS must act with the knowledge that his conduct is unlawful — even if the defendant is unaware that his conduct violates the AKS specifically. The court rejected the relator's suggestion that it was sufficient to show that the defendant offered something of value while generally knowing that remuneration provided to induce referrals could violate the AKS. The court went on to analyze the alleged facts and found they did not give rise to an inference of willfulness. Though Hart alleged that the defendants destroyed documents to conceal misconduct, the court found that the alleged concealment did not happen concurrently with the violation, so it was not probative of their mental state at the time of the alleged violation. Hart also alleged that he had sent messages at the time to his supervisor expressing his concerns, but the court found those messages to suggest only that Hart believed the conduct violated the AKS, not that his supervisor or others at the defendant entity agreed with him or shared his concerns.

PUBLIC DISCLOSURE BAR

A court is required to dismiss an FCA action "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed… unless the action is brought by the Attorney General or the person bringing the action is an original source of the information" (31 U.S.C. § 3730(e)(4)(A)). Only certain types of disclosure, however, qualify as public disclosures under the statute. This year the appellate courts addressed what type of disclosure qualifies under the statute and the required specificity of the disclosure.

***U.S. ex rel. Jacobs v. JP Morgan Chase Bank, N.A.*, 113 F.4th 1294 (11th Cir. Aug. 26, 2024)**

The Eleventh Circuit concludes that blog posts qualified as "news media" under the FCA's public disclosure bar.

Relator Bruce Jacobs brought a *qui tam* action against JP Morgan Chase Bank, alleging that JP Morgan violated the FCA by forging mortgage loan promissory notes and submitting false reimbursement claims for loan servicing costs to Fannie Mae and Freddie Mac. The district court dismissed the case, finding that the suit was foreclosed by the public disclosure bar because the gravamen of Jacobs' claims already had been disclosed in three online blog posts.

The Eleventh Circuit affirmed dismissal. It found that the blog posts qualified as "news media" under the test that is used to determine whether the public disclosure bar applies, rejecting Jacobs' argument to the contrary. The court emphasized that the term "news media" in the public disclosure provision should be interpreted broadly to include not only traditional forms of news media but also "publicly available websites… intended to disseminate information." Because the blogs at issue were publicly available websites that advertised themselves as disseminating foreclosure and mortgage-related information to the public, they clearly qualified as "news media." The court left open the question of whether private or personal social media pages constitute "news media" under the FCA.

The court also concluded that the allegations in the blog posts were "substantially the same" as the allegations in Jacobs' complaint due to the significant overlap between the content of the blog posts and the complaint.

***U.S. ex rel. Heron v. Nationstar Mortg., LLC,* No. 21-1362, 2024 WL 3770843 (10th Cir. Aug. 13, 2024)**

The Tenth Circuit affirms the dismissal of relator's complaint as precluded by the public disclosure bar, finding that the "substantially the same" standard applies even when the public disclosure involves a different defendant.

Relator James Heron filed a *qui tam* suit against Nationstar Mortgage, LLC, Aurora Loan Services, LLC, Aurora Bank FSB, and Aurora Commercial Corporation after losing his home through foreclosure.

Heron alleged that Nationstar and Aurora violated the FCA through illegal foreclosure practices and false claims submitted to the government under federal programs aimed at assisting homeowners during the 2008 financial crisis. To support his argument, Heron claimed that the mortgage servicers submitted fraudulent promissory notes in his foreclosure proceedings after he defaulted on his mortgage loan payments.

Nationstar moved to dismiss Heron's complaint as precluded by the FCA's public disclosure bar. The mortgage servicer argued that Heron's allegations were substantially the same as allegations found in several public disclosures, including consent orders regarding the improper use of promissory notes in foreclosure proceedings, a mortgage fraud notice issued by the FBI and Mortgage Bankers Association, and a related criminal prosecution against an individual involved in the sale of fake mortgages. The district court agreed and dismissed Heron's complaint.

On appeal, Heron argued that the district court improperly relied on sources that do not qualify as public disclosures because they did not all involve the same defendant, that his complaint was not about allegations already in the public domain, and that he was an original source to the underlying information found in the public disclosures.

The Tenth Circuit affirmed. The court agreed with the lower court that Heron's complaint was based on public disclosures and further found that he waived this argument by failing to raise it to the district court. Finally, the court found that Heron was unable to satisfy the original source exception to the public disclosure bar because he failed to provide new and independent information significant enough to influence government action against Nationstar.

***Silbersher v. Valeant Pharms. Int'l., Inc.*, 89 F.4th 1154 (9th Cir. Jan. 5, 2024)**

The Ninth Circuit reverses the dismissal of an FCA case based on the public disclosure bar, determining that any prior public disclosures in the course of proceedings before the PTAB did not reveal substantially the same allegations or transactions described in the relator's *qui tam* complaint.

Relator Zachary Silbersher brought an FCA action against Valeant Pharmaceuticals in the Northern District of California, alleging that Valeant fraudulently obtained a patent for an ulcerative colitis drug, which allowed them to raise the price for the prescription drug by wrongfully excluding generic competitors. The alleged false claim was the inflated prices that Medicare, Medicaid, and other government agencies paid for the prescriptions.

Valeant moved to dismiss the action, arguing in relevant part that Silbersher's claim was foreclosed by the FCA's public disclosure bar. The district court granted the motion, finding that the allegations underlying the fraudulently obtained patent were all disclosed in Patent Trial Appeals Board (PTAB) proceedings, which fit squarely into one of the enumerated public channels (here, a federal hearing) under §3730(e)(4)(A) that constitutes public disclosure.

The Ninth Circuit disagreed, finding that none of the disclosure "channels" in §3730(e)(4)(A) applied. Specifically, it explained that the second channel, on which the district court pinned its dismissal, "primarily involves federal investigatory proceedings" designed to "gain information" and "find out the truth about something." Ultimately, the court determined that the *inter partes* review proceeding before the PTAB at which the disclosures concerning the fraudulently obtained patent were made was not a channel one proceeding because the government was not a party and was not a channel two proceeding because its primary function was not investigative. Moreover, the court concluded that the prior public disclosures did not reveal "substantially the same" allegations or transactions as described in Silbersher's *qui tam* complaint. Accordingly, the public disclosure bar was not triggered, and the court reversed the order below dismissing the FCA action based on the public disclosure bar and remanded for further proceedings.

***Omni Healthcare Inc. v. U.S. Oncology, Inc.*, No. 23-1334-cv, 2024 WL 4751635 (2d Cir. Nov. 12, 2024)**

The Second Circuit reinforces the stringent requirements of the FCA's public disclosure bar and original source exception, emphasizing that mandatory disclosures are not "voluntary" and that derivative knowledge does not qualify as direct knowledge.

Omni Healthcare filed two related *qui tam* actions (Omni I and II) alleging that U.S. Oncology engaged in fraudulent overfill-harvesting practices in cancer treatment between 2003 and 2014.

The district court dismissed the Omni II complaint, finding it precluded by the public disclosure bar. The court concluded that Omni failed to qualify as an original source because Omni's principal source, oncologist Dr. Craig Deligdish, did not have direct and independent knowledge. In addition, the disclosure was mandatory rather than voluntary and the additional information did not materially add to existing public disclosures.

On appeal, the Second Circuit affirmed the lower court's reasoning. The court found that the public disclosure bar applied due to substantially similar allegations in Omni I and *United States ex rel. Underwood v. Amgen, Inc*. (a *qui tam* action that was filed in 2010 and unsealed in 2016). The court held that Deligdish's knowledge, derived from third-party conversations, failed the direct and independent knowledge requirement. Moreover, the court rejected Omni's argument that mandatory FCA disclosures could be considered "voluntary," and found that identifying specific individuals did not materially add to publicly available information.

***U.S. ex rel. Stebbins v. Maraposa Surgical, Inc.*, No. 24-1626, 2024 WL 4947274 (3d Cir. Dec. 3, 2024)**

The Third Circuit finds that the public disclosure bar applies if either the fraud is disclosed or both mispresented facts and true facts are publicly disclosed by way of a listed source.

The relator David Stebbins filed a *qui tam* complaint against a medical office, Maraposa Surgical, alleging that Maraposa defrauded the government by improperly seeking reimbursement for arteriograms — imaging used to identify and assess potential blockages in arteries — that were being performed in its office. Stebbins argued that those services were not reimbursable as they were performed outside of an ambulatory surgery center (ASC). Stebbins also alleged that Maraposa failed to obtain informed consent to administer anesthesia when performing the arteriograms.

Maraposa moved to dismiss. The district court granted the motion, holding that the public disclosure bar precluded Stebbins' claims because both the allegedly "misrepresented facts" — Maraposa's certifications to the government that its claims were eligible for reimbursement — and the "true facts" — the absence of Maraposa from the list of licensed ASCs — were publicly available in news media and federal reports.

On appeal, Stebbins argued that Maraposa failed to demonstrate that the information publicly disclosed in any of the sources cited by the district court constituted allegations of fraud or transactions warranting an inference of fraud. The Third Circuit disagreed, noting that a transaction warranting an inference of fraud is one that is composed of a misrepresented state of facts plus the actual state of facts. Thus, the public disclosure bar applies if either the fraud is disclosed or both mispresented facts and true facts are publicly disclosed by way of a listed source. Because the essential elements of Stebbins' claims were previously disclosed in publicly available databases, the Third Circuit affirmed the district court's dismissal of the claims.

FIRST-TO-FILE RULE

Under 31 U.S.C. § 3730(b)(5), the FCA bars anyone other than the government from bringing "a related action based on the facts underlying the pending action." Courts have interpreted the relationship necessary to trigger the first-to-file rule in different ways.

***Stein v. Kaiser Found. Health Plan, Inc.*, 115 F.4th 1244 (9th Cir. Sept. 24, 2024)**

By its plain language, False Claims Act's first-to-file provision is not jurisdictional.

Plaintiffs Marcia Stein and Rodolfo Bone brought an FCA action against various Kaiser-related entities alleging Medicare fraud. The district court dismissed plaintiffs' lawsuit under the FCA's first-to-file rule because plaintiffs' lawsuit "related" to earlier-filed, pending actions against the same defendants and other related Kaiser entities. On appeal, the Ninth Circuit affirmed, applying precedent that the first-to-file rule is jurisdictional. The Ninth Circuit then took the case *en banc*.

Sitting *en banc*, the Ninth Circuit joined five other circuits in reversing its precedent and holding that the first-to-file rule is not jurisdictional. The court reasoned that other provisions of the FCA explicitly use jurisdictional language. Accordingly, the omission of such language in the first-to-file provision signifies the provision is not jurisdictional.

DAMAGES & PENALTIES

The FCA requires trebling of damages and penalties between the minimum of $13,946 and the maximum of $27,894 per claim in 2024. Many cases, particularly in healthcare, can involve thousands of claims resulting in staggering penalties and ruinous liability.

***Grant on behalf of U.S. v. Zorn*, 107 F.4th 782 (8th Cir. July 5, 2024)**
The Eighth Circuit limits FCA damages under the Excessive Fines Clause.

Plaintiff Dr. Stephen Grant was a sleep medicine practitioner who worked at a medical practice substantially owned by Dr. Steven Zorn. Grant filed an FCA complaint in the Southern District of Iowa, alleging that the defendants had overbilled Medicare, Medicaid, and Tricare for patient visits. Following a bench trial, the district court found that the defendants had submitted 1,050 false claims to the United States and the State of Iowa and awarded a total judgment of $7,598,992 for the FCA violations. Both sides appealed.

The Eighth Circuit found that the Excessive Fines Clause applies in *qui tam* FCA litigation. Under this clause the gravity of a defendant's offense is a factor in determining the constitutionality of the amount of the fine. The court found that while single damages are compensatory, the treble damages imposed by the FCA are punitive. Only the compensatory (i.e., single damages) should be used to represent the "gravity of the defendant's offense" in purely economic damages cases.

The Eighth Circuit affirmed the lower court's judgment in part but remanded for a re-calculation of the penalty after concluding that the penalties were disproportionate to the actual harm and, therefore, the award violated the Excessive Fines Clause. The court found that the district court erred in using the entire amount of treble damages as its measure of the gravity of the defendant's offense because the punitive damages should be excluded. Additionally, the court found that the total award of 78 times the single damages was far greater than any award it had previously upheld, noting that "an award of more than four times the compensatory damages might be close to the line of constitutional propriety."

The Eighth Circuit remanded to the lower court with instructions to use only compensatory damages (i.e., single damages) to assess the gravity of the offense, apply a baseline civil penalty of $5,500 for violations, and "ensure the punitive sanction falls within an appropriate single-digit multiplier of the amount of compensatory damages."

Commentary

PENALTIES INCREASE

DOJ once again adjusted the statutory penalty range for FCA violations in 2024, increasing the minimum per claim penalty to $13,946 and the maximum to $27,894. The Bipartisan Budget Act of 2015 requires these revisions each year to account for inflation. This new penalty range for 2024 was applicable to penalties assessed after February 12, 2024 — the date of publication in the Federal Register — for violations occurring after November 2, 2015 — the date of the Bipartisan Budget Act of 2015. In 2025, the DOJ is expected to adjust the penalties again, increasing the minimum per claim penalty to $14,308 and the maximum to $28,619.

RETALIATION

***Monroe v. Ft. Valley State Univ.*, 93 F.4th 1269 (11th Cir. Feb. 15, 2024)**

Because Congress did not abrogate sovereign immunity for lawsuits against states under the FCA's anti-retaliation provision, state university's Head Start Department is entitled to sovereign immunity in suit brought under that provision.

Plaintiff Taquila Monroe was terminated from her position as program director of Fort Valley State University's Head Start and Early Head Start Department after reporting alleged improprieties with the department's use of federal and state funds to the executive director. Monroe filed suit under state law and the FCA's anti-retaliation provision, alleging that she was discharged because of her efforts to stop the presentment of false claims to the federal government.

The board filed a motion to dismiss, which the district court granted, finding that the Eleventh Amendment shielded the board from liability on Monroe's claims.

On appeal, the Eleventh Circuit addressed two issues: whether Congress abrogated sovereign immunity for lawsuits against states under the FCA's anti-retaliation provision, and whether the board is an arm of the state entitled to immunity. On the first question, the court joined every circuit that has addressed the issue in holding that the FCA's anti-retaliation provision did not abrogate sovereign immunity because the statute does not contain an unequivocal abrogation of sovereign immunity.

On the second question, the court considered four factors to determine whether the board is an arm of the state entitled to Eleventh Amendment immunity. Applying those factors, the court determined that the board is an arm of the state because the board is defined as an agency of the state under Georgia law; Georgia would be responsible for any judgment against the board; Georgia exercises control over the department and its employees; and Georgia partially funds the Head Start Program. Accordingly, the court affirmed the lower court's dismissal of Monroe's complaint.

***Mooney v. Fife*, 118 F.4th 1081 (9th Cir. Sept. 30, 2024)**

The Ninth Circuit clarifies that the *McDonnell Douglas* burden-shifting framework applies to FCA retaliation claims and that employees with compliance duties should not be treated differently than employees without such duties.

Relator Thomas Mooney brought a claim for FCA retaliation against his former employer, Vivida Dermatology, alleging that Vivida defrauded Medicare and Nevada Medicaid by overbilling Medicare and Nevada Medicaid for various medical services.

An FCA retaliation claim requires proof of three elements: (1) protected conduct, (2) notice, and (3) causation. To show notice, the employer must have known that the employee was engaging in protected conduct. Mooney alleged that he reported his concerns to Vivida about their questionable billing practices on numerous occasions. Vivida argued that since ensuring compliance with billing regulations was part of Mooney's job responsibilities, his reporting did not put Vivida on notice that Mooney was engaging in a potentially protected activity. The district court agreed and granted summary judgment for Vivida because it found that Mooney failed to satisfy the notice element.

The Ninth Circuit reversed. First, the Ninth Circuit clarified that the *McDonnell Douglas* burden-shifting framework applies to FCA retaliation claims. This imposes a "but for" causation standard and, under this framework, once the employee has established a *prima facie* case of FCA retaliation, the burden shifts to the employer to produce a legitimate, non-retaliatory reason for the employee's termination. As to the notice requirement, the Ninth Circuit held that employees with compliance duties should not be held to a different standard than employees without such duties. In doing so, the court stated that to satisfy the notice requirement of an FCA retaliation claim, the employer need only be aware of an employee's "efforts to stop one or more violations of the FCA."

Commentary

SETTLEMENTS HIGHLIGHT DOJ PRIORITIES

The Department of Justice announced multiple high-profile settlements in 2024. Some are notable for their eye-popping amounts, while others demonstrate DOJ priorities in certain areas of enforcement last year and what we can expect in 2025.

Big Numbers in Healthcare and Procurement Fraud

Blockbuster amounts in several healthcare cases and one procurement case paved the way to DOJ's $2.9 billion in recoveries this year. In December 2023, Community Health Network Inc. entered a $345 million settlement with DOJ to resolve allegations that it knowingly submitted claims to Medicare that were not payable due to violations of the Stark Act. The government alleged the company hired doctors at salaries far above fair market value to capture their downstream referrals. As part of the scheme, the company allegedly provided false information to consulting services to obtain favorable fair market value opinions on physician compensation. DOJ filed suit against the company after a four-year investigation. The case settled after nearly three years of litigation.

In October 2024, Teva Pharmaceuticals USA, Inc. entered a $450 million settlement with DOJ to resolve allegations that it engaged in two schemes that violated the Anti-Kickback Statute and resulted in the submission of false claims. First, the government alleged that Teva conspired with two copay assistance programs to ensure that its donations to these organizations were used to cover the patient copayments for a Teva drug. Additionally, the government alleged that Teva conspired with other drug manufacturers to fix prices for a widely used high cholesterol drug. Having entered separate resolution with the Antitrust Division, Teva paid an additional amount to resolve the AKS claims associated with the anti-competitive arrangements.

In July 2024, Rite Aid Corporation and several subsidiaries entered a $101 million settlement agreement with the DOJ to settle allegations that it failed to accurately report drug rebates to Medicare denying the federal programs the financial benefit of manufacturer discounts and rebates on the drugs.

In October 2024, Raytheon Company entered a $428 million settlement with DOJ to resolve allegations that it provided false cost and pricing data when negotiating with the United States in numerous government contracts and double billed the government on a weapons maintenance contract. DOJ noted that this was the second largest government procurement fraud recovery under the False Claims Act.

Opioid Cases Generate Important Settlements

DOJ's opioid enforcement efforts continued to show fruits in 2024. Repeatedly cited as a department priority, settlements in this area demonstrate that DOJ is actively bringing long-term investigations to fruition. We can expect more activity in this area in 2025.

In February 2024, Endo Health Solutions Inc. entered a $475.6 million FCA settlement with DOJ as part of a global resolution of civil and criminal liability for its sales and marketing practices for the opioid drug Opana ER with INTAC. The FCA settlement and criminal penalties were all subject to an additional settlement in Endo's bankruptcy pursuant to which the government may be paid up to $464.9 million over 10 years. The government alleged that Endo used a marketing scheme to target healthcare providers that the company knew were prescribing Opana for non-medically accepted indications. Endo allegedly targeted high prescribing physicians who were responsible for a disproportionate amount of Opana prescriptions.

In December 2024, McKinsey & Co. entered a $323 million False Claims Act settlement with DOJ to settle allegations that it caused the submission of false claims by advising Purdue to intensify marketing to healthcare providers, some of whom were already prescribing very large quantities of opioids. The FCA settlement was part of a global resolution with the United States that included a deferred prosecution agreement and additional forfeiture, criminal penalties, and fines.

In July 2024, Rite Aid Corporation entered a settlement with DOJ to resolve allegations that it knowingly dispensed hundreds of thousands of unlawful prescriptions for controlled substances that lacked a legitimate medical purpose and were not issued in the usual course of professional practice or that were not dispensed pursuant to a valid prescription. The government alleged that prescriptions were repeatedly flagged as suspicious internally, but the red flags were ignored. Rite Aid paid $7.5 million at the time of the settlement and allowed the United States an unsubordinated, general unsecured claim of $401.8 million in its bankruptcy.

Though many opioid cases against individual doctors have been pursued criminally, DOJ announced a $4.8 million consent judgment with Dr. Gregory Gerber in August 2024. The government accused Gerber of unlawfully issuing opioid and controlled substances prescriptions without a legitimate medical basis and of receiving kickbacks from a drug manufacturer as part of a scheme to unlawfully prescribe an opioid drug containing fentanyl. Gerber was also sentenced to 42 months in prison in a related criminal case.

Pandemic Fraud Enforcement Accelerates

Pandemic-related fraud enforcement accelerated in 2024 on many fronts. From Paycheck Protection Program (PPP) cases to COVID-19 testing schemes, the government's priority enforcement in this area is continuing to take shape. The government reports $250 million in pandemic-related recoveries in the last fiscal year. Additionally, multiple settlements this year are the fruition of whistleblower complaints filed during the pandemic. As noted in the introduction to this *FCA Year in Review*, record numbers of *qui tam* cases are being filed. It is virtually certain that pandemic-related fraud is at least in part driving these numbers, and these cases will multiply as they come out from under seal.

In the largest PPP case to date, in May 2024, Kabbage Inc., a PPP loan processor, entered an FCA settlement with DOJ to resolve allegations that it inflated borrower PPP loans causing the SBA to guarantee and forgive loans that exceeded the maximum amount borrowers should have received. The inflated loan amounts benefited Kabbage because loan processors were paid based on percentage of loan amount. Because Kabbage is in bankruptcy, the United States received an unsubordinated, general unsecured claim of up to $120 million in the bankruptcy. This settlement was the result of two *qui tam* cases filed in 2020 and 2021.

In August 2024, West Coast Dental Administrative Services, LLC, and several of its owners entered a $6.3 million settlement with DOJ to resolve allegations that they knowingly applied for and received PPP loans for which they were ineligible. The government alleged that West Coast Dental and six of its affiliated dental practices applied for PPP loans falsely representing they had fewer than 300 employees to qualify for the loans. The companies, however, failed to disclose common ownership that resulted in the seven entities being "affiliated" under the SBA's rules. Affiliated companies must aggregate their employee counts for PPP eligibility. The aggregate employee count for these companies was greater than 300, thus none of them were eligible for PPP loans. This settlement was the result of a *qui tam* case filed in 2022.

In July 2024, Hemisphere GNSS (USA), Inc., entered a $2.6 million settlement agreement with DOJ to settle allegations that it falsely represented that "no entity created in or organized under the laws of the People's Republic of China" owned or held 20% or more of an economic interest in the company, and that it did not retain on its board anyone who was a resident of China. Due to the false representations, the company was not eligible for a PPP loan. This settlement was the result of a *qui tam* complaint filed in 2022.

In July 2024, a group of entities collectively doing business as CityMD entered a $12 million settlement agreement with DOJ to resolve allegations that they billed COVID-19 tests to a federal government program for uninsured individuals for individuals who had health insurance. The government alleged that CityMD did not adequately check to see if individuals had health insurance and submitted tests to laboratories falsely stating that the patients had no insurance causing the laboratories to submit false claims to the government program. This settlement was the result of a *qui tam* complaint filed in 2020.

The significant settlements of 2024 demonstrate that traditional enforcement in healthcare through the AKS and Stark Law, along with government procurement cases, continue to drive large recoveries for DOJ. Opioid enforcement and pandemic-related cases, however, are clearly important DOJ priorities where we can expect to see additional activity in 2025. Pandemic fraud enforcement in particular appears to be accelerating as *qui tam* complaints under seal for years are investigated by the government and moved toward resolution or litigation.

Commentary

DOJ EXPANDS WHISTLEBLOWER PROGRAMS

Recognizing the remarkable success of the False Claims Act's *qui tam* provisions in expanding FCA enforcement, DOJ launched an expanded whistleblower program in April 2024. Although separate from the False Claims Act, the new whistleblower program touches on many areas of criminal law enforcement that are often parallel to civil enforcement efforts under the FCA. Companies and practitioners in FCA law should be aware of this relatively recent program and its implications.

While observing that whistleblower programs, including those in the FCA, help to "successfully uncover corporate criminal schemes, advance criminal investigations, and prosecute the most culpable individuals and entities," DOJ noted that these "programs do not cover the full scope of corporate crime the Department investigates and prosecutes, leaving gaps the Department now seeks to fill." The program therefore focuses on specific areas of enforcement, including:

- Violations by financial institutions, their insiders, or agents, including schemes involving money laundering, anti-money laundering compliance violations, registration of money transmitting businesses, and fraud statutes, as well as fraud against or non-compliance with financial institution regulators.
- Violations related to foreign corruption and bribery by, through or related to companies, including violations of the Foreign Corrupt Practices Act, violations of the Foreign Extortion Prevention Act, and violations of the money laundering statutes.
- Violations committed by or through companies related to the payment of bribes or kickbacks to domestic public officials, including federal, state, territorial, or local elected or appointed officials and officers or employees of any government department or agency.
- Violations related to (a) federal healthcare offenses and related crimes involving private or other non-public healthcare benefit programs, where the overwhelming majority of claims are submitted to private or other non-public healthcare benefit programs; (b) fraud against patients, investors, and other non-governmental entities in the healthcare industry, where the overwhelming majority of the actual or intended loss was to patients, investors, and other non-governmental entities; and (c) any other federal violations involving conduct related to healthcare not covered by the Federal False Claims Act, 31 U.S.C. § 3729, *et seq.*

FCA practitioners will note that the emphasis on federal healthcare offenses detailed above is tailored to those offenses that cannot be reached by the FCA. Because the FCA requires claims on governments funds, the DOJ apparently believes a broad swath of fraud aimed at non-governmental payers may go unreported and undetected. We expect robust enforcement in this area in the future.

DOJ's program is designed to entice potential whistleblowers by making them eligible for financial awards if they provide original information in writing that leads to criminal or civil forfeiture exceeding $1 million. Companies or other types of entities cannot obtain awards under the program. Further, certain categories of people cannot obtain awards under the programs, including those employed by DOJ or other law enforcement and their family members, those who *meaningfully* participated in the criminal activity, and those who make any false statements or withhold material information in the course of their disclosures under the program.

Awards under the program could be significant, but the policy emphasizes that they are "entirely discretionary and an award is not guaranteed." If DOJ finalizes a successful forfeiture, the whistleblower may be eligible for an award of up to 30% of the first $100 million and up to 5% of the amount between $100 million and $500 million. DOJ will consider the significance of the information provided by the whistleblower and the amount of assistance provided in assessing the amount of the award. Additionally, and because DOJ seeks to encourage internal reporting and self-policing within companies, reporting the illegal activity to the company's internal compliance department before reporting to DOJ will positively affect a whistleblower's award.

Companies previously attuned to FCA risk due to claims on government programs or contracts should take note that the whistleblower and associated compliance risk has now expanded significantly. Compliance programs in some industries, such as healthcare, that previously focused primarily on government programs compliance may need to be reevaluated to account for this expanded risk.

Although this policy appears to offer significant incentives for increased whistleblower activity, it is too soon to judge its effects. Certain differences from the FCA's *qui tam* provisions may make it a less attractive program for whistleblowers and their counsel. Specifically, unlike the FCA, there is no right to pursue the case if the government declines it. Additionally, and perhaps even more significantly, there is no legal right to an award. Unlike the FCA, which establishes a statutory right to a minimum percent of the government's recovery, DOJ repeatedly emphasizes that awards under the new program are entirely discretionary. Finally, there is no attorney's fee provision. Thus, whistleblowers' counsel must rely entirely on payment from their client presumably through a percentage of the award. Developments in this program and its implementation by DOJ over the next year will certainly impact its attractiveness to potential whistleblowers and their lawyers.

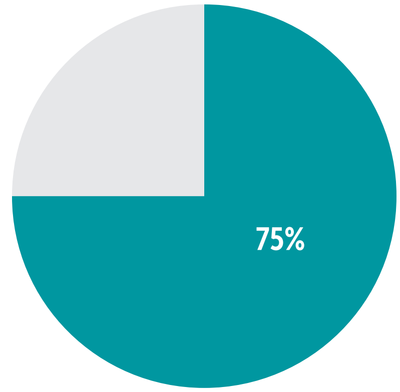
SETTLEMENT ENFORCEMENT

***State Farm Mut. Automobile Ins. Co. v. Angelo*, 95 F.4th 419 (6th Cir. Mar. 5, 2024)**
The Sixth Circuit holds that a release clause in a settlement reached in a RICO proceeding applied to a later-filed FCA case. It further agreed that the district court could order the relator to seek the government's consent to voluntarily dismiss the FCA claims against parties to the settlement agreement.

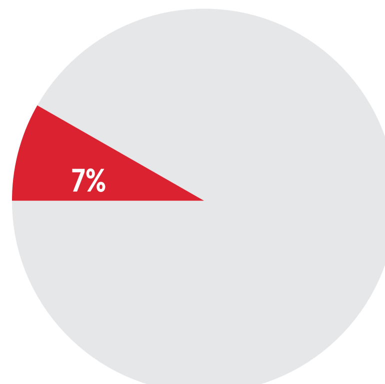
Plaintiff State Farm brought a Racketeer Influenced and Corrupt Organizations Act (RICO) action against defendant Michael Angelo, alleging that Angelo was the "primary driver" of a "scheme" to "fraudulently obtain money from State Farm." While that case was being litigated, Angelo brought a *qui tam* action against State Farm alleging that it improperly avoided paying medical benefits to its insureds, causing the federal government to foot the bill without reimbursement by State Farm. The parties settled the RICO claim. When the *qui tam* complaint was unsealed and served, State Farm argued that the claim release provision in the RICO settlement provision applied to Angelo's FCA claims.

The district court agreed, holding that the *qui tam* action fell within the scope of the settlement agreement because the release provision applied to any claims arising from any healthcare services provided by any of Angelo's entities to any State Farm insured patients, and the FCA complaint clearly related to healthcare services provided by the Angelo entities. As to remedy, the court determined that it could not enforce the settlement agreement by mandating dismissal of the *qui tam* action, but it could require Angelo "to take all necessary steps... to secure the discontinuance of" the action as to State Farm. Namely, the court ordered Angelo to "request the federal government's consent to dismiss" State Farm.

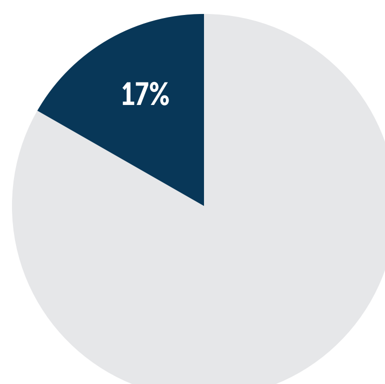
The Sixth Circuit affirmed. After addressing some gamesmanship employed by Angelo in seeking the government's consent to dismiss and a question of whether there remained an independent co-relator, the Sixth Circuit echoed the district court, holding that the language in the RICO settlement release provision "clearly encompasses the FCA action." The Sixth Circuit further concluded that the district court's remedy — requiring Angelo to seek the government's consent to dismiss — was appropriate.



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



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



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

**Percentages in the graphs above do not total 100 because numbers were rounded down*

WHAT TO WATCH IN 2025

ELEVENTH CIRCUIT DECISION IN *ZAFIROV*

In fall 2024, the defense bar witnessed its first district court dismissal on constitutional grounds based on Justice Clarence Thomas' dissent in *Polansky*. In *U.S. ex rel. Zafirov v. Fla. Med. Assocs., LLC.*, discussed in more depth elsewhere in this *FCA Year in Review*, the United States District Court for the Middle District of Florida concluded that the FCA's *qui tam* provision violates the Appointments Clause of Article II of the Constitution. It remains to be seen if any district courts will join *Zafirov* in 2025 — to date, none have. The Eleventh Circuit, however, is expected to be the first circuit court to address the issue post-*Polansky*, with a ruling expected sooner rather than later in 2025 as a result of the pending *Zafirov* appeal.

SCOTUS DECISION IN *WISCONSIN BELL, INC. V. U.S. EX REL. HEATH*

The Supreme Court is poised to address whether the FCA applies to claims involving quasi-governmental funds, with potentially significant implications for organizations receiving indirect federal funding or oversight.

Relator Todd Heath alleged that an AT&T subsidiary overcharged schools and libraries under the FCC's E-Rate program, which provides discounted telecommunications services through a private not-for-profit administrator using primarily private carrier fees rather than government funds.

The district court granted summary judgment to Wisconsin Bell based on Heath's failure to establish falsity and scienter. Heath appealed to the Seventh Circuit where Wisconsin Bell raised an issue that the district court did not get to address: whether reimbursement requests submitted to the E-rate program are "claims" under the FCA. Wisconsin Bell argued that requests for payment from the E-Rate fund were not "claims" under the FCA because the funds were neither public nor under direct government control. The Seventh Circuit found that the reimbursement requests are claims under the FCA because the "government provides a portion of the money" to the Universal Service Fund. Wisconsin Bell appealed to the Supreme Court.

The Court has not issued an opinion yet, but oral arguments were held recently. Based on the questions the justices were asking, they appear inclined to accept the narrow position that government contributions to the fund established FCA claims but expressed concern about Heath's broader arguments regarding government oversight. Justice Amy Coney Barrett noted the limited circuit court precedent on this issue, while Justice Brett Kavanaugh worried about unintended consequences of an expansive ruling. Justice Neil Gorsuch raised questions about the damages calculation and traceability of government funds. The case highlights the continuing expansion of FCA litigation to entities with even minimal connections to federal funding or oversight, emphasizing the importance of internal compliance programs for organizations participating in public programs.

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