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FALSE CLAIMS ACT
2023 YEAR IN REVIEW

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As we do every year, this issue revisits the key cases and other developments from the year gone by. And by most metrics, 2023 was a notable year for the False Claims Act (FCA).

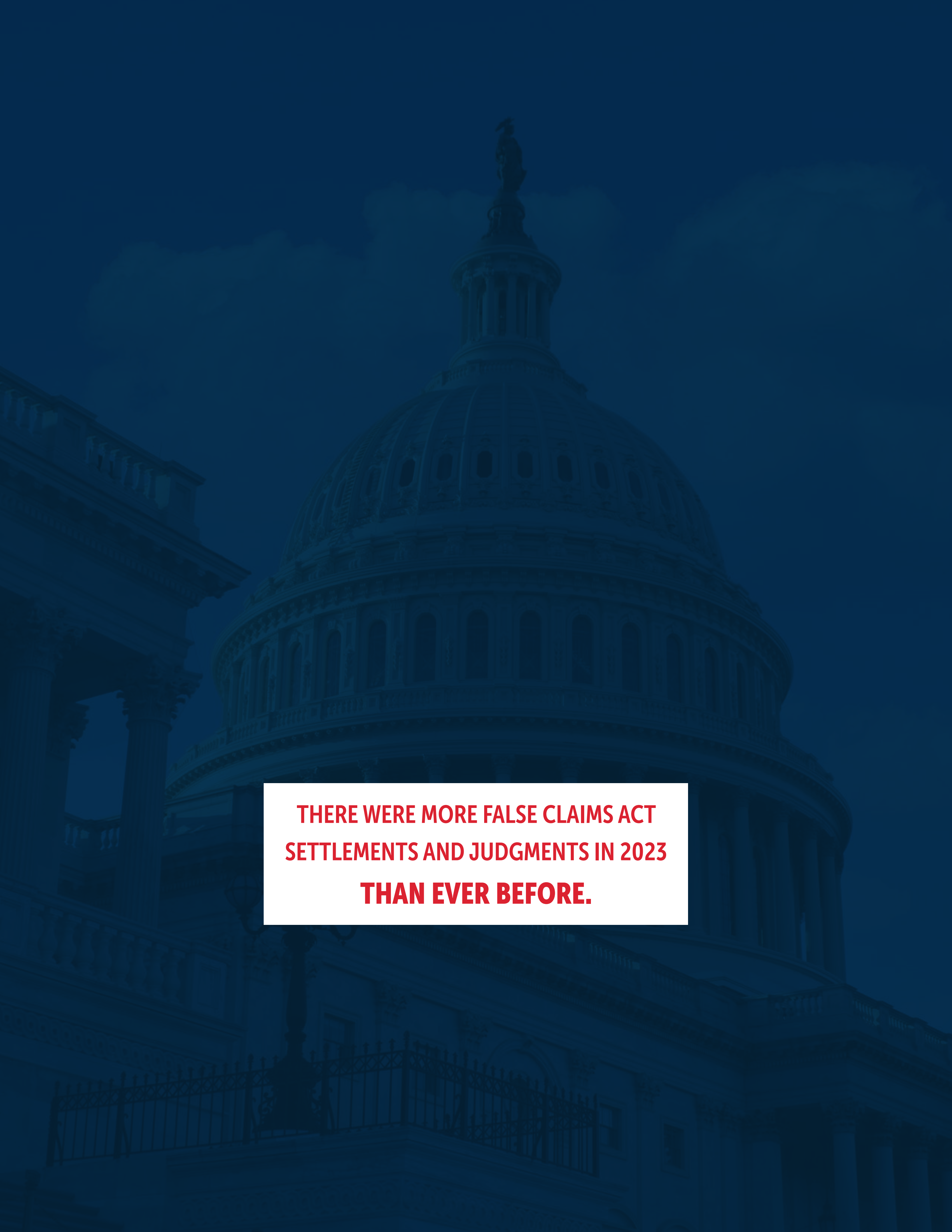
We start with the numbers: The Department of Justice (DOJ) released its report on settlements and recoveries later than usual, with the figures not becoming public till mid-February. But while the timing was different, the content was much the same. In fiscal year 2023, DOJ recovered over $2.68 billion in settlements and judgments from civil FCA cases. That represents an increase of nearly $500 million from 2022 when the total was just over $2.2 billion.

Once again, the healthcare industry led the way among targeted industries with over $1.8 billion — nearly 67% of the total amount — in recoveries. That marks the ninth consecutive year that the healthcare industry had the largest share of recoveries.

In the courts, two U.S. Supreme Court cases addressed the FCA in 2023: First, the Court addressed the timing and standards around the government's right to dismiss FCA cases in *U.S. ex rel. Polansky v. Exec. Health Res. Inc.,* concluding that the government may intervene and dismiss a *qui tam* suit at any point in a case's life, subject to the default standard for such motions under Fed. R. Civ. P. 41 (full summary on page 12). Second, in *U.S. ex rel. Schutte v. SuperValu*, the Court reviewed the FCA's scienter element, overturning the Seventh Circuit and holding that a defendant's subjective belief about its compliance with the law when it submits a claim is relevant to FCA liability (full summary on page 3). Neither decision was a surprise to most observers — though the Justice Clarence Thomas's dissent in *Polansky*, questioning relators' authority to bring *qui tam* suits under Article II, grabbed attention and may make for interesting future litigation (see page 14 for more on the dissent).

The lower courts continued to wrestle with myriad FCA issues, including materiality and causation. As we note in the feature on page 10, the causation issue in particular seems ripe for future Supreme Court review, as a circuit split deepens on the appropriate causation standard in FCA cases premised on violations of the Anti-Kickback Statute.

Finally, on the legislative front, Sen. Charles Grassley, the FCA's most ardent supporter in Congress, introduced legislation that would amend the FCA in several ways, most notably regarding materiality. The bill, if enacted, would limit the weight given to the government's payment of claims after learning of falsity or fraud in a court's analysis of materiality, effectively mooting the Supreme Court's materiality analysis from 2016 in *United Health Servs. v. U.S. ex rel. Escobar.*



THERE WERE MORE FALSE CLAIMS ACT SETTLEMENTS AND JUDGMENTS IN 2023 **THAN EVER BEFORE.**

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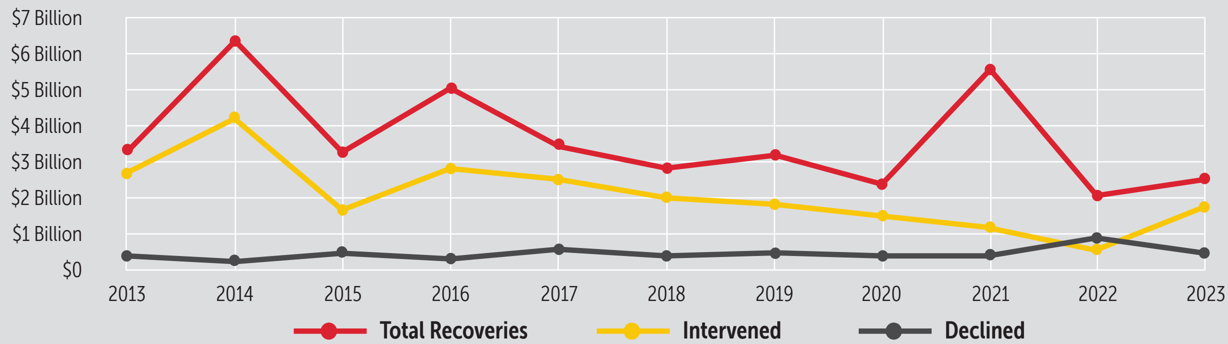
DOJ YEAR-END STATS

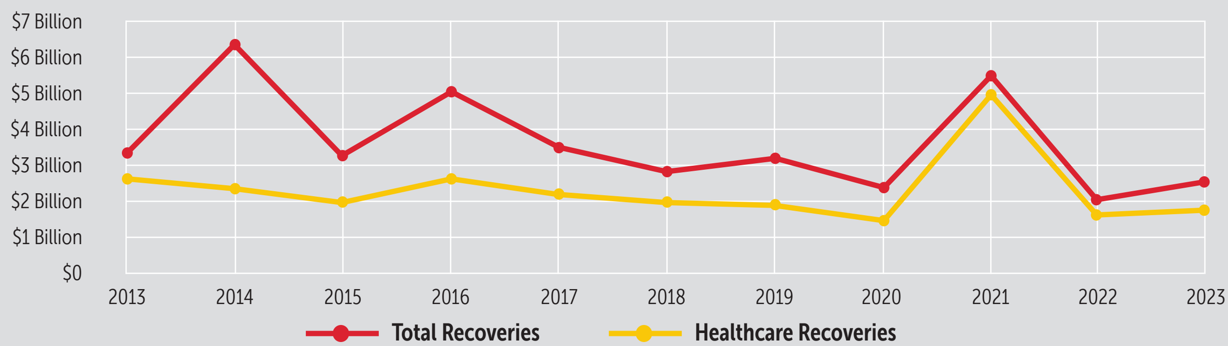
In fiscal year 2023, FCA recoveries topped $2.68 billion. The charts below and throughout the FCA Year in Review track notable trends in recoveries and other key metrics over the last decade.

Total FCA Recoveries 2013-2023

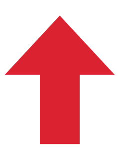


Recoveries rebounded in 2023 with an increase of nearly $500 million. Intervened cases accounted for over four times the amount of recoveries than non-intervened cases.

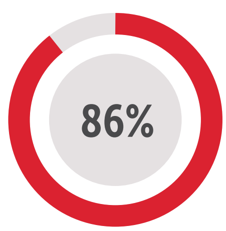
Healthcare Recoveries vs. Total Recoveries 2013-2023



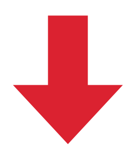
FCA recoveries from the healthcare industry make up the largest portion of FCA recoveries with no sign of changing over the past 10 years.



64%
Percentage increase in non-*qui tam* cases from 2022 to 2023



Percentage of recoveries in 2023 from relator-filed cases



-82%
Percentage decrease in relator share awards for declined matters from 2022 to 2023

KEY DECISIONS & DEVELOPMENTS

SCIENTER

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.*, 598 U.S. 739 (June 1, 2023)**

On June 1, 2023, the Supreme Court unanimously held that defendant's subjective belief of its compliance with the law at the time of submitting a claim is relevant to liability under the FCA. The case overturns the Seventh Circuit opinion that held that if a defendant's subjective belief as to compliance with the law was irrelevant it could express an objectively reasonable interpretation of the law that supported its claims.

This decision arose from separate Seventh Circuit cases: *U.S. ex rel. Schutte v. SuperValu Inc.*, 9 F.4th 455 (7th Cir. 2021), and *U.S. ex rel. Proctor v. Safeway, Inc.*, 30 F.4th 649 (7th Cir. 2022). Whistleblowers alleged that SuperValu and Safeway, supermarket chains, overcharged Medicare and Medicaid when the companies sought reimbursement for prescription drugs. Certain regulations require companies to disclose their "usual and customary" prices for drugs. Both SuperValu and Safeway sold most of their generic drugs at discounted prices, but charged the government significantly higher, non-discounted prices and reported those as their "usual and customary" prices.

Despite evidence that SuperValu and Safeway knew that the higher prices were not their "usual and customary" prices, the companies won summary judgment in the district court. The Seventh Circuit affirmed. It concluded that the defendants could not have acted "knowingly" under the FCA if their actions were consistent with an objectively reasonable interpretation of the underlying regulation, even if the defendants did not believe that interpretation at the time the claims were submitted. For SuperValu and Safeway, the Seventh Circuit held that the phrase "usual and customary" and the regulation were ambiguous, and that it was an objectively reasonable interpretation of the rules to apply them to their non-discounted prices.

The Supreme Court rejected the Seventh Circuit's view. The Court determined that "[t]he FCA's scienter element refers to respondents' knowledge and subjective beliefs — not to what an objectively reasonable person may have known or believed." There are three mental states that satisfy the knowledge requirement under the FCA: i) actual knowledge that a claim is false; ii) deliberate ignorance of the truth or falsity of a claim; and iii) reckless disregard of the truth or falsity of a claim. Thus, the focus is on "what the defendant thought when submitting the false claim — not what the defendant may have thought after submitting it." The Court held that to demonstrate that a defendant "knowingly" submitted a false claim for payment, a plaintiff can prove that a defendant knew or suspected the submission was false, even if an objectively reasonable person may not have known or believed it. Here, because the relators could demonstrate that SuperValu and Safeway knew that the discounted prices were not the "usual and customary" prices, both companies had the subjective belief that the claims submitted were false.

> "The Supreme Court determined that '[t]he FCA's scienter element refers to respondents' knowledge and subjective beliefs — not to what an objectively reasonable person may have known or believed.'"

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. Johnson v. AmeriHealth Ins. Co. of N.J., **No. 22-1542, 2023 WL 3221746 (3d Cir. May 3, 2023)**

In an FCA complaint premised on false certification with New Jersey health insurance law, the Third Circuit affirms dismissal for failure to allege falsity. Companies selling health insurance in states that have opted for a health insurance exchange operated by the federal government are not required to comply with state regulations.

Relator Eric Johnson brought a *qui tam* action against AmeriHealth Insurance Co. of New Jersey, a health insurance company, alleging that it defrauded the government by falsely certifying that its plans complied with New Jersey regulations.

Under the Affordable Care Act (ACA), companies that sell health insurance "must adhere to the requirement of this subpart and any provisions imposed by the Exchange, or a state in connection with its Exchange." New Jersey state law requires health insurance issuers to certify that copayments for rehabilitative services do not exceed half of the service's total cost. Johnson alleged that AmeriHealth was required, under federal regulations, to comply with that New Jersey regulation, and that AmeriHealth falsely claimed that it did so to receive government payments. The district court dismissed Johnson's suit, finding that the ACA did not require companies selling insurance to comply with state regulations if those states had opted to have the federal government operate their exchange.

The Third Circuit agreed. The court held that the ACA drew a sharp distinction between state and federal exchanges, reasoning that

it would not make sense to apply a patchwork of disparate state requirements to exchanges operated by the federal government. Likewise, AmeriHealth's certification stating that it complied with New Jersey law was not false because its attestation was limited to "applicable" state law — which did not include regulations beyond those enumerated in the ACA in this case.

U.S. ex rel. Heath v. Wisconsin Bell, Inc., **75 F.4th 778 (7th Cir. Aug. 2, 2023)**

The Seventh Circuit reversed summary judgment in favor of defendant Wisconsin Bell, Inc., finding that a reasonable jury could conclude that Wisconsin Bell overcharged schools and libraries for telecommunication services that were being subsidized by federal funding.

Relator Todd Heath brought this *qui tam* action against telecommunication services provider Wisconsin Bell, Inc., alleging that Wisconsin Bell overcharged schools for federally subsidized telecom services.

The allegations centered on the E-Rate Program, a federal program that required telecom providers to provide the lowest price for services based on the prices it charged similarly situated, non-residential customers. Heath alleged that Wisconsin Bell violated this requirement — known as the "lowest-corresponding price rule" — and charged schools and libraries more than allowed.

The district court granted summary judgment in favor of Wisconsin Bell, concluding that Heath failed to establish falsity or knowledge to support FCA liability. On appeal, the Seventh Circuit reversed.

As to falsity, Wisconsin Bell had argued that Heath failed to put forth summary judgment evidence to show that the customers who were charged a lower price were similarly situated to the eligible schools and libraries. The Seventh Circuit rejected that argument,

finding that Heath's expert report precluded summary judgment because it sufficiently provided the key factors necessary for a reasonable jury to conclude the customers were similarly situated.

As to knowledge, applying *SuperValu*, the Seventh Circuit found that Wisconsin Bell's conduct raised a genuine issue of material fact as to knowledge because of its subjective belief regarding the prices it was charging. In so ruling, the court pointed to undisputed evidence that (i) Wisconsin Bell did not always have a process in place to ensure compliance with the lowest-corresponding price rule even though it knew of the rule's requirements; (ii) Wisconsin Bell did not always have a system for identifying similarly situated customers to ensure it was providing the lowest price to eligible schools and libraries; and (iii) even when Wisconsin Bell had controls in place to effectuate compliance, there was evidence to show that Wisconsin Bell was still potentially overcharging.

U.S. ex rel. Quartararo v. Catholic Health Sys. of Long Island, Inc., **84 F.4th 126 (2d Cir. Oct. 16, 2023)**

In a case of first impression, the Second Circuit held that a New York health system did not violate the FCA by diverting Medicare reimbursements from its nursing home to another one of its facilities.

Catholic Health System of Long Island received Medicare reimbursements for services it provided to elderly residents at St. Catherine Siena Nursing Home. Instead of using those reimbursements to further benefit these nursing home residents, Catholic Health System instead sent the money to another one of its facilities: St. Catherine of Siena Medical Center. Relator Michael Quartararo alleged that this diversion constituted a violation of the Benefits Conversion Statute, which prohibits someone from knowingly converting the benefits of another for use by someone else. Quartararo further alleged that this amounted to a violation of the FCA because the Catholic Health System falsely certified that it complied with federal law in order to receive Medicare reimbursements.

The district court denied Catholic Health System's motion to dismiss, holding that Quartararo had articulated a viable argument for implied false certification.

The Second Circuit reversed this ruling, holding instead that Catholic Health System did not violate the Benefits Conversion Statute. Medicare payments reimburse *past* services already rendered, without any requirement that the funds be used to confer a *future* benefit on a specific person. As such, the Medicare reimbursements "ended the life cycle of the claim," and Catholic Health System was free to spend that money as it wished. The Second Circuit remanded the case for dismissal.

Fed. Deposit Ins. Corp. ex rel. Moncho v. Fifth Third Bank N.A., **No. 23-209, 2023 WL 7130553 (2d Cir. Oct. 30, 2023)**

The Second Circuit affirmed dismissal of *qui tam* complaint that accused Fifth Third Bank of failing to minimize the Federal Deposit Insurance Corp.'s (FDIC) losses under a shared-loss agreement because relator did not allege the defendant had any contractual obligation to do so.

MB Financial Bank N.A. purchased a portfolio of loans in 2010 from the FDIC, which was then acting as the receiver for Broadway Bank. Pursuant to this transaction, the FDIC and MB Financial entered into a shared-loss agreement in which the FDIC agreed to assume 80% of all future losses that MB Financial incurred on these loans. Four years later, relator Lee Moncho sued Fifth Third Bank N.A. — which had acquired MB Financial — alleging that MB Financial violated the FCA by (1) failing to minimize the FDIC's losses under the shared-loss agreement; and (2) submitting claims to the FDIC for loans that were ineligible for reimbursement under the agreement.

The district court granted Fifth Third's motion to dismiss all claims, holding that the FCA's public disclosure bar precluded Moncho's claims and that Moncho did not qualify as an original source.

In a nonprecedential summary order, the Second Circuit reached the same result but on different grounds, holding that Moncho failed to plausibly allege falsity, scienter, and materiality. For example, Moncho did not plausibly allege that the bank made any specific representations to the FDIC about the services it provided, nor that the bank omitted any critical information from its claims. Moreover, Moncho did not allege a plausible motive for the scheme, and there was no provision in the shared-loss agreement that conditioned payment by the FDIC on the bank's alleged obligation to minimize losses.

MATERIALITY

***U.S. ex rel. Gharibian v. Valley Campus Pharmacy, Inc.,* No. 21-56253 2023 WL 195514 (9th Cir. Jan. 17, 2023)**

To adequately allege materiality, a complaint must claim that insurers would have refused to pay had they been aware of the misrepresented information.

The relator alleged that the pharmacies violated the False Claims Act by instructing their employees to misrepresent who their employers were and to falsify patient records to procure prior authorizations for prescription medications. The district court dismissed relator's complaint for failure to state a claim, finding that relator failed to adequately plead materiality and failed to allege with specificity that the claims involved federal payors. Relator appealed.

The Ninth Circuit affirmed on both grounds. The majority of the allegations were dismissed for failing to satisfactorily plead that the claims were made to a government payor. The court conducted a materiality analysis for the remaining two allegations pertaining to the pharmacies' instruction to their employees to misrepresent their identities to insurers when seeking prior authorizations. The court found that, to plead materiality in this context, the relator must have alleged that insurers would have refused to pay for prescription medicines had they known the request for prior authorization was coming from a pharmacy rather than a physician's office. Because relator failed to allege this influence and because certain Medicare regulations contemplate individuals other than physicians obtaining prior authorizations, the court found relator failed to adequately plead materiality and affirmed the district court's dismissal.

***United States v. Walgreen Co.,* 22-1491 & 22-1492 (4th Cir. Aug. 15, 2023)**

In contesting materiality, it is not a defense that a state was only influenced by a misrepresentation because it applied a federally impermissible standard.

The United States and Virginia lodged claims against Walgreens for violations of the False Claims Act and various state claims pertaining to Walgreens' alleged misrepresentations that certain patients met Virginia Medicaid-eligibility requirements for drugs requiring prior authorization. The district court found that the misrepresentations were immaterial because Virginia had enacted eligibility requirements that violated the Medicare Act, such that the alleged misrepresentations impacted reimbursement only under the impermissibly restricted coverage in Virginia but would not have impacted reimbursement under the proper standard. The government appealed.

The Fourth Circuit reversed and remanded, finding that Walgreens' alleged misrepresentations materially affected the decision to reimburse for certain drugs. In its analysis, the court determined that regardless of the legality of Virginia's eligibility requirements, Walgreens' misrepresentations influenced the decision to reimburse for the drugs, thus meeting the materiality requirement. The court did not address the legality of Virginia's eligibility requirements, finding that Walgreens could not collaterally challenge the requirements' legality when Walgreens allegedly attempted to avoid the issue through fraudulent behavior.

***U.S. ex rel. Druding v. Care Alternatives,* 81 F. 4th 361 (3d Cir. Aug. 25, 2023)**

In a second appeal to the Third Circuit following a 2020 remand, the Third Circuit again reversed the lower court, this time finding that its materiality analysis overlooked several factors that weighed in favor of materiality.

Former employees brought an FCA action against Care Alternatives, a for-profit hospice provider, alleging that it submitted false claims for Medicare reimbursement for ineligible patients. The relators' medical expert reviewed 47 patient records and found that hospice records did not support a terminal prognosis, and thus did not support hospice eligibility, 35% of the time.

Relying on *United States v. AseraCare, Inc.,* 938 F.3d 1278 (11th Cir. 2019), the district court granted summary judgment for Care Alternatives. As in *AseraCare*, the district court found that a mere difference in medical opinion between the relators' expert and the defendant's physicians without more was not sufficient to show that the claims submitted to Medicare were false. Relators appealed. In a 2020 opinion, the Third Circuit reversed, holding

Commentary

BIPARTISAN CONGRESSIONAL BILL SEEKS TO WEAKEN THE FALSE CLAIMS ACT'S MATERIALITY STANDARD

On July 25, 2023, U.S. Sen. Chuck Grassley (R-IA) introduced a bill (S. 2466) that aims to, among other things, make it easier for the government to satisfy the False Claims Act's materiality requirement when the government has made payment on a claim the government knows to be false or fraudulent. The bill, titled the "False Claims Amendments Act of 2023," has bipartisan support in the Senate and is co-sponsored by Sens. Dick Durbin (D-IL), John Kennedy (R-LA), and Roger Wicker (R-MS). On Nov. 3, 2023, Reps. Jodey Arrington (R-TX) and Jimmy Panetta (D-CA) introduced an identically worded bill (H.R. 6214) in the House of Representatives. Each of these bills is currently pending before its chamber's respective Judiciary Committee.

The proposed amendments seek to make three changes to the False Claims Act. *First*, the bill states that "[i]n determining materiality, the decision of the Government to forego a refund or to pay a claim despite actual 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." *Second*, the amendments would extend the act's anti-retaliation protections to former employees. *Third*, the amendments would require the U.S. Government Accountability Office to report on the effectiveness of the FCA, measured in part by the funds the government recovers under the act.

The most significant of these proposed amendments to the act is the first, which amounts to a congressional attempt to modify the U.S. Supreme Court's 2016 ruling in *Universal Health Services, Inc. v. U.S. ex rel. Escobar,* 579 U.S. 176 (2016), by softening the FCA's materiality requirement. The FCA imposes liability only for a defendant's violation of a material statutory, regulatory, or contractual requirement. *Escobar* held that "[t]he materiality standard is demanding," as the False Claims Act is "not an all-purpose antifraud statute . . . or a vehicle for punishing garden-variety breaches of contract or regulatory violations" (579 U.S. at 194 (internal quotation marks omitted)). *Escobar* further held that it is "very strong evidence" that particular statutory, regulatory, or contractual requirements are not material "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated" (*Id.* at 195). By mandating that the government's continued payment, despite its actual knowledge of fraud or falsity, shall not be dispositive of the materiality inquiry if other reasons exist for the decision, the proposed amendment would soften without directly contradicting the materiality standard set forth in *Escobar*. It would also make the materiality inquiry more fact-intensive, which may impact defendants' ability to win motions to dismiss based on materiality grounds.

Defense counsel should track this bill's progress given its aim to weaken the *Escobar* materiality standard and thus strengthen the litigating position of *qui tam* plaintiffs and the government in pursuing False Claims Act liability against entities that do business with the government.

that a difference in medical opinion could raise questions of "legal falsity" and remanded the case back to the district court.

On remand, defendant again moved for summary judgment, arguing that the missing documentation was not "material" under the FCA. The district court agreed again and granted the motion. It ruled that there was no evidence demonstrating that documentation deficiencies were material to the government's decision to grant reimbursement, particularly noting that the government knew the defendant's records were missing information yet decided to pay the claims anyway. Relators appealed again.

On the second appeal, the Third Circuit again vacated the grant of summary judgment and remanded. The court found that the district court erred by giving dispositive weight to Medicare's decision to pay the claims while overlooking other factors that could have shown materiality. The court considered three factors from Escobar to determine materiality: (1) whether the requirement is expressly identified as a condition of payment, (2) whether the noncompliance is minor or insubstantial or instead goes to the "very essence of the bargain," and (3) the government's action. For the first factor, it found that the requirement of clinical documentation that supports the medical prognosis is a condition of payment, which is relevant but not dispositive of materiality. For the second factor, it found that the requirement of supporting documentation is an essential form of oversight and that the defendant's alleged deficiencies were pervasive, supporting materiality. For the third factor, the Third Circuit found that the government's "inaction over the past fifteen years is evidence of immateriality" but declined to find that the government had actual knowledge of the violations, noting that knowledge of allegations of fraud are not the same as actual knowledge of fraud. Examining the three factors, the Third Circuit reversed summary judgment so that the issue of materiality could be determined by a jury.

***U.S. ex rel. Kenneth Kraemer, et al. v. United Dairies, LLP, et al.,* 82 F.4th 595 (8th Cir. Sep. 20, 2023)**

In an FCA case based on alleged false statements in crop insurance applications, the Eighth Circuit affirms dismissal for lack of materiality and other necessary elements.

Relators Kenneth Kraemer and Kraemer Farms, LLC (collectively "Kraemer") filed a *qui tam* suit against a group of dairy farmers, alleging that they filed false insurance claims. According to Kraemer, the claims were paid by the Federal Crop Insurance Corporation (FCIC) for corn the farmers certified as grain when, in fact, it was silage to feed their cattle. The government declined to intervene, but Kraemer proceeded with the litigation. After a bench trial, the district court found that there was no FCA liability but granted relief on a common-law unjust enrichment claim. That relief was later vacated, on the government's motion, because Kraemer did not have standing to seek common-law relief on behalf of the United States. Kraemer appealed.

On appeal, the Eighth Circuit affirmed, finding that Kraemer failed to establish a false claim, materiality, and knowledge. The Eighth Circuit found that the mere submission of an insurance application was not a false claim because there was no demand for payment yet.

The court also found that Kramer failed to establish materiality because the FCIC and others responsible for administering the program audit of the dairy farmers' crops knew of the alleged noncompliance and paid the insurance claims anyway.

Lastly, the Eighth Circuit held that the underlying policy related to the insurability of the corn was ambiguous and the dairy farmers' interpretation of that ambiguous policy was objectively reasonable. In doing so, it distinguished the Supreme Court's recent holding in *SuperValu*, noting that, unlike in *SuperValu*, there was no evidence that the defendants had a culpable statement of mind when the alleged false claim was made.

CAUSATION

***U.S. ex rel. Calderon v. Carrington Mortg. Servs., LLC*, 70 F.4th 968 (7th Cir. Jun. 14, 2023)**

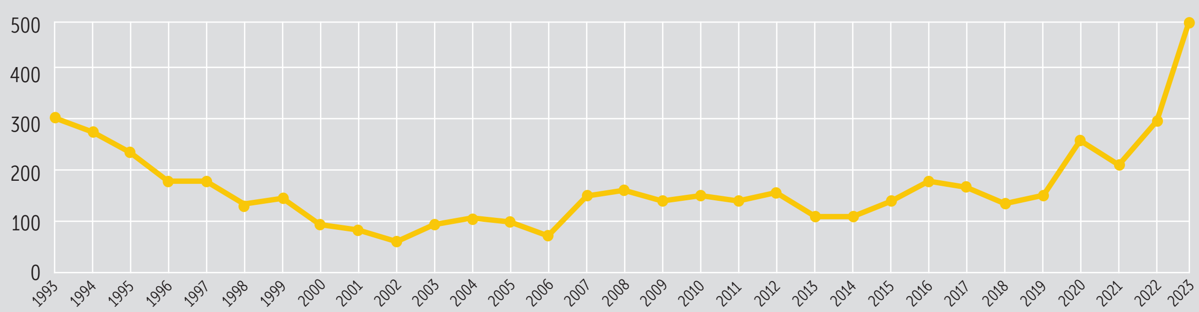
Affirming the district court's grant of summary judgment, the Seventh Circuit holds that relator failed to show that mortgage company's false statements to FHA about certain federally insured loans were the proximate cause of those loans' eventual default.

Relator Michelle Calderon filed an FCA action against Carrington Mortgage Services, her former employer. She alleged that Carrington made false representations to the U.S. Department of Housing and Urban Development (HUD) when certifying residential mortgage loans for insurance coverage from the Federal Housing Administration (FHA). Carrington moved for summary judgment, arguing that Calderon failed to meet her evidentiary burden as to materiality and causation. The district court granted Carrington's motion on both points, and Calderon appealed.

On appeal, the Seventh Circuit affirmed. In doing so, however, the court disagreed with the district court on materiality. Specifically, the court held that Calderon proffered enough evidence of material false certifications to survive summary judgment. The Seventh Circuit further held that HUD's knowledge of the alleged false certification — a fact that could undermine materiality — was sufficiently contested that it did not defeat materiality at this stage.

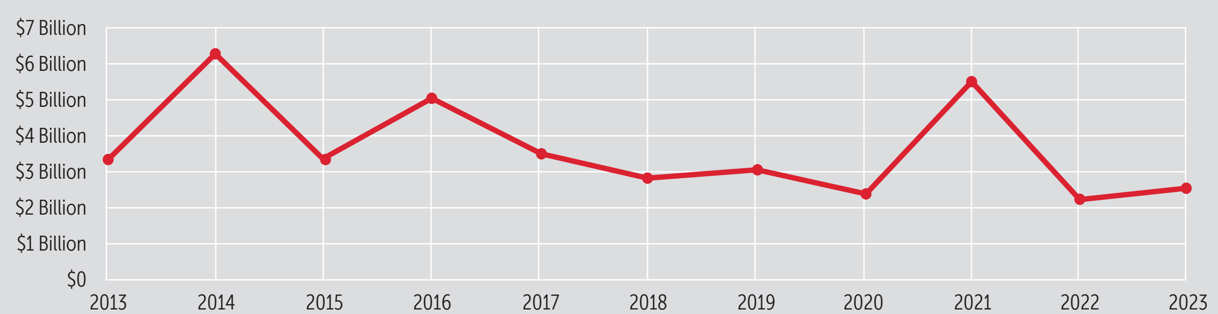
Nonetheless, the Seventh Circuit concluded that Calderon failed to meet her burden on causation. The court reiterated that to plead a successful FCA claim, a plaintiff must establish both actual and proximate cause. The parties offered competing opinions on how a plaintiff could meet that burden in the federal mortgage context: Calderon argued for extrapolation causation from a generalized statistical analysis of Carrington's federal insured loans. By contrast, Carrington argued for a loan-by-loan analysis showing how each allegedly false statement caused each loan's default. In the end, the Seventh Circuit held that Calderon failed to meet either burden. It also rejected the D.C. Circuit's approach that misrepresentations foreseeably increase the risk of default by their very nature.

Non-*Qui Tam* Actions Filed 1993-2023



Driven by a large increase in non-healthcare and non-DOD cases, the government independently brought more actions in 2023 than in any year included in the reported statistics going back to 1987.

Total FCA Recoveries 2013-2023



The amount of recoveries was up 20% in 2023, but the number of recoveries was up 54%, representing more but smaller recoveries driven by pandemic relief fraud enforcement.

Commentary

CAUSATION SHOWDOWN: COURTS DEEPEN DIVIDE OVER APPROPRIATE CAUSATION STANDARD IN KICKBACK FCA CASES

The circuit split continued to widen last year over what causation standard applies in FCA cases that are based on Anti-Kickback Statute (AKS) violations, with the Sixth Circuit joining a growing chorus of courts that have adopted a more stringent but-for causation standard.

At issue is language added to the AKS in 2010 that states "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 are split as to what level of causation the phrase "resulting from" requires.

Circuit Split Deepens

In *U.S. ex rel. Martin v. Hathaway,* 63 F.4th 1043 (6th Cir. Mar. 28, 2023), the Sixth Circuit recently joined the Eighth Circuit in adopting but-for causation, i.e., requiring a showing that the defendant would not have submitted the claim to a federal healthcare program but for the payment of the alleged kickback. The Third Circuit currently stands as the only circuit court to have adopted the more lenient standard, which merely requires a "link" between the claim and the alleged kickback. The First Circuit is expected to rule on this issue in 2024 after two district courts in its jurisdiction reached opposite conclusions.

> "This causation standard would require relators to prove that the 'referrals would not have been made without remuneration, and that claims would not have been submitted to the government without those referrals.'"

In *Hathaway*, relators' allegations arose out of a dispute between two ophthalmologists who practiced together in a small, one-hospital town. Dr. Darren Hathaway owned the only ophthalmology group in the area, and the hospital and ophthalmology group would regularly send each other patient referrals. One relator, Dr. Shannon Martin, was an ophthalmologist employed by Hathaway's ophthalmology group who received a tentative offer from the hospital to serve as its internal ophthalmologist. The hospital ultimately decided not to hire her.

Martin and her husband filed a *qui tam* suit alleging that the hospital rescinded the offer in exchange for Hathaway's commitment to keep sending the hospital referrals. The court took a similar approach as the Eighth Circuit in *U.S. ex rel. Cairns v. D.S. Med. LLC,* 42 F.4th 828 (8th Cir. July 26, 2022). It focused on the phrase "resulting from" in the 2010 amendments and the Supreme Court's interpretation of that phrase in *Burrage v. United States,* 571 U.S. 204 (2014), where the Supreme Court analyzed analogous language in the Controlled Substances Act, finding that it required "but-for" causation. The Sixth Circuit concluded that the "resulting from" language in the AKS creates a similar "but-for causation" requirement. This causation standard would require relators to prove that the "referrals would not have been made without remuneration, and that claims would not have been submitted to the government without those referrals." Under the court's standard, relators' allegations failed.

District Courts Split

In *United States v. Regeneron Pharma., Inc.,* No. 20-11217-FDS, 2023 WL 6296393 (D. Mass. Sept. 27, 2023), the District of Massachusetts followed the Eighth and Sixth circuits in adopting a but-for causation standard in FCA cases predicated on the AKS.

In *Regeneron*, the government alleged that the defendant biotechnology company violated the AKS by improperly funneling millions of dollars into a charitable foundation to subsidize patient copays for its drug Eylea. With the help of its expert, the government claimed that it had "linked" more than a hundred thousand claims for the drug submitted to Medicare during the relevant time period. The government urged the court to adopt the "exposure test" and conclude that the defendant's alleged violations of the AKS rendered the claims false.

The district court rejected this argument, ruling that mere "exposure" to a kickback is insufficient to establish causation – that is, once the government has proven that an AKS violation occurred, all that is required for causation is that "a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient." The court took the approach of the Sixth and Eighth circuits in holding that the "resulting from" language in the AKS requires a but-for causation standard.

In *United States v. Teva Pharms. USA, Inc.,* No. 20-11548-NMG, 2023 WL 4565105 (D. Mass. July 14, 2023) a different judge in the District of Massachusetts ruled the opposite way and adopted the Third Circuit's more lenient standard.

In *Teva Pharms.,* the government accused Teva Pharmaceuticals of using illegal kickbacks to boost its drug sales, thereby causing Medicare to pay $1.49 billion in tainted claims. Specifically, the government alleges that Teva paid two charitable foundations illegal copay subsidies in connection with the sale of Copaxone, a multiple sclerosis drug. Teva estimates its potential exposure in this case may exceed $10 billion — "an enterprise-threatening amount."

U.S. District Judge Nathaniel Gorton sided with the Third Circuit, holding that the government need not prove a "but-for" causal connection between an AKS violation and an allegedly false claim. But, recognizing the "substantial ground for difference of opinion" on this issue, Judge Gorton took the unusual step of certifying his ruling for interlocutory appeal to the First Circuit.

In *U.S. ex rel. Louderback v. Sunovion Pharmaceuticals, Inc.,* No. 17-cv-1719, 2023 WL 8188879 (D. Minn. Nov. 27, 2023), the District of Minnesota joined the debate, following the Sixth and Eighth circuits in requiring but-for causation.

Relator Scott Louderback accused drug manufacturer Sunovion Pharmaceuticals of violating the AKS and the FCA through its rebates-for-prescriptions programs. Specifically, Louderback alleged that Sunovion paid rebates to pharmacies in exchange for the pharmacies prescribing the COPD drug Brovana to Medicare patients.

In dismissing Louderback's claims, the court explicitly adopted the but-for causation standard, citing the Eighth Circuit's decision in *Cairns*, the Sixth Circuit's decision in *Hathaway*, and the Massachusetts district court's decision in *Regeneron*. Louderback was required to show that the pharmacies would not have prescribed Brovana but for the rebates. The court held that his conclusory allegations fell far short of this requirement.

No Supreme Court Intervention, For Now

The U.S. Supreme Court declined to weigh in on the growing circuit divide last year, denying a petition for certiorari that challenged the Sixth Circuit's adoption of the but-for causation standard. But the Supreme Court may not remain on the sidelines for long, considering the First Circuit's expected opinion on the issue and the strong likelihood that other circuit courts will enter the debate soon. As this issue continues to play out, defendants should continue advocating for the more stringent but-for causation standard, which would provide a crucial check on the increasing use of the AKS as a predicate for FCA liability.

STANDARD FOR DISMISSAL BY GOVERNMENT

In January 2018, Michael Granston, the director of the Commercial Litigation Branch, Fraud Section, issued a memo providing DOJ lawyers guidance on the factors to consider in evaluating possible dismissal of an FCA case under 31 U.S.C. § 3730(c)(2)(A). Before the Granston Memo, most circuit courts were undecided on the standard to apply to government requests for dismissal. The U.S. Court of Appeals for the Ninth and D.C. circuits issued the leading cases addressing the government's authority under this section of the FCA. In *Sequoia Orange*, the Ninth Circuit required the government to demonstrate a valid purpose for the request and a rational relationship between dismissal and that purpose. By contrast, in *Swift*, the D.C. Circuit took a more deferential view and held that the government has an "unfettered right to dismiss" an FCA case.

After 2018's Granston Memo, courts faced an increasing number of requests by DOJ to dismiss FCA cases. The uptick in government-initiated motions to dismiss has forced courts to explore the nuances of § 3730(c)(2)(A) and define the parameters of the government's power. This year, the divide between the *Sequoia Orange* and *Swift* standards reached the Supreme Court, which decided that neither standard was correct.

***U.S. ex rel. Polansky v. Executive Health Resources,* 599 U.S. 419 (June 16, 2023)**

The Supreme Court holds that the government may intervene and move to dismiss an FCA suit at any time during the life of the case, and that such motions should be evaluated under the Federal Rule of Civil Procedure 41(a) voluntary dismissal standard.

Dr. Jesse Polansky filed suit against his former employer, alleging the company overbilled Medicare for various medical services. The government declined to intervene in the case. Five years of discovery imposed a substantial burden on the government, prompting it to intervene and dismiss Polansky's suit. The district court granted the government's motion to dismiss, and the Third Circuit affirmed, holding that the government was required to intervene before seeking dismissal and, once it had, the standard for evaluating a voluntary motion to dismiss was FRCP 41.

In taking up the case, the Supreme Court addressed two issues: first, must the government intervene before seeking to dismiss a suit, and second, what standard applies to the government's attempt to dismiss. In an 8-1 decision, the Supreme Court affirmed the Third Circuit and confirmed that the government may intervene and move to dismiss a *qui tam* suit *at any point* in the case's life. It further held that the default standard for evaluating voluntary motions to dismiss was FRCP 41.

However, the Court rejected the government's position that it has complete discretion to dismiss an action. Rather, relators can challenge the government's decision to dismiss their cases but "[i]f the Government offers a reasonable argument for why the burdens of continued litigation outweigh its benefits, the court should grant the motion." The government is afforded "substantial deference," and so long as the government demonstrates why the suit would not further the government's interest, the motion will be granted "in all but the most exceptional cases."

***U.S. ex rel. Carver v. Physicians Pain Specialists of Alabama, P.C.,* 22-13608BU, 2023 WL 4853328 (11th Cir. July 31, 2023)**

The Eleventh Circuit was the first court of appeals to apply the Supreme Court's holding in *Polansky* and uphold the DOJ's dismissal of a *qui tam* suit over the relator's objections.

Relator Lori Carver, a former employee of a pain management clinic, allegedly discovered that the two physician owners of the clinic had submitted false claims to federal healthcare programs in violation of the FCA. In 2013, she filed a *qui tam* suit against the clinic, the two physicians who owned the clinic, their pharmacy, and a company they contracted with to perform urine drug screening services. The government declined to intervene but brought criminal charges against the physicians, which partially overlapped with Carver's *qui tam* complaint. The government obtained a jury verdict against the doctors, resulting in criminal forfeiture proceedings. The physicians, their clinic, and the pharmacy defaulted in the civil *qui tam* case, and Carver simply needed to obtain a default judgment against them.

Rather than pursue a default judgment in her case, Carver spent the next several years attempting to obtain a portion of the funds recovered from the criminal forfeiture proceeding. Nearly nine

> "The government is afforded 'substantial deference,' and so long as the government demonstrates why the suit would not further the government's interest, its motion to dismiss will be granted 'in all but the most exceptional cases.'"

years after she filed her original complaint, the United States moved to intervene and dismiss her case. The government argued that Carver "failed to prosecute this action to an enforceable judgment, neglected her responsibilities as a relator, burdened the United States with discovery requests that are either irrelevant or premature, and undercut the United States' FCA enforcement efforts in this district." The district court granted the government's motion.

The Eleventh Circuit affirmed on appeal. The court focused its analysis on Polansky and found that the government "gave good grounds for thinking that this suit would not do what all *qui tam* actions are supposed to do: vindicate the [g]overnment's interests." Despite Carver expending considerable resources pursuing her case, the court noted that "the record amply support[ed] the government's charge that Carver failed to meaningfully prosecute the *qui tam* action and obtain a judgment in favor of the government." Ultimately, the court determined that the government "did more than enough to establish reasonable grounds for its view that the burdens of the continued litigation outweigh its benefits."

***Brutus Trading v. Standard Chartered Bank,* 20-2578, 2023 WL 5344973 (2d Cir. Aug. 21, 2023)**

The hearing requirement for a government dismissal under Section 3730(c)(2)(A) may be satisfied with written submissions from the parties.

The Second Circuit recently addressed whether the hearing requirement of Section 3730(c)(2)(A) could be satisfied by written submissions alone. The relator, whistleblower Brutus Trading LLC, brought an FCA suit alleging that Standard Chartered Bank illegally facilitated transactions on behalf of individuals and entities subject to U.S. sanctions due to their ties to Iran. Brutus further alleged that Standard concealed the true extent of its activities (and its illegal conduct) from the government when Standard entered into a deferred prosecution agreement with the government in 2012, thereby defrauding the government.

The government intervened and requested dismissal, arguing that Brutus' claims lacked sufficient evidence, that Brutus' legal theory was invalid, and that pursuing the case would waste government resources. The district court ruled on the respective parties' briefs without holding a hearing and dismissed Brutus' lawsuit. Brutus appealed the district court's decision, arguing that dismissing the case without a hearing violated statutory requirements and Brutus' due process rights.

However, the Second Circuit ultimately sided with the government, agreeing that Brutus' dearth of supporting evidence, as well as its case's legal weaknesses, justified the district court's dismissal. Referencing the Supreme Court's *Polansky* opinion, the court found that "the district court afforded Brutus the opportunity to be heard via its written submissions." The circuit court acknowledged that although *Polansky* "did not mandate universal requirements for [the FCA] hearing in every case," it did "confirm[] that, in order to comply with the FCA's 'hearing' requirement, a district court must exercise some degree of scrutiny in evaluating the government's motion to dismiss." Rejecting Brutus' argument that the district court "held no hearing of any kind," the Second Circuit held that the district court satisfied the hearing requirement by "carefully considering" "the parties' voluminous briefs, declarations, and exhibits before granting the government's motion."

Commentary

THE *POLANSKY* DISSENT: ARE THE *QUI TAM* PROVISIONS UNCONSTITUTIONAL?

For years, defendants have challenged the power that the False Claims Act (FCA) gives relators to prosecute cases on behalf of the United States. These arguments, based on the Appointments Clause of Article II of the Constitution, historically have failed, but Justice Clarence Thomas' dissent in *U.S. ex rel. Polansky v. Exec. Health Res.,* Inc., 599 U.S. 419 (2023), has created renewed interest and hope by the defense bar.

In *Polansky*, the Supreme Court majority focused on the government's ability to dismiss FCA lawsuits after the government has initially declined to intervene in a suit. In dissent, however, Justice Thomas opined that "there is 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, while concurring with the majority's focus, held that "competing arguments on the Article II issue" should be considered "in an appropriate case" (*Id.* at 442). Two district courts have addressed *Polansky*-based arguments since Justice Thomas issued his dissent on June 16, 2023.

On Aug. 30, 2023, the Central District of California was one of the first district courts to address constitutional challenges to the FCA post-*Polansky* (*U.S. ex rel. Miller v. ManPow, LLC,* No. 2:21-cv-05418-VAP-ADSx, 2023 WL 8290402, at *1 (C.D. Cal. Aug. 30, 2023)). In denying the defendant's motion for judgment on the pleadings, the court based its opinion on Ninth Circuit precedent concluding that the FCA did not run afoul of separation of powers concerns, or the Take Care Clause that directs the president specifically to "take care that the laws be faithfully executed." The Ninth Circuit cases cited by the court held that the FCA included mechanisms to afford the government supervision and control over relators sufficient to mitigate constitutional concerns (*Id.* at *2-3). Although the *ManPow* court cited *Polansky*, it did so only to emphasize that the government has broad power to control FCA litigation.

The defendant also raised Appointments Clause arguments, maintaining that a private party cannot exercise governmental powers exclusively reserved for United States officers. Again, the court rejected the defendant's position based on precedent, concluding that the defendant "has not provided any persuasive reason why this Court should deviate from [the Ninth Circuit's] binding conclusion" regarding the constitutionality of the FCA. According to the Ninth Circuit, because the authority provided to relators by the FCA is so limited, the function need not be performed by an officer of the United States (*Id.* at *4). Again, the *ManPow* court made no reference to Justice Thomas' dissent in its opinion.

The Northern District of Alabama also showed its hesitance to embrace arguments based on the Polansky dissent. On Nov. 20, 2023, in *U.S. ex rel. Wallace v. Exactech, Inc.,* No. 7:18-CV-01010-LSC, 2023 WL 8027309, at *1 (N.D. Ala. Nov. 20, 2023), a defendant facing a *qui tam* based on Medicare billing allegations argued that because the role of relators under the FCA is unconstitutional under the Appointments Clause, relators lacked standing, thereby depriving the court of subject matter jurisdiction (*Id.* at *3). In rejecting the argument, the Northern District of Alabama held, similarly to the Central District of California, that relators are not officers of the United States, because relators possess only temporary authority (*Id.* at *4). As a result, relators need not be appointed, and the FCA's empowerment of relators does not violate the Appointments Clause.

The Northern District of Alabama also rejected the defendant's request for dismissal based on the Take Care Clause, holding that, although relators bring actions in the name of the United States, "they wield only the limited powers of a civil litigant," whereas the Take Care Clause cases cited by the defendants related to criminal prosecution powers (*Id.* at *5). Additionally, even if the civil FCA implicated the Take Care Clause, the government maintains a degree of oversight and retains the power to control an FCA litigation, which satisfies constitutional requirements, regardless of whether the government exercises that power. The Northern District of Alabama acknowledged Justice Thomas' position that "enactment by the First Congress [is not] a guarantee of a statute's constitutionality," but nonetheless concluded that historical evidence of private prosecutions was sufficient to put challenges to the FCA's constitutionality to rest.

As demonstrated above, district courts are hesitant to disturb precedent and take action based on the *Polansky* dissent or concurrence. But with three justices interested in the issue, defendants in appropriate cases will likely continue raising arguments about the FCA's constitutionality, even if only to preserve them on appeal.

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.

***Jane Doe v. eviCore Healthcare MSI, et al.,* No. 22-530-cv, 2023 WL 2249577 (2d Cir. Feb. 28, 2023)**

The Second Circuit affirms dismissal of FCA claims because allegations of auto-approved medical procedures without individualized medical necessity determinations were not false without particular allegations that approved medical procedures were medically unnecessary.

The anonymous relators were former employees who alleged that (1) eviCore's system would direct clinical reviewers to auto-approve all requests from certain providers, therapies, and populations, bypassing any clinical judgment and (2) eviCore's artificial intelligence system approved treatments based on flawed criteria without any subsequent manual review. These systems caused insurance companies that contracted with eviCore to unnecessarily bill Medicare and Medicaid for worthless services or at least provide services without medical necessity review.

While the district court dismissed the claims for both lack of falsity and lack of particularity, the Second Circuit affirmed the dismissal for lack of particularity. The Second Circuit reiterated that relators failed to allege that any of the auto-approved medical procedures were fraudulent. The court rejected relators' speculation that the sheer volume of approved procedures essentially guaranteed that fraudulent claims were approved. Nor was the court convinced by internal eviCore documents showing eviCore approved entire categories of requests. Relators again failed to allege that any of these requests were medically unnecessary.

The court also noted that relators' reliance on eviCore's contracts with insurance companies was similarly lacking in specifics. Relators did not identify any specific provision that eviCore breached but generally plead that eviCore was expected to only approve medically necessary treatments. Even assuming eviCore breached its contracts, the court noted that breaching a contract alone does not amount to fraud.

***U.S. ex rel. 84Partners, LLC v. Nuflo, Inc.,* 79 F.4th 1353 (11th Cir. Aug. 17, 2023)**

Standing alone, a fraudulent scheme, no matter how egregious, is not enough; relators must plead an actual false claim.

This False Claims Act action arose from the delivery of defective pipe fittings for installation in nuclear attack submarines. For over 20 years, the Navy contracted with defendant General Dynamics Electric Boat Corporation (known as "EB") for the construction, testing, and delivery of Virginia-class nuclear attack submarines. EB in turn entered into a subcontract with the defendant-appellee Huntington Ingalls Industries, Newport News Shipbuilding Division (NNS). EB and NNS had a "teaming arrangement" under which they built submarines for final delivery to the Navy. According to the complaint, EB and NNS procured parts known as pipe fittings from Nuflo, Inc., either directly or through a distributor, Synergy Flow Systems, LLC.

According to the second amended complaint, roughly 4,000 of the 225,000 parts supplied by Nuflo were defective. Some had improper materials or welds. Others had not been properly inspected, tested, or traced through the process. While EB or NNS discovered and rejected some defective parts, at least 42 allegedly made it onto Navy submarines. The complaint did not identify any claim for payment from the Navy that included any of those 42 defective parts. Instead, it alleged broadly that the Navy made payments covering all allowable costs.

The district court dismissed the first and second amended complaints for failure to state a claim. The Eleventh Circuit affirmed the dismissal because despite years of investigation with cooperation from the Navy, the relator was unable to identify any single claim for a defective part that was presented to or paid by the government. The court stated that "standing alone, a fraudulent scheme, no matter how egregious, is not enough; there must be an actual false claim." Further, relator did not allege what happened between the parts leaving Nuflo and the eventual installation of a small subset of them into submarines, including whether it was EB or NNS that failed to discover the alleged defects. Without a particularized allegation of the presentment or payment of a false claim, the second amended complaint was dismissed with prejudice.

U.S. ex rel. Miniex v. Houston Housing Authority, **No. 21-20435, 2023 WL 6174416 (5th Cir. Sep. 22, 2023)**

The Fifth Circuit affirms dismissal of most defendants under Rules 12(b)(6) and 9(b) for failure to sufficiently allege necessary facts but reversed as to one defendant finding the pleading sufficient.

Relator Karen Miniex sued the Houston Housing Authority (HHA), the City of Houston, and five property management companies under the FCA for failing to follow federal regulations in submissions to the U.S. Department of Housing and Urban Development. Her allegations were primarily against HHA, and she claimed HHA acted as an agent of the city and that the property management companies carried out the fraudulent conduct on HHA's behalf after being contracted to handle HHA's property procurement.

The district court dismissed the entire case on the pleadings under Fed. R. Civ. P. 12(b)(6) and 9(b), finding that Miniex failed to sufficiently allege her claims for relief. The district court also dismissed HHA under the "government action bar" of 31 U.S.C. § 3730(e)(3), which prohibits a suit against the government when the government is already a party to a lawsuit or an administrative civil money penalty proceeding based on the same facts or allegations. The ongoing proceeding underlying this finding was a HUD OIG audit.

The Fifth Circuit reversed and remanded as to HHA and affirmed as to all the other defendants. As to HHA, the court found that Miniex sufficiently pleaded facts pertaining to all four elements of an FCA claim and that she pleaded her fraud allegations with sufficient particularity. The court also found that a HUD OIG audit does not invoke the government action bar. Thus, Miniex was allowed to proceed against HHA.

As to the city, the court found that Miniex failed to allege sufficient facts to show that HHA acted with actual or apparent authority of the City of Houston or that the city was vicariously liable for HHA's actions. She failed to allege facts that anyone acted on a belief that HHA was acting as an agent for the city.

As to the property management defendants, the court found that Miniex failed to allege facts raising a reasonable inference that these defendants acted with scienter – that is, that they knew they were violating the law or were recklessly indifferent to that fact. The complaint's allegations of wrongful conduct are insufficient without alleging knowledge. Moreover, as to three of the property management defendants, Miniex failed to allege the "who, what, when, where, and how" of the alleged fraudulent conduct as required by Rule 9(b).

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.

***U.S. ex rel. Piacentile v. U.S. Oncology, Inc.*, No. 22-18, 2023 WL 2661579 (2d Cir. Mar. 28, 2023)**

In the Second Circuit, the pre-2010 public disclosure bar applies to organizations implicated by publicly disclosed information, even if that organization was not specifically named.

Relators Joseph Piacentile and Kevin Kilcoyne brought a *qui tam* action on behalf of the federal and certain state governments, alleging that U.S. Oncology, Inc. submitted false Medicare and Medicaid reimbursement claims. The district court dismissed the claims for two independent reasons. First, the FCA's pre-2010 public disclosure bar applied, thus divesting the district court of subject-matter jurisdiction. Second, even if the court had jurisdiction, the complaint failed to plead fraud with the requisite specificity under Fed. R. of Civ. P. 9(b).

On appeal, the Second Circuit agreed that the public disclosure bar applied. The court keyed in on the pre-2010 text defining an "original source" as "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action." In holding that Piacentile and Kilcoyne were not "original sources," the Second Circuit examined the three complaints identified by the district court as public disclosures. The three complaints described U.S. Oncology's involvement in an alleged kickback scheme by implication but, importantly, not by name. Piacentile and Kilcoyne relied on Eleventh Circuit precedent holding that the public disclosure bar did not apply when the defendant was not specifically named. The Second Circuit disagreed, holding that the bar applied when a claim is "based in any part upon publicly disclosed allegations or transactions."

> "A relator's identification of specific examples of the conduct at issue does not provide significant new information where the underlying conduct already was publicly disclosed."

***Silbersher v. Valeant Pharms. Int'l, Inc.*, 76 F.4th 843 (9th Cir. Aug. 3, 2023)**

The Ninth Circuit holds that an inter partes review before the U.S. Patent and Trademark Office (USPTO) is not a qualifying proceeding under the FCA's public disclosure bar.

Relator Zachary Silbersher filed an FCA action against drugmaker Valeant, alleging that Valeant fraudulently obtained certain drug patents so that that it could continue to charge artificially high prices for its drug Apriso. Silbersher also claimed that Valeant defrauded the federal government by overcharging the government for Apriso while simultaneously certifying that the price was fair and reasonable. Silbersher previously sued to invalidate one of the relevant patents, arguing that the key discovery that Valeant used to obtain the patent was obvious. The patent was challenged through an inter partes review (IPR) by the USPTO, and it was invalidated.

The district court dismissed Silbersher's *qui tam* action under the FCA's public disclosure bar. The public disclosure bar applies when a disclosure is made through one of three enumerated channels. The district court concluded that the IPR was a federal hearing under channel (ii) of the bar and that all Silbersher's allegations had been disclosed in the IPR. Silbersher appealed.

The Ninth Circuit reversed and remanded. It analyzed the types of proceedings that qualify under channels (i) and (ii) of the public disclosure bar, emphasizing that "[c]hannel (i) primarily involves adversarial proceedings that are adjudicated on the merits before a neutral tribunal or decisionmaker, whereas channel (ii) primarily involves federal investigatory proceedings." The court determined that the IPR did not qualify under channel (ii) because it was an adversarial adjudicatory proceeding — not an *ex parte* investigative proceeding. Additionally, the IPR was not a channel (i) disclosure because the government was not a party to the proceeding. Therefore, the IPR was not a qualifying proceeding under the public disclosure bar.

While other qualifying public disclosures existed, the court determined that those disclosures did not contain facts sufficient to permit a reasonable inference of the fraud alleged by Silbersher. As a result, the prior public disclosures did not reveal substantially the same allegations as Silbersher's *qui tam* complaint and therefore did not trigger the public disclosure bar.

U.S. ex rel. Vaughn v. Harris Cnty. Hosp. Dist., **No. 22-20659, 2023 WL 8649876 (5th Cir. Dec. 14, 2023)**

The Fifth Circuit applies the First Circuit's definition of "material addition" in analysis of original source exception to public disclosure bar.

Relator Kent Vaughn brought an FCA action against the Harris County Hospital District and other hospital and medical school defendants, alleging that defendants violated the FCA by claiming and receiving excessive Medicaid funding. Specifically, Vaughn claimed that defendants committed Medicaid fraud by participating in a "collaborative program" through which they used payments deemed to be "donations" from the private hospitals to gain federal matching funds for Medicaid patients. The district court found that Vaughn's allegations were substantially the same as publicly disclosed allegations and dismissed the case.

The Fifth Circuit concluded that the public disclosure bar barred Vaughn's claims and affirmed the district court's order dismissing the action. First, the court determined that Vaughn's complaint was based upon numerous public disclosures, which alleged facts that made a potentially fraudulent scheme readily identifiable. It rejected Vaughn's assertion that the public disclosure bar did not apply because the publicly available information did not identify the means used to perpetrate the fraud. The court emphasized that public disclosures need not expressly allege fraud. Instead, the relevant question was whether the relator could have synthesized an inference of fraud from the disclosures.

Next, the court determined that the original source exception to the public disclosure bar did not apply. Vaughn was not an original source because his allegations did not materially add to the public disclosures. While the court noted that the Fifth Circuit had not yet opined on what it means for an original source to "materially add" to a public disclosure, it quoted the First Circuit's definition of that term from *Winkelman v. CVS Caremark Corp.,* 827 F.3d 201, 211 (1st Cir. 2016), noting that "an addition is material if it is '[o]f such a nature that knowledge of the item would affect a person's decision-making,' or if it is 'significant,' or if it is 'essential.'" The court also cited *Winkelman* for the proposition that a relator's identification of specific examples of the conduct at issue does not provide significant new information where the underlying conduct already was publicly disclosed. Because the public disclosures identified a quid pro quo in which private hospitals provided services and money in order to receive greater government funding, the purportedly non-public details of the scheme alleged by Vaughn were not a material addition.

STATUTE OF LIMITATIONS

Under the FCA, an action must be brought within the later of (a) six years after the date the violation is committed, § 3731(b)(1), or (b) three years after the date when facts are known or reasonably should have been known to the United States, § 3731(b)(2).

U.S. ex rel. Aldridge v. Corp. Mgmt., Inc., **78 F.4th 727 (5th Cir. Aug. 21, 2023)**

The Fifth Circuit holds that the FCA's statute of limitations bars significant portions of the government's complaint-in-intervention, filed eight years after the relator's initial complaint and the government's 18 sealed motions for extension of time.

In 2007, relator James Aldridge filed a *qui tam* action against Corporate Management, Inc. (CMI), Stone County Hospital (SCH), and their owner and executives (collectively, the "defendants"). The owner, Ted Cain, operated CMI, a management company for Cain's businesses, including SCH, a critical access hospital. Aldridge, a former CMI employee and CEO of SCH, alleged that CMI, SCH, and its executives inflated supply costs, "ping-ponged" patients between nursing homes and SCH to manipulate the facilities' "swing bed" status, and improperly waived copays and deductibles.

On Aug. 13, 2007, the government filed its first of what became 18 motions for extension of time to consider whether to intervene. Eight years after its initial extension motion, on Sept. 15, 2015, the government intervened in Aldridge's action, alleging for the first time that Cain and other executives took advantage of Medicare's 101% reimbursement rate to defraud Medicare out of millions of dollars from 2002 to 2013.

Defendants moved to dismiss, arguing that the government's eight-year delay in intervening violated the FCA and prejudiced them. The district court denied defendants' motion, and, after a nine-week jury trial, the jury found the defendants' jointly and severally liable for approximately $10 million, which the district court trebled to over $32 million.

The Fifth Circuit reversed in part and barred the government's recovery for events that occurred before the FCA's six-year statute of limitations, measured from the date of its intervention on Sept. 15, 2015. The court, interpreting Federal Rule of Procedure 15, reasoned that the government's new allegations related to excessive and unwarranted salaries and other luxuries did not relate back to Aldridge's more limited *qui tam* complaint. Likewise, the court held that the FCA's tolling provision also could not save the government's pre-September 2009 claims because the government did not act with diligence to preserve its claims. Instead, the evidence showed that the government knew the material facts of its 2015 complaint-in-intervention as early as 2011.

SOVEREIGN TRIBAL IMMUNITY

Mestek v. LAC Courte Oreilles Community Health Center, 72 F.4th 255 (7th Cir. June 29, 2023)

Sovereign immunity insulates Indian tribe and certain organizations acting as arms of the tribe from anti-retaliation provision of the False Claims Act.

Plaintiff alleged violations of the False Claims Act's anti-retaliation provision following her termination by the Community Health Center of the Lac Courte Oreilles Band of Lake Superior Chippewa Indians. She claimed her termination arose as retaliation for her raising concerns about improper billing practices for Medicare and Medicaid claims. The district court found that the health center and the individuals were protected by tribal sovereign immunity, thereby rejecting plaintiff's argument that Congress abrogated tribal sovereign immunity in the False Claim Act's anti-retaliation provision. Plaintiff appealed.

The Seventh Circuit affirmed the district court, finding tribal sovereignty extended to the health center and the individuals sued in their official capacities. First, the court determined that Congress did not abrogate tribal sovereignty in the anti-retaliation provision of the False Claims Act because the provision neither explicitly references "Indians" or "tribes," nor does it use any catchall language meant to "cover the waterfront." Next, the court determined that the health center operated as an "arm of the tribe," thus extending the tribe's sovereign immunity to the center, as the center's governance documents evidenced the exercise of tribal authority, the center's mission clearly indicated the nexus between the center and the tribe's health and welfare, and the tribe plainly intended to confer its sovereign immunity on the center. Finally, the court determined sovereign immunity applied to the individuals that plaintiff sued, where the relief plaintiff sought would effectively run against the tribe rather than the individuals.

DAMAGES & PENALTIES

Hendrix ex rel. U.S. v. J-M Manufacturing Co., 76 F.4th 1164 (9th Cir. Aug. 8, 2023)

The Ninth Circuit found that in FCA cases, in assessing statutory penalties, one penalty per project or FCA violation is proper, rather than one penalty per line item or good contained in the project.

Between 1996 and 2006, relator John Hendrix and other public agencies bought and installed PVC pipes for water and sewer projects, which were manufactured by defendant J-M Manufacturing. In its successful bids for those projects, J-M had indicated that its pipe complied with industry standards. In this *qui tam* action, Hendrix and five public agency exemplar plaintiffs claimed that J-M violated federal and various state False Claims Acts by representing that its PVC pipes were compliant when, in fact, they were not.

The district court bifurcated the trial, with the first phase addressing whether J-M violated the FCAs and the second phase addressing damages. Following trial on phase one, the jury returned a verdict against J-M. During the damages phase, Hendrix and the other plaintiffs argued that they were entitled to recover either the entire contract price or the total cost of replacing the offending pipe with compliant pipe. They also sought statutory penalties for the compliance stamps on each individual stick of pipe.

At the close of evidence, the district court found that Hendrix and the other plaintiffs were not entitled to recover the costs of removing and replacing the installed J-M pipes. The court also rejected that the compliance stamping on each pipe could serve as a basis for imposing civil penalties for each stick of pipe. Instead, the court awarded one penalty for each of the 26 projects at issue. The jury was unable to reach a verdict and a mistrial was declared. After the mistrial, the court granted J-M judgment as a matter of law on actual damages.

Hendrix and the other plaintiffs appealed the damages ruling. The Ninth Circuit found that the district court did not err in awarding only one penalty per project. Specifically, the court noted that the phase one finding of falsity and materiality did not mean that every stick of pipe was non-compliant. Rather the jury found only that J-M did not uniformly comply with industry standards and could have delivered some non-compliant pipe. Similarly, on actual damages, the court found that the district court correctly rejected Hendrix and the other plaintiffs' theory of the entire contract amount paid because it would impose a strict liability standard under which J-M would be obligated to refund the contract price regardless of any evidence of actual damages.

Penalties Increase

DOJ once again adjusted the statutory penalty range for FCA violations in 2023, increasing the minimum per claim penalty to $13,508 and the maximum to $27,018. The Bipartisan Budget Act of 2015 requires these revisions each year to account for inflation. This new penalty range for 2023 was applicable to penalties assessed after Jan. 30, 2023 — the date of publication in the Federal Register — for violations occurring after Nov. 2, 2015 — the date of the Bipartisan Budget Act of 2015. Prior to our publication of this review, the DOJ adjusted the penalties again for 2024, increasing the minimum per claim penalty to $13,946 and the maximum to $27,894 for violations assessed after February 12, 2024.

TIMING FOR SERVICE OF PROCESS

***U.S. ex rel. Weiner v. Siemens AG,* 87 F.4th 157 (2d Cir. Nov. 28, 2023)**

The Second Circuit found that, in a *qui tam* action, the time limit of Rule 4(m) to effectuate service of process is calculated starting from the date the district court orders the relator to serve the defendants, not from the date the case is unsealed.

Relator Clifford Weiner filed suit in February 2012 on behalf of the United States and the state of New York, alleging violations of the FCA and state law. About nine months later, the United States declined to intervene. In December 2015, the district court declined to exercise supplemental jurisdiction of the state law claims. In its order dismissing the state law claims, the district court ordered the case to remain sealed until the relator requested a status conference. The relator did nothing, and the case languished.

The United States asked that the case be unsealed in June 2018. One year later, the district court docketed an order unsealing the case. After yet another year of inaction, the district court ordered a status report, and the relator replied that he was ready to effectuate service once the district court ordered him to do so. Defendants moved to dismiss for insufficient service and failure to prosecute. The district court granted the motion on the basis that a nine-year delay in service must be untimely. The district court denied the alternative ground for dismissal under Rule 41 for failure to prosecute.

The Second Circuit reversed, finding that, under 31 U.S.C. § 3730, a relator in a *qui tam* case is not permitted to serve as a defendant until the district court issues an order authorizing service. Therefore, the time to serve under Rule 4(m) does not start to run in such a case until the district court issues such an order. Because the district court had not ordered service in this case, the time to effectuate service had not yet begun to run and dismissal for insufficient service was premature.

The court further rejected defendants' argument that the service clock began ticking automatically when the district court unsealed the case, finding that this interpretation defied the plain reading of the statute. Regarding the failure to prosecute the claim, the court left open the possibility that the nine-year delay could justify dismissal under Rule 41(b) for failure to prosecute but declined to reverse the district court's holding rejecting dismissal on that ground.

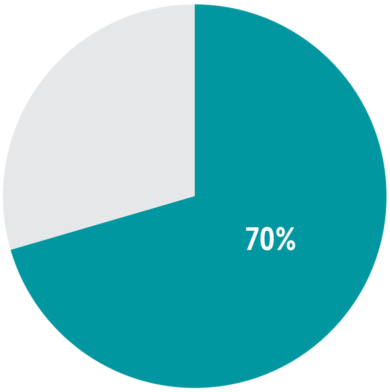
INSURANCE COVERAGE

***SHH Holdings, LLC v. Allied World Specialty Ins. Co.,* 65 F.4th 830 (6th Cir. Apr. 21, 2023)**

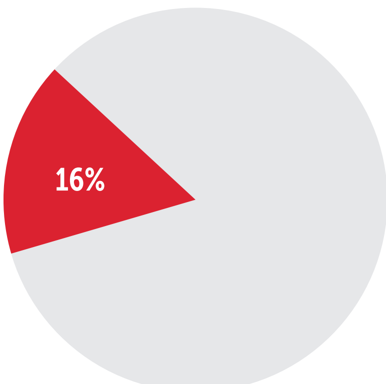
The Sixth Circuit holds that broad insurance exclusions are not necessarily ambiguous, so insurance coverage can cover a wide array of investigations, regardless of subject matter.

In 2016, a *qui tam* action against SHH Holdings was filed under seal. The next year, DOJ sent SHH a civil investigation demand (CID), to which SHH later began responding. The CID did not, however, inform SHH of retaliation claims against it.

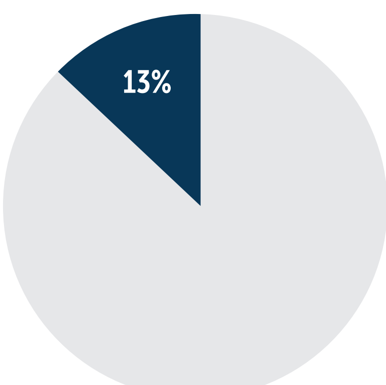
In April 2019, SHH applied for insurance coverage with Allied World. On its application, SHH responded in the negative to two questions asking about knowledge of ongoing or recent investigations, claims, or lawsuits against it. The application also had an exclusion section (incorporated into the policy) that if anything applicable to those two questions existed, they would be excluded from coverage. Based on the application, Allied World



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*

issued SHH a policy. Later in 2019, the *qui tam* was partially unsealed, and SHH learned for the first time about retaliation allegations. SHH notified Allied World and sought coverage for legal costs to defend against the retaliation claims, but Allied World denied coverage.

SHH sued Allied World for breach of contract and breach of the duty of good faith and fair dealing. On dueling motions for summary judgment, the district court granted SHH summary judgment on breach of contract, but for Allied World on the bad faith claim. The district court interpreted the two questions as encompassing only investigations that related to the liability coverage sought, so the application exclusion didn't apply. Allied World appealed the breach of contract judgment, as well as attorneys' fees awarded to SHH.

On appeal, the Sixth Circuit sought to discern the parties' intent regarding the two questions and the application exclusion. In the end, the Sixth Circuit disagreed with the district court, finding that the two application questions unambiguously encompassed the *qui tam* complaint, such that the investigation into SHH fell under the application exclusion. Further, even though SHH argued that it did not have notice of retaliation claims against it at the time of submitting its insurance application, the court answered that "SHH knew that it took adverse employment actions against the relators."

Astellas US Holding, Inc. v. Federal Insurance Co., **66 F.4th 1055 (7th Cir. May 3, 2023)**

The Seventh Circuit rejected the argument that settlements arising under the FCA and the Anti-Kickback Statute constitute restitution, instead ruling in favor of the policyholder based on the FCA allowing for compensatory damages, not restitution.

In 2012, plaintiff Astellas launched a new cancer drug to treat metastatic prostate cancer. Initially priced at $7,800 per month, even with Medicare coverage up to about $6,000 per month, patients were left with a steep monthly co-pay of about $1,800. To offset these costs, Astellas began making contributions to patient assistance plans. The government began investigating Astellas' contributions for potential healthcare offenses. In 2019, Astellas paid the government $100 million to settle potential claims for violations of the federal Anti-Kickback Statute and the federal False Claims Act.

Astellas turned to several liability insurers, including defendant Federal Insurance Company, to cover portions of the settlement payment. Astellas' director-and-officer excess liability insurance policy with Federal had a policy limit of $10 million, which Astellas demanded. Federal denied coverage. On summary judgment, the district court ruled in favor of Astellas, concluding that Illinois law and public policy did not prohibit insurance coverage of the settlement payment.

The Seventh Circuit affirmed. The court found that under Illinois law, a party may not obtain liability insurance for genuine restitution it owes the victim of its intentional wrongdoing, but a party may obtain insurance for compensatory damages it may owe. Here, the court rejected Federal's arguments that the settlement payment constituted uninsurable restitution because the FCA allows for only civil penalties and compensatory damages, not restitution. Federal also argued that the settlement was uninsurable as proceeds of a "knowing fraud" because the underlying violations required proof that Astellas acted "knowingly and willfully." The court also rejected this argument, noting that Federal's position confused mere allegations of fraud with conclusive proof of fraud.

RETALIATION

U.S. ex rel. Toledo v. HCA Holdings Inc., **No. 21-20620, 2023 WL 2823899 (5th Cir. Apr. 7, 2023)**

The Fifth Circuit affirms summary judgment against relator on retaliation claim where relator failed to show that decision-makers knew she had engaged in protected activity and failed to show that her engagement in protected activity caused her supervisors to terminate her.

Relator Clarisse Christine Toledo was fired from her job as a Prospective Payment System coordinator at an inpatient hospital, a job that included monitoring the accuracy of patient data entered into the hospital's system. Before her termination, she had raised concerns about inaccurate patient-data entries with her supervisors. After her termination, Toledo filed suit claiming that the hospital unlawfully retaliated against her for reporting possible illegal conduct. The hospital claimed it fired her for poor job performance. The district court granted summary judgment to the hospital.

The Fifth Circuit affirmed. The court explained that an employee claiming retaliation under the FCA must make a *prima facie* showing that (1) he engaged in protected activity, (2) the employer knew about the protected activity, and (3) the employer retaliated because of the protected activity. The court did not address the first prong because it found that she failed on both of the other two prongs.

The evidence showed that when Toledo reported errors in the hospital's data entry, she characterized those errors as mistakes or inaccuracies rather than as "fraud" or "illegal" conduct. Particularly because reporting such errors fell within her job description, there was no basis for Toledo's supervisors to believe she was engaged in a protected activity rather than simply doing her job. Therefore, she failed to show that her employer knew about the protected activity.

Furthermore, Toledo admitted that when she reported mistakes, her supervisors responded appropriately, and she did not feel retaliated against at the time. Therefore, she failed to show that her alleged protected activity caused her supervisors to terminate her. Toledo provided no evidentiary basis to disbelieve the hospital's non-retaliatory purpose in firing her for poor job performance.

U.S. ex rel. Barrick v. Parker-Migliorini Int'l, LLC, **79 F.4th 1262 (10th Cir. Aug. 22, 2023)**

The Tenth Circuit clarifies the standard for notice for FCA retaliation claims, concluding that an employer merely needed to know that an employee was engaged in a protected activity and did not need to know that the activity had a nexus to the FCA.

Brandon Barrick brought FCA and retaliation claims against his former employer, Parker-Migliorini International (PMI). While Barrick's underlying FCA claims were dismissed, his retaliation claim proceeded to trial, and a jury ruled in his favor.

On appeal, PMI argued that the district court improperly denied its motion for judgment as a matter of law because the evidence was insufficient to satisfy the notice and causation elements of an FCA retaliation claim. PMI claimed that Barrick's actions needed to convey a connection to the FCA to provide the requisite notice. Because Barrick presented no evidence of such a connection, PMI argued that the notice requirement was not satisfied. By contrast, Barrick argued that the notice element only required that his employer know that he was engaged in a protected activity; it did not need to know that the activity had a nexus to the FCA specifically.

The Tenth Circuit affirmed, concluding that the notice element of an FCA retaliation claim is satisfied by evidence that an employer knew that an employee was engaged in a protected activity. The employer does not need to know that the protected activity had a nexus to the FCA. To establish the requisite notice, the employee does not need to use "magic words" such as "FCA violation." While the employee's actions must convey that the employee was attempting to stop the employer from (1) engaging in fraudulent activity to avoid paying an obligation owed to the government or (2) claiming unlawful payments from the government, the employer does not need to know that those activities violated the FCA specifically. Here, the court concluded that there was sufficient evidence of notice to defeat PMI's motion for judgment as a matter of law. It also rejected PMI's argument that the causation element of Barrick's retaliation claim had not been satisfied since that argument was premised entirely on the contention that PMI lacked notice.

The Tenth Circuit also rejected PMI's argument that it was entitled to a new trial due to the district court's use of an erroneous jury instruction regarding causation. The court found no error in the jury instructions.

WHAT TO WATCH IN 2024

FIRST CIRCUIT RULING ON AKS CAUSATION ISSUE

The First Circuit is expected to weigh in on the circuit split regarding whether or not there must be but-for causation between a violation of the Anti-Kickback Statute and the submission of a claim to a federal healthcare program. The Sixth and Eighth circuits require but-for causation. The Third Circuit does not. With two prominent cases out of the District of Massachusetts reaching opposing conclusions, the issue has been certified for interlocutory appeal, teeing up a potential decision on the issue from the First Circuit in 2024. See further discussion of this issue at page 10.

CONTINUED RAMIFICATIONS OF *SUPERVALU*

When and where is it effective for defendants to continue arguing about reasonable interpretations of ambiguous regulations? Will courts apply the *SuperValu* decision narrowly as the Eighth Circuit did in *U.S. ex rel. Kraemer,* distinguishing it when there is no evidence of a culpable mental state?

Will the Supreme Court's statement that the scienter standard requires being "'aware of information" for actual knowledge, being "aware of a substantial risk" of falsity and "intentionally avoiding taking steps to confirm" for deliberate ignorance, and being "conscious of a substantial and unjustifiable risk" of falsity for reckless disregard lead to arguments about when risks are "substantial" and "unjustifiable?" The next year of decisions interpreting the *SuperValu* opinion may shed additional light on our evolving understanding of the FCA's scienter element.

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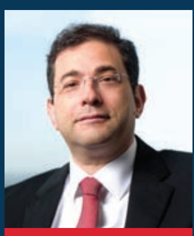

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