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# FALSE CLAIMS ACT
## 2022 YEAR IN REVIEW

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In 2022, the False Claims Act (FCA) continued to be the federal government's chief tool for combatting fraud. Many trends in recent years were likewise present in 2022: robust FCA enforcement generally, healthcare as the prime industry target, and courts wrestling with nuances over FCA's scienter requirements, DOJ's dismissal authority, and the long-evolving materiality standard, among other issues.

Arguably the most notable development in 2022 became even more notable in early 2023. That's when the U.S. Supreme Court agreed to consider whether a defendant that relied on an objectively reasonable interpretation of an ambiguous law acts "knowingly" under the FCA. As discussed more below, the underlying cases — *SuperValu* and *Safeway*, both from the Seventh Circuit — have revealed differing approaches to, and vigorous dissents about, construing the FCA's scienter requirement when there is an "objectively reasonable" interpretation of an underlying statute or regulation. The Supreme Court will resolve that dispute in 2023 in a decision likely to rival 2016's Escobar decision as the most consequential FCA decision in recent history.

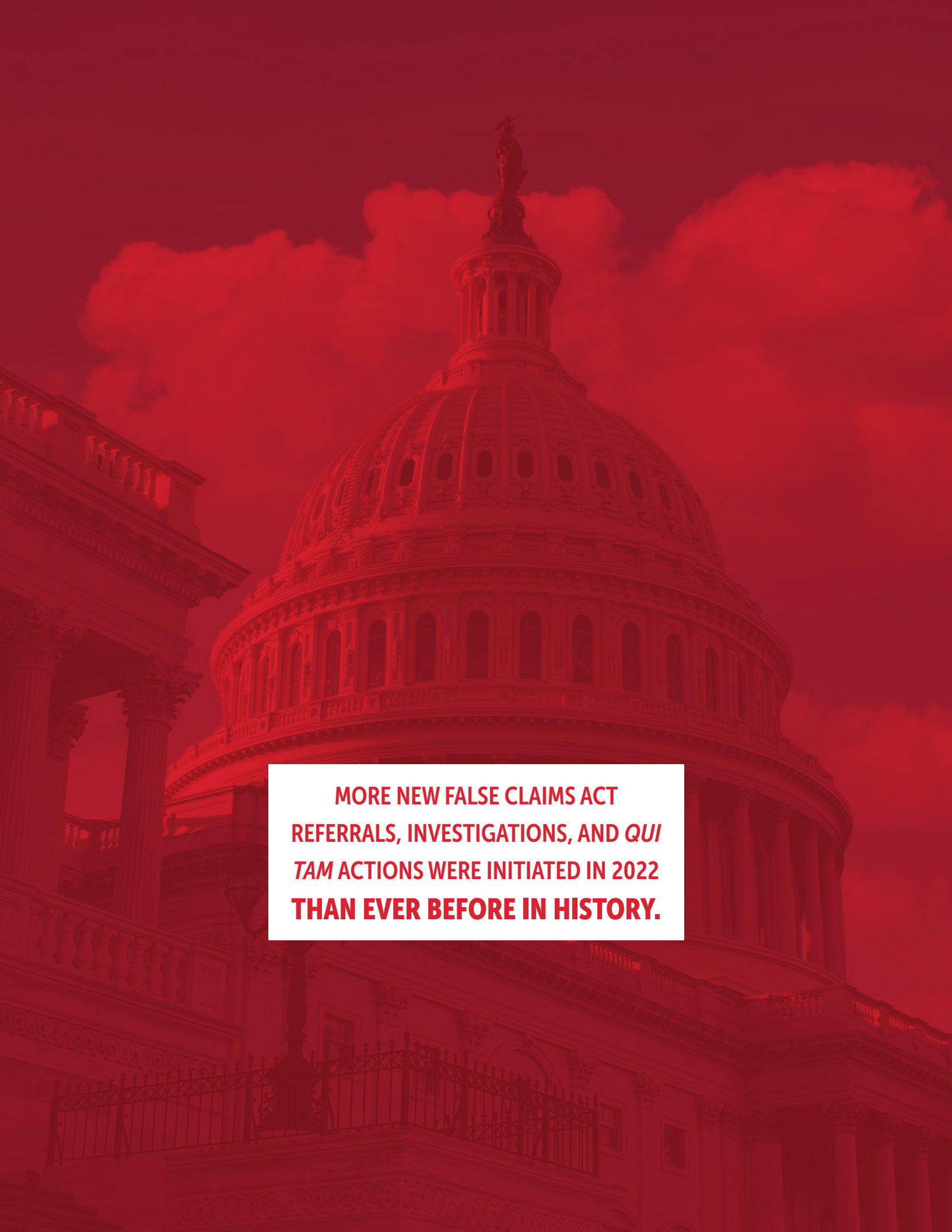
Elsewhere, DOJ released in early February 2023 the FCA statistics for fiscal year 2022 (FY2022). While difficult to draw firm conclusions from a single year's statistics, a few items stand out:

- **Non-intervened actions** - In perhaps the most notable development, settlements and judgments from declined *qui tams* were up over 240% from FY2021 ($1.18 billion from $480 million) — nearly double the previous record amount ($602 million in FY2017). Relator share awards from declined matters also jumped over 5.5 times from FY2021, from $62 million to $347 million. This is far and away the most ever recovered by relators for non-intervened matters, nearly equaling the previous five fiscal years combined.

- **Settlements and judgments aggregate value** - Although DOJ brought in the second-highest number of settlements and judgments that the government has ever collected in a single year, the dollar value of those settlements is down significantly from 2021 and remains below pre-pandemic recovery levels. The increased number of total actions coupled with the decrease in total recoveries may be explained by DOJ's stated emphasis on investigating COVID-19-related stimulus fraud – cases that, on average, tend to produce smaller recoveries compared to large corporate investigations.

- **Notable cases** - The largest single settlement was from drug manufacturer Biogen, which paid $843.8 million to resolve allegations that it offered kickbacks to physicians in order to boost sales of its multiple sclerosis therapies. The DOJ also pursued several cases of Medicare Advantage overpayments, where insurers knowingly submitted inaccurate information, or failed to correct it, in order to increase reimbursements. The DOJ's actions on Medicare Advantage organizations signal a continued focus in this area as the Centers for Medicare and Medicaid Services attempts to revamp its approach to risk adjustment audits in order to reduce overpayments. DOJ also intervened in a case against insurer Cigna and is still litigating other cases against Elevance Health, UnitedHealth Group, and Kaiser Permanente.

In the pages that follow, we analyze those cases, recent trends, and other key FCA decisions and developments of the year gone by. From Medicare Advantage to the Anti-Kickback Statute, from fee awards to damages calculations, and all points between, 2022 was another notable year in FCA jurisprudence — a trend surely to continue throughout 2023.

**MORE NEW FALSE CLAIMS ACT REFERRALS, INVESTIGATIONS, AND *QUI TAM* ACTIONS WERE INITIATED IN 2022 THAN EVER BEFORE IN HISTORY.**

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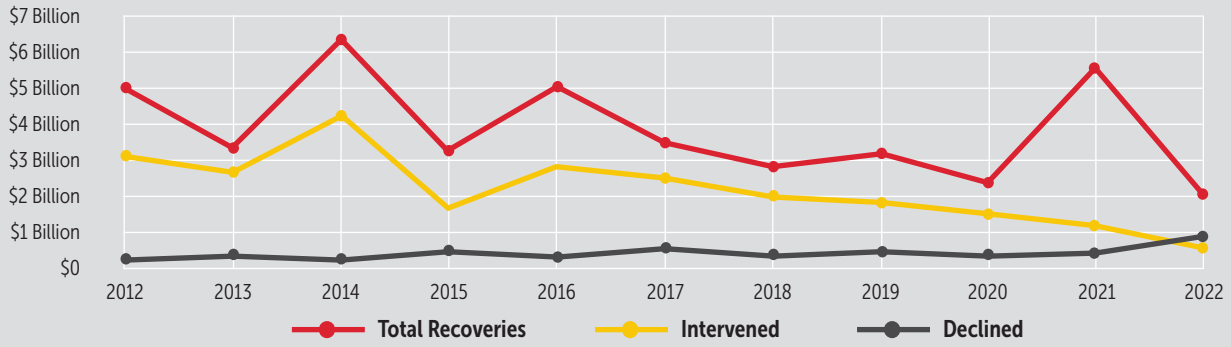
# DOJ YEAR-END STATS

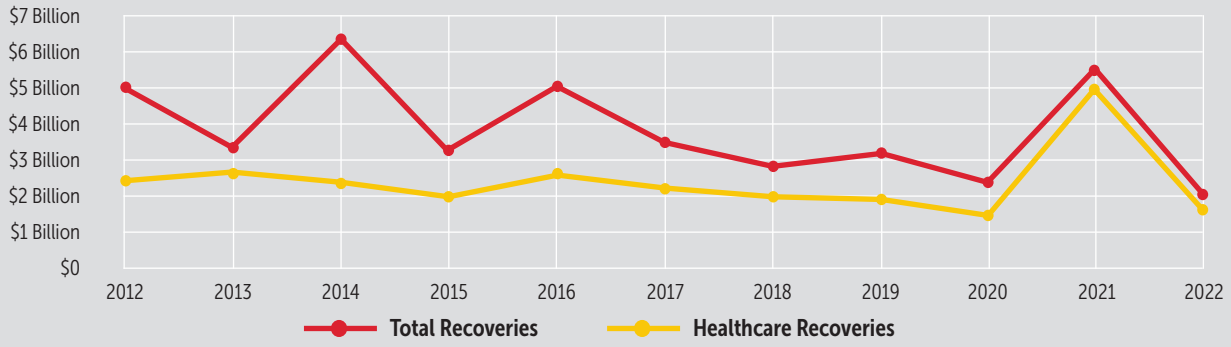
In fiscal year 2022, FCA recoveries topped $2.2 billion. The charts below and throughout the FCA Year in Review track notable trends in recoveries and other key metrics over the last decade.

### Total FCA Recoveries 2012-2022



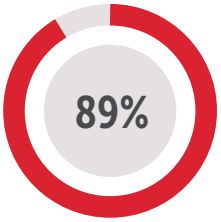

Recoveries overall and recoveries from intervened cases declined in 2022, whereas recoveries from declined matters nearly doubled the previous record.

### Healthcare Recoveries vs. Total Recoveries 2012-2022




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

**+39.6%**
**Percentage increase in non-*qui tam* cases from 2021 to 2022**




**Percentage of recoveries in 2022 from relator-filed cases**

**+556%**
**Percentage increase in relator share awards for declined matters from 2021 to 2022**

# KEY DECISIONS & DEVELOPMENTS

## FALSITY

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

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

***Holzner v. DaVita Inc.,* No. 21-55261, 2022 WL 726929 (9th Cir. Mar. 10, 2022)**

Joining a growing number of courts to wrestle with the clinical disagreements in the context of FCA claims, the Ninth Circuit holds that a disagreement in clinical judgment is not sufficient to establish falsity under the FCA.

Relator Charles M. Holzner, M.D., appealed the dismissal of FCA claims premised on allegedly medically unnecessary products and services or unreasonably expensive medications. Holzner argued that the district court erred in dismissing the claims and in denying him leave to further amend the complaint.

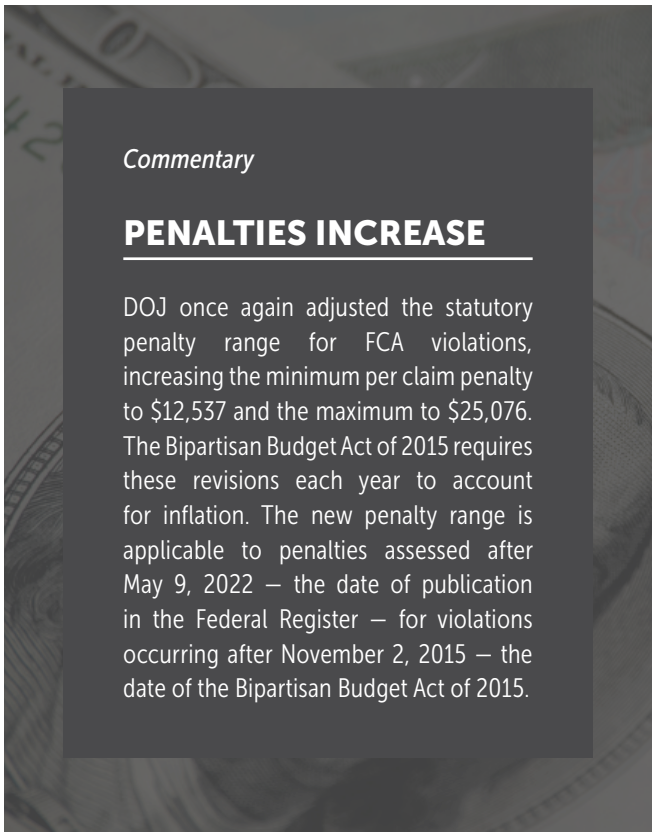
The Ninth Circuit agreed with the district court that the allegations of the fourth amended complaint showed no more than a disagreement in clinical judgment, and that Holzner "has not raised a plausible inference that the nephrologists' certifications that these interventions are medically necessary — or appellees' reliance on those certifications — were false or fraudulent." Therefore, the Ninth Circuit affirmed the district court's dismissal of relator's claims for failure to plausibly allege a false statement in order to establish FCA violation.

***McElligott v. McKesson Corp.,* No. 21-15477, 2022 WL 728903 (9th Cir. Mar. 10, 2022)**

Ninth Circuit affirms dismissal of case alleging McKesson made false certifications about products when it allegedly failed to provide adequate security at opioid distribution center.

In 2019, relators Michael McElligott and Carl Kelley brought an FCA claim against McKesson Corporation regarding the company's alleged failure to disclose its Comprehensive Drug Abuse Prevention and Control Act violations to the federal government when submitting claims for payment under various federal programs. After amending the initial complaint, the relators alleged that McKesson violated the FCA under an express and implied certification theory. The Northern District of California dismissed relators' second amended complaint without granting further leave to amend.

On appeal, the Ninth Circuit affirmed, holding that the lower court did not abuse its discretion in determining that the relators had not adequately pleaded express or implied false certification or materiality. With regard to the latter, the court noted that the complaint did not provide information that would lead to a reasonable inference that the security of McKesson's supply chain was material in the government's decision to pay for the medical supplies delivered by McKesson.



*Commentary*

## PENALTIES INCREASE

DOJ once again adjusted the statutory penalty range for FCA violations, increasing the minimum per claim penalty to $12,537 and the maximum to $25,076. The Bipartisan Budget Act of 2015 requires these revisions each year to account for inflation. The new penalty range is applicable to penalties assessed after May 9, 2022 — the date of publication in the Federal Register — for violations occurring after November 2, 2015 — the date of the Bipartisan Budget Act of 2015.

***U.S. ex rel. USN4U, LLC v. Wolf Creek Fed. Servs., Inc.,* 34 F.4th 507 (6th Cir. May 16, 2022)**

Sixth Circuit reverses dismissal, finding that allegations regarding inflated fixed-price proposals were sufficient to state an FCA claim based on fraudulent inducement.

Starting in 2013, Wolf Creek began providing facilities management maintenance services to NASA under an indefinite delivery indefinite quantity (IDIQ) contract. Per the contract, NASA would approve certain projects for Wolf Creek to perform on a firm fixed-price basis. After Wolf Creek received a work order from NASA, it was required to submit a proposal for a schedule of completion and total costs of labor and materials, which NASA would evaluate to determine the final fixed-price amount.

The relator USN4U, LLC, brought a *qui tam* action under the FCA against Wolf Creek Federal Services, alleging that Wolf Creek submitted falsely inflated project estimates to NASA for the facilities maintenance projects, resulting in falsely induced and inflated contract prices. Wolf Creek moved to dismiss, which the district court granted. In doing so, the court noted that the work order proposals submitted by Wolf Creek did not constitute "claims" under the FCA, serving only as estimates, not demands or invoices. Additionally, the district court found that USN4U did not satisfy its burden to plead falsity under the FCA as its allegations merely compared the labor costs with industry standards to support its claims of false inflation. Finally, the court held that USN4U failed to satisfy its burden to plead fraud in the inducement based on Wolf Creek's continued performance under the contract with NASA, even after the fraud allegations came to light.

On appeal, the Sixth Circuit reversed, holding USN4U sufficiently alleged a claim of fraudulent inducement under the FCA. Turning to the elements of that claim, the court first addressed falsity, noting that reliance on industry standards as the basis for a fraud claim is not presumptively insufficient. Regarding scienter, the court found USN4U satisfied the pleading standard through USN4U's submission of a recorded conversation in which Wolf Creek employees discussed their knowledge of the falsely inflated cost estimates. On materiality, the court found that Wolf Creek's falsely inflated cost estimates could have had the tendency to influence NASA's contracting decisions, given that NASA relied on Wolf Creek's estimates rather than its own research into the costs. Further, the court found that NASA's decision to allow Wolf Creek to continue its performance of the contract after the fraud allegations came to light was not dispositive of actual knowledge of fraud because various factors could influence the decision to allow the continuation of performance of the contract. Finally, the court found that USN4U satisfied the pleading requirement for

causation, noting that NASA asked Wolf Creek for estimates and, when it awarded Wolf Creek the contracts, NASA always awarded the contracts for the quoted amount, indicating NASA's reliance upon Wolf Creek's estimates when it entered into the contracts at the quoted prices.

***U.S. ex rel. Osinek v. Permanente Med. Grp. Inc.,* No. 13-CV-03891-EMC, 2022 WL 16925963 (N.D. Cal. Nov. 14, 2022)**

Medicare Advantage Organizations, such as Kaiser, are required to comply with International Classification of Diseases (ICD) coding standards and failure to do so can result in the finding of legal falsity and materiality for an FCA cause of action.

The government brought an FCA complaint against Kaiser alleging that Kaiser had systematically altered patient medical records for Medicare Advantage patients to either (1) add diagnoses that did not exist or (2) add diagnoses unrelated to the patient's visit in addenda to the medical records after the patient's visit. In opposing Kaiser's motion to dismiss, the government argued that Kaiser's conduct resulted in FCA liability because both the contract between Kaiser and CMS and federal regulations require Kaiser to abide by ICD Guidelines. Under ICD Guidelines, a diagnosis can only be made on a medical record if it required or affected patient care treatment or management at the time of the visit. In response, Kaiser countered the government's argument by stating that neither the contract nor the federal regulations require Kaiser to comply with ICD Guidelines and, at best, ICD Guidelines are subregulatory and lack any force of law.

The court held that, due to the express provision in the contract and the data-accuracy requirements in the federal regulations, Medicare Advantage Organizations such as Kaiser are required to comply with the ICD Guidelines. Having reached this conclusion, the court agreed that the government had a plausible case of legal falsity against Kaiser for implicitly certifying that it complied with the ICD Guidelines in making a claim for payment.

***U.S. ex rel. Jehl v. GGNSC Southaven, LLC,* No. 22-60209, 2022 WL 17443684 (5th Cir. Dec. 6, 2022)**

Fifth Circuit affirms dismissal of FCA lawsuit, finding no false certification related to nursing licensure because defendant properly relied on CMS guidance regarding when such state license is considered invalid.

Relator Cameron Jehl filed an FCA lawsuit alleging that the defendant, a nursing facility operator, violated the FCA by billing the government for healthcare services while falsely certifying that the company had complied with Mississippi's nursing-licensure law. Specifically, Jehl contended that the company's director of nursing was not licensed to work in that state. The underlying

licensure issue was convoluted because, while the director had an ostensibly valid multistate license, the relator argued that it was actually invalid due to misstatements about her state of residence in the underlying application.

The U.S. District Court for the Northern District of Mississippi, facing the possibility of trial on what it termed a "novel theory of liability" based on a "rather minor licensing issue," *sua sponte* ordered the plaintiff to show cause why the case should not be dismissed. The court suggested that the matter should be dismissed because it was better left to state and federal regulators to police given that "[t]he mandatory penalties and treble damages which exist in FCA claims are much too strong medicine for the conduct alleged."

Particularly, the court concluded that the FCA was an inappropriate enforcement mechanism under the circumstances, because evidence developed during discovery suggested that "actual Medicaid regulators would not have regarded the alleged violation in this case as something worthy of their time." After the close of discovery, relator sought to introduce an affidavit from a Mississippi state Medicaid official declaring the licensing violation would have been material to his office. The court determined "the opinion of a single state official, offered in support of litigation, to be much less reliable than formal guidance issued by CMS to its surveyors."

On appeal, the Fifth Circuit affirmed, finding that the relator failed to establish falsity as the defendant "fully comported with CMS guidance," which states that a license is invalid only after a state governing board determines it is invalid in a final adverse action from which there is no appeal. Although the nursing director's license was temporarily revoked, it was reinstated prior to the date she began her employment with the defendant. Because no "final adverse action" had been taken to invalidate the nursing license, the license was still valid, and the claims the defendant submitted were not false under the FCA.

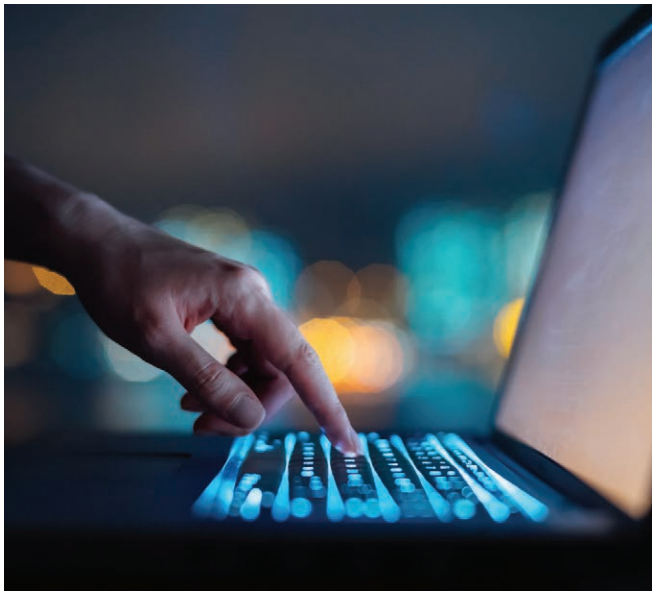
## FALSITY: FRAUD-ON-THE-FDA THEORY

***U. S. ex rel. Crocano v. Trividia Health Inc.,*** **No. 22-CV-60160-RAR, 2022 WL 2800380 (S.D. Fla. July 18, 2022)**

Court rejects DOJ's "fraud-on-the-FDA" theory of FCA liability, holding that violations of the Food Drug and Cosmetic Act (FDCA) cannot create FCA liability where the "connection to claims for payment by the government is tenuous at best."

Relator Patricia Crocano accused Trividia Health Inc. of violating the FCA by knowingly manufacturing defective and misbranded glucose test strips that were reimbursable through federal health insurance. According to Crocano, because Trividia knew the strips were defective and therefore not eligible for government reimbursement, any claim for reimbursement was necessarily false. The government declined to intervene in Crocano's case, but it filed a statement of interest supporting this "fraud-on-the-FDA" theory of FCA liability.

The court dismissed the case. Although Crocano alleged violations of the FDCA, she failed to connect these violations to the government's reimbursement decisions. There is no law barring federal reimbursement of products that violate the FDA's safety regulations. "[The FCA] is not a catch-all statute targeting any conceivable form of misconduct connected with the government's spending programs — particularly when such misconduct is proscribed by separate enforcement regimes." Crocano could not overcome this deficiency by alleging in a conclusory manner that the product defects "would be material" to the government's decision to pay for the products.



## FALSITY: CYBERSECURITY

***U.S. ex rel. Markus v. Aerojet Rocketdyne Holdings, Inc.,*** **No. 2:15-cv-02245, 2022 WL 297093 (E.D. Cal. Feb. 1, 2022)**

Eastern District of California rejected a defense contractor's argument that non-compliance with cybersecurity requirements was immaterial to the government's decision to approve contracts. This decision represents the first major ruling in an FCA case testing DOJ's new Civil Cyber-Fraud Initiative.

Relator Brian Markus brought this action against defendants Aerojet Rocketdyne Holdings, Inc. and Aerojet Rocketdyne, Inc., arising from the defendants' alleged noncompliance with government cybersecurity requirements in violation of the FCA. Markus, the former senior director for Cyber Security, Compliance & Controls for Aerojet, alleged that the company knew its cybersecurity programs fell short of Department of Defense and NASA acquisition regulations, which were part of contracts between Aerojet and the agencies. Moving for summary judgment, Aerojet argued that compliance with the Department of Defense (DoD) and NASA regulations at issue was immaterial because the government awarded contracts to other contractors and Aerojet despite knowledge that they were noncompliant.

Despite declining to intervene in the Aerojet case in June 2018, the government filed a statement of interest two weeks after the DOJ announced the Civil Cyber-Fraud Initiative, assailing Aerojet's arguments that it was entitled to summary judgement. Notably, the government argued that the contractual deficiencies were a source of damages even if Aerojet otherwise complied with the contracts because "the government did not just contract for rocket engines, but also contracted with [Aerojet] to store the government's technical data on a computer system that met certain cybersecurity requirements." The government also argued that assertions that the entire defense industry is not compliant with cybersecurity requirements has no bearing on whether such compliance is material to the government's payment decision in any particular case.

The court denied summary judgment, commenting on how the relevant regulations required government contractors to implement specific safeguards to protect unclassified technical information from cybersecurity threats. Although the court acknowledged that Aerojet may have disclosed certain cybersecurity shortcomings to the government, it questioned whether Aerojet failed to disclose key events, and the results of audits showing gaps in Aerojet's cybersecurity. The court also expressed concern as to whether Aerojet knowingly misrepresented its intention to comply with the cybersecurity provisions of their contracts in the first place.

## MATERIALITY

***United States v. Vora,* No. 4:20-CV-66-BJB, 2022 WL 89177 (W.D. Ky. Jan. 7, 2022)**

Court concluded that government agencies cannot categorize certain regulations as *per se* material based on its post-hoc characterization of them as conditions of payment.

The Western District of Kentucky dismissed the government's implied false certification claim, finding that it failed to adequately plead materiality in alleging that a laboratory paid kickbacks to the defendant physician so that he would order allegedly unnecessary genetic tests reimbursed by Medicare. Holding that the government's allegations were conclusory, the court stated that the government cannot rely on its own characterization of certain regulations as conditions of payment to argue that the regulations are *per se* material. The government gave the court "no basis to conclude that a physician's use of pre-signed lab order forms, failure to eventually use a test result, or decision to order a test outside CMS's specific warfarin limitations would be material to the payment decision."

The court set forth a three-part test for materiality: "materiality turns on what the government previously did (a factual question), whether payment is conditioned on that requirement's satisfaction (a legal question), and the significance of the requirement to the bargain (a mixed question)." Under this test, the court found that the government's allegations were lacking.

In so holding, the court rejected the government's reliance on its own retrospective review of claims submitted by the defendant, in which it determined that "similarly deficient claims" were medically unnecessary. First, the court noted that the government did not specify whether the claims were deficient due to violations of the same regulations at issue or merely other "similar" regulatory requirements. Second, the court expressed concern that the government may have denied the claims as medically unnecessary "in anticipation of litigation," explaining that "the government points to no authority for the proposition that it may rely on only an after-the-fact rejection of the same claim it seeks to litigate."

***U.S. ex rel. Taylor v. Boyko,* 39 F.4th 177 (4th Cir. June 29, 2022)**

Fourth Circuit finds that violations of corporate licensure laws were not material to Medicare's payment decision and that the relator failed to plead with particularity that upcoded invoices were presented to the government.

Relator Cortney Taylor filed a *qui tam* suit against two doctors, five medical companies, and an accounting firm for (1) knowingly submitting false claims after dissolution of a corporate charter and revocation of its certificate of corporate authorization and (2) upcoding mid-level practitioner services as physician services. Taylor was a prior patient in an emergency room staffed by employees of BestPractices of West Virginia, Inc. A substitute physician not employed by BestPractices signed Taylor's chart even though Taylor was seen by a nurse practitioner. That physician claims that the BestPractices medical director instructed him to sign the medical charts of patients seen by mid-level practitioners. These charts were then sent to an accounting firm that billed Medicare for the services as if they were completed by a physician, resulting in increased reimbursement.

The Fourth Circuit concluded that Taylor failed to plead the presentment of false claims for patients other than herself. While there were allegations that BestPractices directed doctors to sign false claims, there was no allegation that false claims were actually submitted for anyone other than Taylor. Taylor failed to provide descriptions of the "time, place, and contents of the false representations." Taylor also failed to adequately plead scienter for BestPractices regardless of the standard used. For the accounting firm defendant, the court refused to infer scienter based on a negligent failure to "read between the lines" of the medical records and infer that care was provided by someone other than the person indicated in the records.

As a separate issue, Taylor also claimed that BestPractices knowingly submitted false claims to Medicare because it failed to pay the annual fee for its certificate of corporate authorization, resulting in BestPractices becoming administratively dissolved. BestPractices never reported these issues to CMS. The Fourth Circuit held that, even though regulatory compliance is a condition of payment under Medicare, BestPractices' failure to maintain its certificate of corporate authorization was not material to Medicare's decision to pay the claims. The maintenance of a certificate of corporate authorization is a "bureaucratic" matter unlike maintenance of medical licenses, which directly impacts patient care. Though Taylor pointed to one instance where CMIS revoked Medicare billing privileges for a company's failure to comply with the state's corporate licensing requirements, the court concluded this one instance failed to show Medicare "consistently" refuses to pay claims for similar failures.


***U.S. ex rel. Hartpence v. Kinetic Concepts, Inc.*, 44 F.4th 838 (9th Cir. Aug. 9, 2022)**

Ninth Circuit found that a medical device manufacturer's use of a claim modifier to certify compliance with payment criteria and ensure payment at the same time it was seeking clarification from the Medicare administrative contractor regarding the parameters of the claim modifier created a genuine issue of material fact as to the elements of materiality and scienter.

Relator Stephen Hartpence brought this *qui tam* suit against Kinetic Concepts, Inc., a medical device manufacturer for wound treatments, alleging that it falsely certified compliance with local coverage determination criteria when it used a "KX" claim modifier. The modifier indicates that the claim meets all conditions for coverage, including that the patient had measurable month-over-month wound healing. Kinetic used the modifier even when a patient's progress stalled in one month and picked up again in the following month (a "stalled cycle"). It also conducted active discussions with its Medicare administrative contractors (MACs) about treatment of these patients. On summary judgment, the district court agreed with Kinetic that Hartpence failed to establish materiality and scienter.

On appeal, the Ninth Circuit reversed and remanded. With regard to materiality, the court found that when the government scrutinized the claims for patients with stalled cycles, it paid some and did not pay others, so using a modifier to ensure automatic payment was not immaterial to the payment decision. Similarly, with respect to scienter, the Ninth Circuit found that Kinetic's "deliberate insistence" on using the modifier when it otherwise knew that the LCD criteria was not met and that it would sometimes lose on case-specific review of its stall-cycle claims created a genuine issue of material fact, and that "a reasonable jury could find that [Kinetic] knew that it did not actually have the [MACs'] endorsement of its billing practices and that it decided to take a calculated risk that it could get away with bending the rules."

***U.S. ex rel. Sorenson v. Wadsworth Brothers Constr. Co.*, 48 F.4th 1146 (10th Cir. Sept. 9, 2022)**

Tenth Circuit affirms dismissal of complaint for failure to sufficiently allege materiality. Noncompliance with a statutory, regulatory, or contractual obligation must go to the very essence of the bargain to be material.

Kelly Sorenson brought a *qui tam* action against his former employer Wadsworth, a contractor working on a federally funded transportation project, alleging that it falsely certified its compliance with the prevailing-wage requirements of the Davis-Bacon Act. The act governs federally funded construction contracts and requires contractors to pay on-site employees minimum wages based on Department of Labor (DOL) determinations. Payment is jobsite and task specific.

Wadsworth obtained a federal grant for construction improvements, including deicing in Salt Lake International Airport. Consistent with the conditions of the grant, the airport required that contractors that were awarded the contract certify employees were paid in compliance with the act. Sorenson worked on the project and was required to scan his badge to get into the airport property. He alleged that there were discrepancies in his pay and that Wadsworth had forged many of his timesheets to show that he had not worked on the jobsite despite the airport's badge scan history indicating otherwise. Sorenson also alleged that when he was given additional wages, they were paid as a "union benefit" rather than under the Davis-Bacon Act.

On appeal, the Tenth Circuit determined that the allegations in Sorenson's complaint were insufficient to meet the "rigorous" materiality standard of the FCA. In reviewing Sorenson's complaint, the court noted that Sorenson had not identified where the deicing project in the airport was located and had not alleged that he performed work at that specific location. Indeed, the court noted that just because Sorenson worked on the project does not mean that he worked at the jobsite. The court questioned whether or not Sorenson was entitled to Davis-Bacon Act wages at all because of the lack of information in relation to his work.

Further, the court found that Sorenson's complaint asserted nothing more than naked act violations in addition to the fact that act compliance is a condition of payment under the deicing contract. The court made


clear that FCA allegations centered on noncompliance with statutory, regulatory, or contractual obligation must go to the very essence of the bargain in order to meet the FCA materiality requirement. In its dismissal, the court pointed to the complaint's lack of indication of whether the amount of payment was minor or significant; lack of indication of how the DOL handles false certifications; and lack of indication of whether the DOL was aware of the alleged false Davis-Bacon Act violations (and if so whether it continued to enter contractual arrangements with Wadsworth). Given the lack of information in relation to the materiality of the noncompliance with the contract, the court affirmed the lower court's dismissal of the FCA claims.

***U.S. ex rel. Yu v. Grifols USA, LLC,* No. 22-107, 2022 WL 7785044 (2d Cir. Oct. 14, 2022)**

Relator fails to plead that compliance with current Good Manufacturing Practices was material to the government's payment decision.

The Second Circuit affirmed the dismissal of a *qui tam* suit by Allen Timothy Yu, a former quality assurance project manager for Grifols. Yu alleged that Grifols made false representations to the FDA to secure approval of its new drug and manufactured the drug in violation of current Good Manufacturing Practices (cGMPs), which in turn allowed Grifols to fraudulently enter into contracts with government healthcare programs to supply the drug.

Yu's complaint failed to plead the necessary materiality to state an FCA violation. The court analyzed materiality in terms of" three factors relevant to the materiality assessment" in *Escobar*: (1) whether compliance is expressly designated as a condition of payment, (2) the government's response to noncompliance, and (3) whether the noncompliance was minor or insubstantial. Here, it found that the complaint failed to demonstrate that Grifols's contracts with government healthcare programs expressly designated compliance with cGMPs as a condition of payment. The complaint also failed to make any non-conclusory factual allegations that the government would have denied payments if it had known of the noncompliance. Yu also did not provide the court with any examples of how Grifols's noncompliance deprived the government of its benefit under the contract. Weighing these three factors, the Second Circuit affirmed the dismissal.

***Lee v. N. Metro. Found. for Healthcare, Inc.,* No. 21-2155, 2022 WL 17366627 (2d Cir. Dec. 2, 2022)**

Summary judgment is affirmed where relators failed to prove that alleged violations of anti-discrimination and medical-model laws were material to the government's payment decision. Asserted common-sense materiality and importance of regulation is not enough.

Relators alleged that Northern, a medical-model adult day healthcare program, discriminated against its non-Russian registrants and provided substandard care to all registrants. Relators contended that, under an implied-false-certification theory of liability, Northern violated the FCA by certifying compliance with various laws prohibiting its alleged discrimination and medical-model failures. After relators presented their case-in-chief, Northern moved for judgment under Rule 52(c). The district court conducted an analysis of the *Escobar* materiality factors and, finding that relators failed to prove materiality, granted Northern's motion.

The Second Circuit agreed. Specifically, the court found that relators adduced no evidence that compliance with the anti-discrimination and medical-model statutes and regulations at issue was expressly designated as a condition of payment and no evidence concerning the government's response to Northern's alleged noncompliance. The court also found that relators presented little evidence that the alleged noncompliance undermined "the essence of the bargain" between Northern and the government.

The Second Circuit also rejected relators' contention that the district court should have made a finding of materiality based on "the common-sense notion that violations of allegedly important statutes and regulations" would have affected the government's decision to pay Northern's Medicaid claims. The court acknowledged that common sense "may have a role" in determining which violations are likely to impact the government's payment. However, where "there is not a tight fit between the implicit representation and the service provided," appeals to common sense and the asserted importance of a given regulatory requirement "cannot clear the rigorous materiality hurdle."

*Commentary*

## OBJECTIVE KNOWLEDGE STANDARD THRIVES & SUPREME COURT GRANTS REVIEW

In 2022, appellate courts continued to apply the Supreme Court's reasoning in *Safeco Ins. Co. v. Burr* to the FCA context, holding that defendants did not act "knowingly" if they had a reasonable interpretation of ambiguous guidance and no authoritative guidance cautioned against the defendant's interpretation. To date, the Third, Fourth, Seventh, Eighth, Ninth, Eleventh, and D.C. circuits have adopted the *Safeco* standard. The Fourth Circuit in particular had a love-hate relationship with this objective knowledge standard this year, both adopting it implicitly in *U.S. ex rel. Gugenheim* and vacating its later decision in *U.S. ex rel. Sheldon*, which had adopted it explicitly.

In January 2023, the Supreme Court granted certiorari in the two recent Seventh Circuit decisions on the issue, ostensibly to decide the related issue of whether a reasonable interpretation of ambiguous guidance defeats scienter when it can be shown that the defendant subjectively believed at the time that it was violating the law.

### *U.S. ex rel. Proctor v. Safeway, Inc.*, 30 F.4th 649 (7th Cir. Apr. 5, 2022), *cert. docketed*, No. 22-111

Divided Seventh Circuit panel applying *Safeco* standard holds that CMS Manual was not sufficiently "authoritative" to warn pharmacy away from its interpretation of "usual and customary" pricing.

The relator sued Safeway, a nationwide grocery chain that operates pharmacies in many of its stores, for misreporting its "usual and customary" (U&C) prices for certain drugs, which resulted in higher claims to federal payors. The relator alleged that Safeway had not taken into account certain discount programs when reporting its U&C pricing to CMS, resulting in higher U&C pricing and thus higher rates of reimbursement.

At issue on appeal was whether, under *Safeco's* "reckless disregard" standard, a footnote in the CMS Manual addressing discount programs sufficiently warned Safeway that its U&C pricing was false. The Seventh Circuit held that it did not. While the footnote was sufficiently specific to put Safeway on notice that the prices under one of its discount programs should have been reported as U&C, it was not sufficiently authoritative. First, the footnote was isolated in a 57-page chapter of the "voluminous" Medicare Prescription Drug Benefit Manual. That chapter did not discuss U&C pricing anywhere but the footnote. Moreover, the footnote's placement in the chapter suggested that the guidance "was directed at correctly calculating a Part D enrollee's out-of-pocket costs, rather than setting out requirements for pharmacies seeking reimbursement under Medicare and Medicaid."

The court, citing due process concerns, expressed hesitancy to hinge treble damages liability on a single footnote in an ever-shifting CMS Manual that may not have provided Safeway with adequate notice of the agency's interpretation. The Seventh Circuit thus affirmed summary judgment for Safeway.

As discussed further below, the Supreme Court granted certiorari in this case in January 2023.

### *U.S. ex rel. Olhausen v. Arriva Med., LLC*, No. 21-10366, 2022 WL 1203023 (11th Cir. Apr. 22, 2022), *cert. docketed*, No. 22-374

Eleventh Circuit applies Safeco to affirm dismissal of *qui tam* for failure to plead a knowing violation of ambiguous Medicare regulations.

The relator sued Arriva Medical, a supplier of mail-order diabetic testing supplies and other medical products, for violating a number of Medicare rules in the course of its business. The relator alleged that Arriva failed to obtain patient signatures for assignment of benefits forms and failed to enroll its call-center locations with CMS.

The Eleventh Circuit joined the Third, Fourth, Seventh, Eighth, Ninth, and D.C. circuits in applying *Safeco's* scienter standard to the FCA. The court held that the regulations that Arriva was alleged to have violated were subject to "multiple reasonable interpretations." Moreover, Arriva's interpretation of those regulations were "objectively reasonable," negating the scienter element as to both the substantive FCA claims and the conspiracy claim. The Eleventh Circuit thus affirmed dismissal of the complaint.

### *U.S. ex rel. Gugenheim v. Meridian Senior Living, LLC*, 36 F.4th 173 (4th Cir. May 26, 2022)

Fourth Circuit finds scienter could not be inferred from an alleged regulatory violation itself, particularly where the regulation is ambiguous.

Plaintiff-relator Stephen Gugenheim alleged that 45 adult care homes knowingly violated a North Carolina Medicaid billing regulation. North Carolina's Medicaid plan reimburses for personal care services (PCS), which assist disabled adults with the activities of daily living. Under the relevant regulation, each patient is authorized a certain number of PCS based on their personal needs. The defendants billed for the authorized hours of PCS rather than the actual number of hours of services provided. Gugenheim alleged that regulation obligated the defendants to track and bill for the time their employees actually spent providing PCS to individual residents rather than for their daily authorized PCS hours.

Gugenheim's evidence of scienter was the supposed clarity of regulation, which he asserted unambiguously put the defendants on notice that they were required to bill by time. According to Gugenheim, this regulation is so clear that if it is violated, it can be inferred it was violated knowingly. However, there was contradictory guidance from North Carolina Medicaid on this issue. Therefore, the Fourth Circuit concluded the regulation and its related guidance are sufficiently ambiguous to foreclose the possibility of proving scienter based solely on the clarity of the regulation, stating it "cannot infer scienter from an alleged regulatory violation itself, and we 'especially' will not do so 'where there is regulatory ambiguity as to whether' Defendants' conduct even violated the policy."

The Fourth Circuit also rejected Gugenheim's argument that, even if the regulation was ambiguous, defendants should have sought more guidance from North Carolina Medicaid. To this argument, the Fourth Circuit stated, "it is not enough to show that Defendants could have sought more guidance about an ambiguous regulation." Thus, because Gugenheim identified no evidence from which a reasonable jury could conclude that the defendants acted with the requisite scienter, the Fourth Circuit held the district court appropriately granted the defendants' motion for summary judgment.

### *U.S. ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340 (4th Cir. Jan. 25, 2022), *vacated on rehr'g en banc*, 49 F.4th 873 (4th Cir. Sept. 23, 2022)

Equally divided Fourth Circuit vacates panel decision applying *Safeco* to the FCA, allowing district court's dismissal of *qui tam* to stand.

Relator Troy Sheldon sued his employer, Forest Laboratories, LLC, for an alleged fraudulent price reporting scheme under the Medicaid Drug Rebate Statute. The complaint alleged that Forest's false pricing reports reduced the rebates Forest paid to participating states and resulted in the federal government paying at least $680 million more than it would have if the pricing reports had been accurate.

A divided Fourth Circuit panel upheld the district court's dismissal of the complaint. It joined the other circuit courts to consider the issue in applying *Safeco's* "reckless disregard" standard to the FCA, holding that an FCA defendant "cannot act 'knowingly' if it bases its actions on an objectively reasonable interpretation of the relevant statute when it has not been warned away from that interpretation by authoritative guidance."

Applying the *Safeco* standard, the Fourth Circuit held that the relator failed to plead that Forest "knowingly" submitted false claims. The court held that the Rebate Statute could be fairly read to permit the pricing scheme Forest used in its reports to the government, so Forest's interpretation was "objectively reasonable." Further, there was no authoritative guidance warning Forest away from its interpretation. The court noted that the exact pricing scheme at issue had been brought to CMS's attention, but CMS declined to issue clarifying guidance. Instead, CMS repeatedly instructed manufacturers to make "reasonable assumptions" in their pricing, which Forest did here. Thus, the relator could not plausibly allege that Forest "knowingly" submitted a false pricing report under the FCA. Judge James Wynn authored a lengthy dissent challenging *Safeco's* applicability in the FCA context.

On rehearing *en banc*, an evenly divided Fourth Circuit issued a per curiam order vacating the original panel's opinion and affirming the district court's dismissal of the complaint. No opinion issued.

#### *Supreme Court Grants Certiorari*

In January 2023, the Supreme Court granted certiorari in a pair of Seventh Circuit cases — *U.S. ex rel. Schutte v. SuperValu Inc.*, No. 21-1326, and *U.S. ex rel. Proctor v. Safeway, Inc.*, No. 22-111. In these cases, the Seventh Circuit joined six other circuits — the Third, Fourth, Eighth, Ninth, Eleventh, and D.C. circuits — in applying the Supreme Court's reasoning in *Safeco Ins. Co. v. Burr* to interpret "reckless disregard" in the FCA context. Specifically, acting under an incorrect interpretation of a relevant statute or regulation is not reckless disregard if the defendant's interpretation was objectively reasonable and no authoritative guidance cautioned against the defendant's interpretation.

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

The relators argued that the *Safeco* standard, as applied in FCA cases, has created a "special rule" that scienter cannot be shown as a matter of law if the defendant's conduct was consistent with a reasonable interpretation of the law even if the defendant subjectively knew its conduct was unlawful. As such, the question relators posed to the Supreme Court is "whether and when a defendant's contemporaneous subjective understanding or beliefs about the lawfulness of its conduct are relevant to whether it 'knowingly' violated the False Claims Act."

## 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. Jacobs v. Walgreen Co.,*** **No. 21-20463, 2022 WL 613160 (5th Cir. Mar. 2, 2022)**
Fifth Circuit holds that complaint alleging examples of fraudulent practices must allege facts that lead to inference conduct was not innocent mistake or even negligence.

In this matter, whistleblower Bridgette Jacobs, a former Walgreens pharmacist, filed a *qui tam* complaint in the Southern District of Texas alleging that Walgreens billed the government for incorrect medications and in incorrect dosing amounts. However, Jacobs's complaint contained only 10 examples of alleged fraudulent billing, which her complaint characterized as "mistakes."

The district court dismissed the case for failure to plead fraud with particularity, and the Fifth Circuit affirmed in a short opinion, reasoning that the plaintiff did not "plead[] facts supporting an inference that the allegedly fraudulent conduct amounted to anything more than innocent mistake or neglect." The complaint therefore failed to state a claim because the FCA does not confer liability "for innocent mistakes or neglect."

***U.S. ex rel. Sibley v. Univ. of Chicago Med. Ctr.,*** **44 F.4th 646 (7th Cir. Aug. 11, 2022)**
Medical debt collection agencies and their clients may be liable under the FCA for the agencies' knowing failure to comply with Medicare's "bad debt" collection requirements.

The relator, Kenya Sibley, filed a *qui tam* action against the University of Chicago Medical Center (and its medical billing and debt collection vendors) alleging that the companies violated the FCA by failing to make reasonable efforts to recoup Medicare deductibles and coinsurance payments. By regulation, CMS reimburses providers when Medicare patients fail to make required deductible or coinsurance payments. As a precondition for such reimbursement, the provider must first make "reasonable efforts" to collect those debts for at least 120 days.

Sibley alleged that Chicago Medical Center (CMC) discovered through an internal audit that its debt collection vendor had tasked only one part-time employee with pursuing all of its Medicare beneficiary debt. As such, Sibley alleged that CMC must have known its vendor was not engaging in reasonable collection efforts on its behalf, therefore rendering any subsequent claims for bad debt reimbursement from CMS false. In addition, Sibley alleged that CMC knowingly avoided an obligation to repay the government for past bad debts claimed following bad-faith collection efforts. The complaint also alleged that CMC's medical billing and debt collection vendors were liable in their own right for causing the CMC to submit false claims.

The district court dismissed the complaint in its entirety, and the Seventh Circuit affirmed in part and reversed in part. In doing so, the Seventh Circuit found that Sibley failed to plead specific examples of patient debts that CMC knew were not reasonably pursued by its vendor, such that they were not eligible for reimbursement by CMS. Sibley, therefore, had not sufficiently pled scienter. However, with respect to the debt collection vendor, the Seventh Circuit reversed the trial court's order of dismissal, noting that the relators had adequately pled materiality, because "it is difficult to imagine that the government would knowingly and systematically reimburse Medicare providers for purported 'bad debts' that they did not actually attempt, in good faith, to collect."

## ANTI-KICKBACK STATUTE

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

***U.S. ex rel. O'Bier v. TidalHealth Nanticoke, Inc.,*** **No. 21-2123, 2022 WL 264554 (3d Cir. Jan. 28, 2022)**

Relator's allegation that a hospital "almost exclusively" refers patients to competitors, without more, is insufficient to state a claim under the FCA.

Realtor Chris O'Bier, owner of a durable medical equipment (DME) supply company, filed an FCA *qui tam* suit against TidalHealth Nanticoke, Inc., premised on violations of the Stark Law, AKS, Medicare's freedom-of-choice rules, and medically unnecessary services. O'Bier claimed that TidalHealth's hospital "almost exclusively" referred patients to O'Bier's competitors and discouraged patients from using O'Bier's company, Peninsula. The district court dismissed the case, and O'Bier appealed.

On appeal, the Third Circuit affirmed. The court noted first that O'Bier failed to identify a compensation arrangement that considered the volume or value of referrals in violation of the Stark Law. While the hospital employed the prescribing physicians, there was no evidence that the prescribers' referral patterns affected their compensation. Second, for purposes of AKS, O'Bier's statement that the prescribers "almost exclusively" referred to competitors does not provide for any specific inducement affecting their referrals. Third, the court observed that, while it was unclear whether Medicare's freedom-of-choice rules applied to private parties, even if they did, O'Bier did not show that any of the patients received Medicare. And fourth, O'Bier failed to allege that the prescribers prescribed medically unnecessary DME.

***U.S. ex rel. Chao v. Medtronic PLC,*** **No. 2:17-cv-01903-ODW, 2022 WL 541604 (C.D. Cal. Feb. 23, 2022)**

California district court denies defendants' motion to dismiss, finding that allegations were sufficient to plead an AKS-based FCA violation and noting that "even some fair-market-value payments will qualify as illegal kickbacks."

Defendants are medical-device manufacturers that make a "Pipeline" device, which is surgically inserted at the site of a brain aneurysm. The relator, Dr. Kuo Chao, alleged that claims for reimbursement for these Pipelines were tainted by a violation of the AKS. After the government declined to intervene, Chao proceeded with the litigation, and defendants moved to dismiss for failure to meet the pleading standards under Rules 12(b)(6) and 9(b).

While Chao alleged four different types of kickbacks, the court focused its analysis on one: that Medtronic overpaid physicians to serve as proctors to teach other physicians how to perform the Pipeline procedure. Medtronic argued that Chao failed to plead Medtronic's noncompliance with the AKS's personal services safe harbor provision, including principally by failing to allege that the payments Medtronic made to its proctors exceeded the fair market value of the proctors' services.

The court disagreed and denied the motion to dismiss. First, it found that Chao's allegations that the payments Medtronic provided to proctors exceeded the fair market value of the proctors' services was sufficient to avoid the personal services safe harbor. The court further noted that "even some fair-market-value payments will qualify as illegal kickbacks, such as when the payor has considered the volume of reimbursable business between the parties in providing compensation and otherwise intends for the compensation to function as an inducement for more business." Finally, Chao's allegation that Medtronic's practice of engaging and paying proctors was a "system … designed to reward doctors for using Pipelines," was a "plausible assertion which, if true, would take the payments out of the safe harbor, regardless of whether those payments were made at fair market value."

*Commentary*

## CIRCUIT SPLIT ON ANTI-KICKBACK STATUTE CAUSATION

The Eighth Circuit established a but-for causation standard in FCA cases based upon alleged violations of the Anti-Kickback Statute (AKS), relying on the plain language of the statute, and creating a split with the Third Circuit.

### *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89 (3d Cir. Jan. 19, 2018)

In its 2018 *Greenfield* decision, the Third Circuit held that a relator pursuing an FCA action based on a violation of the AKS does not have to show that a "kickback directly influenced a patient's decision to use a particular medical provider." It found that a causal connection between the alleged AKS violation and the submission of a false claim was unnecessary, emphasizing the legislative history and intent of the drafters, as well as the "incongruous results" that might occur if the court accepted a but-for causation standard. Instead, the Third Circuit held that a relator need only show that *at least one* of the treated patients for whom the defendant medical provider submitted claims for reimbursement was exposed to a referral or recommendation to that provider in violation of the AKS. The court held that a relator need not show that a kickback *actually* influenced a patient's or medical professional's judgment.

### *U.S. ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828 (8th Cir. July 26, 2022)

The Eighth Circuit rejected *Greenfield* this year in the Cairns decision, finding that the plain language "resulting from" the statute requires that the AKS violation be the but-for cause of the false claims submitted.

In reaching this conclusion, the court declined to consider legislative history, stating "[s]tarting with legislative history and purpose . . . is no way to read a statute" and "when a statute is unambiguous, we start and end in the same place: with the words of the statute itself."

In *Cairns*, a set of physician relators filed a complaint against another physician, alleging that he violated the FCA because he submitted claims for items that resulted from a violation of the Anti-Kickback Statute. Specifically, Cairns submitted claims for spinal implants that he ordered from a single distributor with which he had a close financial relationship and, later, an ownership stake.

The government intervened, and the case eventually went to trial on several of the FCA counts. The jury found for the government on two counts. Cairns appealed, principally challenging the district court's jury instruction regarding the standard required to prove causation between an AKS violation and the "items or service" included in the false claim.

On appeal, the Eighth Circuit held that the plain meaning of the FCA requires a but-for causal connection between an AKS violation and the "items or services" included in the claim. The court focused on the meaning of the phrase "resulting from" within the 2010 amendments to the AKS, which is not defined by statute. Relying on the dictionary definition and analogous terminology in the 2014 Supreme Court opinion, *Burrage v. United States*, the Eighth Circuit concluded that the statutory text required a but-for standard.

In adopting this standard, the court rejected the government's "alternative causal standards" for proving causation, including whether the alleged kickbacks "tainted" the claims or the AKS violation "may have been a contributing factor." To support its argument, the government relied on pre-2010 cases, which concluded that the non-disclosure of an AKS violation was enough to make a claim false regardless of whether a causal relationship existed. The government argued that the 2010 amendment "simply codified" these holdings. The court disagreed, noting that in the 2010 amendment of the AKS, Congress chose to add the phrase "resulting from," which it stated was "unambiguously causal." The court similarly rejected the government's arguments based on the legislative history of the 2010 amendment.

## STANDARD FOR DISMISSAL BY GOVERNMENT

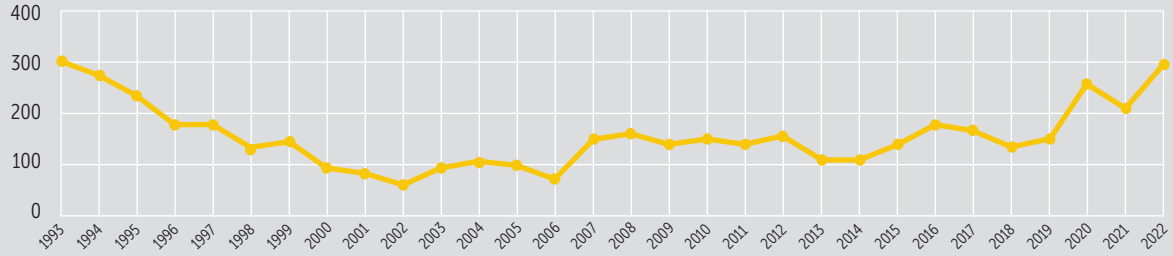
***U.S. ex rel. Borzilleri v. Bayer Healthcare Pharms. Inc.,* 24 F.4th 32 (1st Cir. Jan. 21, 2022)**

First Circuit addresses the purpose of the statutorily required hearing held when the government moves to dismiss a relator's FCA action.

Section 3730(c)(2)(A) requires a hearing when the government moves to dismiss an FCA action. In a case of first impression, the First Circuit addressed the purpose and applicable standards for that hearing. After analyzing the statutory text, the court declined to follow other courts, such as the Ninth Circuit, that place an "extra-textual" burden on the government to provide a rational relation between dismissal and a valid governmental purpose. The First Circuit concluded that type of burden would often turn such hearings into time-consuming mini trials that would be inappropriate, especially where government resources are at issue. Instead, the court held that the government must only provide its reasons for dismissal so that a relator can articulate its arguments for why the government should withdraw its motion.

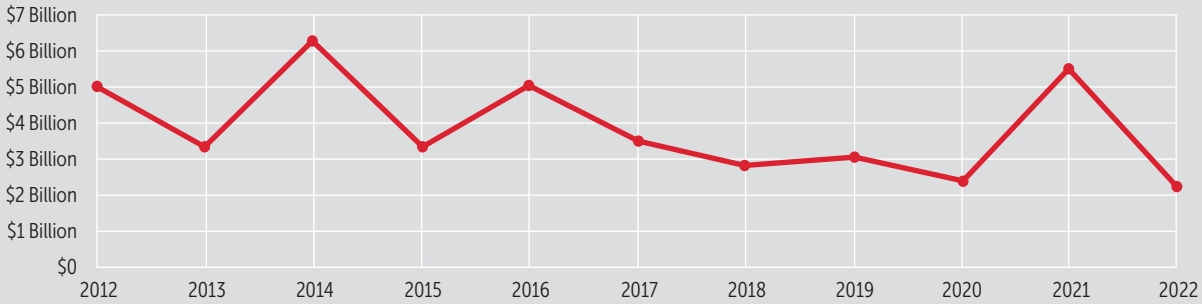
Additionally, the court held that a relator may also use the hearing to make arguments that the government, in attempting to dismiss the action, exceeds its constitutional limitations (e.g., by using arbitrary or unjustifiable standards such as race or religion) or attempting to interfere with the judicial system's ability to adjudicate the matter (e.g., by submitting false documents). But unless the relator can show that either situation is occurring, a district court should be required to grant the government's motion.

**Non-*Qui Tam* Actions Filed 1993-2022**




The government independently brought more total actions in FY2022 (296) than any year since 1993.

**Total FCA Recoveries 2012-2022**




Judgements overall are down significantly ($2.2 billion from $5.7 billion in FY2021). However, even accounting for the Purdue Pharma settlement in FY2021, settlements and judgements do not appear to have reverted to pre-pandemic levels ($3.07 billion in FY2019). The increased number of total actions coupled with the decrease in total recoveries is likely explained by DOJ's stated emphasis on investigating stimulus fraud, which often results in low-dollar recoveries.

## 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.

***Lanahan v. Cnty. of Cook*, 41 F.4th 854 (7th Cir. July 20, 2022)**

Seventh Circuit applies rigorous standard for linking false claims to alleged wrongful behavior in rejecting a relator's attempt to base FCA claims on actions the defendant took after receiving federal payments.

Relator Noreen Lanahan accused Cook County of violating the FCA by accumulating millions of dollars through federal grants for which it was not legally entitled. Lanahan alleged that the county engaged in several fraudulent practices involving federal grants, including submitting inaccurate reimbursement requests for an H1N1 influenza grant and facilitating a kickback scheme wherein the Hektoen Institute of Medicine retained up to 15% of its doctors' federal research grants.

The Seventh Circuit affirmed the case's dismissal with prejudice stating that allegations for false claims must include specific facts demonstrating what occurred at the "individualized transactional level." As an example, Lanahan alleged required expense reports regarding the grants were false because they were based on expenses estimated after the fact as opposed to contemporaneously recorded. The court found this insufficient as it did not allege how the allocations were calculated or how the expense reports were prepared. Additionally, Lanahan largely based her claims on events that occurred after the federal government disbursed the grant money to Cook County infer falsity at the time of the certification based solely upon conduct that occurred after the certification. As such, Lanahan failed to allege that Cook County submitted false statements to the federal government. Additionally, although Lanahan's allegations may raise concerns about accounting failures, procedural irregularities, and regulatory violations, these concerns do not automatically give rise to an FCA claim. "Relator's assertions of regulatory or contractual violations are similarly incapable of establishing an FCA claim absent some connection between the breaches and a false statement or claim for payment, which Relator has not pleaded."

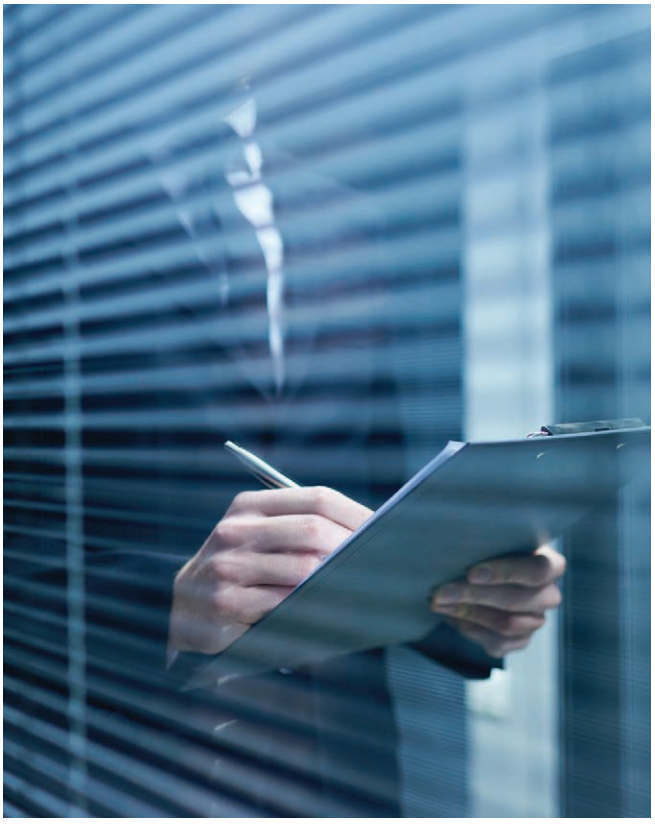
***U.S. ex rel. Nicholson v. Medcom Carolinas, Inc.*, 42 F.4th 185 (4th Cir. July 21, 2022)**

Fourth Circuit affirms dismissal of AKS-based FCA complaint for failure to meet Rule 9(b)'s pleading standards.

Relator Haile Nicholson accused Medcom Inc. of violating the FCA by paying independent contractors commissions based on their sales of skin grafts to a Veterans Administration hospital. The district court dismissed, finding that Nicholson failed to meet the pleading standards under Fed. R. Civ. P. 9(b).

On appeal, the Fourth Circuit noted that an FCA violation could be based on a company paying "a medical-device salesperson by commission per sale or based on the value of sales and get paid back in federal healthcare money."

But the court nonetheless affirmed, agreeing with the district court that the complaint fell far short of the necessary specificity to survive a motion to dismiss under Rule 9(b). It noted, for example, that Nicholson failed to allege any information about how the independent contractors were paid, how they were instructed to push the product, or how they induced sales. As a result, Nicholson's complaint amounted to "classic conclusory language . . . not much more than saying that [the defendants] were using commissions salespeople to submit false claims, a legal conclusion."



***UPPI LLC v. Cardinal Health, Inc.,*** **No. 21-35905, 2022 WL 3594081 (9th Cir. Aug. 23, 2022)**

Ninth Circuit reversed a ruling that relator UPPI LLC failed to allege falsity and materiality under Rule 9(b) where the district court impermissibly inferred that the government agency was aware of the arrangement that gave rise to FCA liability.

UPPI LLC alleged that service-disabled veteran-owned small businesses (SDVOSBs) and Cardinal Health misled the government into awarding contracts to the SDVOSBs while Cardinal Health performed most of the work and kept most of the revenue, leaving only a nominal amount of work and payment for the SDVOSBs. The Eleventh Circuit found that UPPI LLC adequately pleaded a claim under the FCA through a promissory fraud and implied false certification theory of liability. Under the promissory fraud, the court found that UPPI LLC specified that defendants fraudulently induced the government into entering into eight contracts with defendants by promising that SDVOSBs would perform the contract, when Cardinal Health would be performing the contract. Under the implied false certification theory, the court ruled that UPPI LLC adequately pled that SDVOSBs submitted invoices implying that they had done the work under the contract.

The Eleventh Circuit found that although the VA was aware of Cardinal's involvement at the time of the award of the contract and payment of claims, the district court impermissibly inferred that the government was aware of the extent Cardinal controlled the contract and the limited involvement of the SDVOSBs, which served as the basis of the violation. To derive the government agency's actual knowledge sufficient to nullify liability from the allegation that Cardinal was involved would be an inference in favor of the moving party, which is not permissible at the motion-to-dismiss stage.

## FIRST TO FILE

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.

***Cho v. Surgery Partners, Inc.,*** **30 F.4th 1035 (11th Cir. Apr. 1, 2022)**

Eleventh Circuit found that, under the plain language of the FCA, the proper point of reference for the first-to-file analysis is the original complaint, not the amended complaint.

Relators Dr. Sheldon Cho and Dawn Baker alleged that defendants H.I.G. Capital, LLC, and H.I.G. Surgery Centers, LLC, ("HIG entities") violated the FCA by billing Medicare and other government programs for medically unnecessary urine drug tests. When Cho and Baker filed their original complaint, which brought claims against the HIG entities and dozens of other defendants, another FCA action related to the same allegedly fraudulent scheme was already pending. The first-filed FCA action, however, did not name the HIG entities as defendants. After the first-filed FCA action settled four years later, Cho and Baker amended their complaint to name only the HIG entities as defendants.

The Eleventh Circuit affirmed the district court's dismissal of Cho and Baker's amended complaint under the FCA's first-to-file bar, holding that the bar applied to the pending case since it "related" to the first-filed action, which had been settled. The court first decided that the relevant inquiry is whether a related action is pending when a relator files her *initial* complaint, not when she files an amended complaint. The court reasoned that the statutory phrase "to 'bring' an 'action'" means "the initiation of legal proceedings in a suit" and noted that Cho and Baker could not "evade" the bar by amending pleadings after an existing action was dismissed.

The court next held that actions are "related" under the first-to-file bar if they "incorporate the same material elements of fraud," i.e., "rely on the same essential facts." The court also advised that courts evaluating actions to "compare[] the complaints side-by-side and ask[] whether the later complaint alleges a fraudulent scheme the government already would be equipped to investigate based on the first complaint." Applying this test, the court held that the actions were related because both alleged the same fraudulent scheme. The court rejected Cho and Baker's argument that, because the HIG entities were not defendants in the earlier action, the two were not related. The court similarly rejected Cho and Baker's argument that their case was distinguished by its conspiracy claim, reasoning that the conspiracy claim was still "based on the same fraudulent scheme that was alleged" in the first-filed action.

*Commentary*

## INSURERS & PROVIDERS BEWARE: MEDICARE ADVANTAGE PROGRAMS SUBJECT TO SIGNIFICANT FCA SCRUTINY

The increasing popularity of Medicare Advantage will continue to attract heightened government scrutiny in 2023, potentially exposing health insurers and medical providers to significant liability under the FCA.

Medicare Advantage — also known as Medicare Part C — allows Medicare beneficiaries to enroll in health insurance plans that are owned and operated by private insurers. Such plans have many important patient benefits, such as improved preventive services, consistency of care, and generally lower rates of hospitalization.

Unlike traditional Medicare, which bills per services rendered, Medicare Advantage bills insurers a fixed rate per beneficiary, regardless of how many services the beneficiary receives. This fixed rate provides the insurers incentives to reduce unnecessary care and improve efficiency, and promotes preventive care, which can in turn reduce costs. The rate paid per beneficiary, however, is determined, in part, through a risk adjustment process that assesses the overall health of each beneficiary to determine whether more money is needed for care. Certain diagnosis codes applied to patients can affect the risk adjustment process and result in higher payments to the plan. The government believes participants in Medicare Advantage plans, including insurers and healthcare providers, may add invalid diagnosis codes or fail to remove outdated diagnosis codes from the beneficiaries' records causing overpayments to the plans. Some put the cost of this alleged "upcoding" at up to $25 billion in overpayments each year.

Medicare Advantage continues to gain popularity. In 2022, 49% of all eligible Medicare beneficiaries were enrolled in Medicare Advantage. This number is expected to increase to 60% by 2030, making Medicare Advantage the predominant form of Medicare in the United States. In 2022, Medicare Advantage accounted for 55% — or $427 billion — of the federal government's total Medicare spending.

As Medicare Advantage continues to grow so, too, does DOJ's scrutiny of the program. In early 2022, DOJ identified Medicare Advantage as an "important priority" in its FCA enforcement strategy. The department emphasized that insurers and healthcare providers face significant risk under the FCA if they "manipulate[] the risk adjustment process by submitting unsupported diagnosis codes to make their patients appear sicker than they actually [a]re." These statements confirm that Medicare Advantage diagnosis coding will continue to be a hot-button enforcement issue in 2023.

Indeed, 80% of the largest Medicare Advantage insurers have been audited or sued for overcharging the program. DOJ has increasingly intervened in such litigation. For example, DOJ accused UnitedHealth Group of running a nationwide program designed to identify additional diagnoses that would inflate its risk adjustment proceeds[1]. Similarly, DOJ accused multiple insurance companies and healthcare providers of violating the FCA by submitting fraudulent diagnosis codes to CMS to increase payments for the plan beneficiaries. Common allegations include (1) using after-the-fact chart reviews to find additional codes; (2) giving physicians problem lists with suggested diagnoses in advance of appointments; (3) post-appointment chart reviews and queries to physicians suggesting additional codes; and (4) in the case of insurance companies, failure to audit codes submitted by providers before sending the data to CMS for the risk adjustment process. While many of these practices appear fraudulent to DOJ, plans argue that missed diagnoses not only cost them money but lead to poor patient care as conditions are going unreported.

1 The court partially dismissed the claims, and DOJ declined to file a second-amended complaint.

Developments in significant cases this year will shed light on whether DOJ's theories of liability will be embraced by the courts and juries.

DOJ, however, is not the only enforcement entity targeting Medicare Advantage plans. The U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG) has issued multiple significant reports on alleged Medicare Advantage plans abuse over the last several years. In additional overall analysis, OIG is also targeting specific plans and publicly announcing allegations of overpayment based on diagnoses not corroborated by medical records. And in April 2022, OIG raised concerns that Medicare Advantage organizations were denying beneficiaries access to services they were entitled to receive so that the organizations could increase their profits.

Some believe the government should take its enforcement efforts even further. In May 2022 — on the heels of OIG's April report — the American Hospital Association (AHA) urged DOJ to "take swift action" against Medicare Advantage plans that violated the FCA by denying patients their rightful Medicare coverage. AHA called for the formation of a task force that would focus directly on commercial insurers that commit Medicare Advantage fraud. The letter stated: "This problem has grown so large — and has lasted for so long — that only the prospect of civil and criminal penalties can adequately prevent the widespread fraud certain [Medicare Advantage organizations] are perpetrating against sick and elderly patients across the country."

It is not surprising that DOJ enforcement efforts often follow the money. Medicare Advantage therefore remains an attractive target for enforcement in 2023. As the government increasingly focuses on Medicare Advantage, so should insurers and providers.

## 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. Mark v. Shamir USA, Inc.,*** **2022 WL 327475, No. 20-56280 (9th Cir. Feb. 3, 2022)**

Ninth Circuit holds that the public disclosure of generalized fraud is insufficient for dismissal under the FCA's public disclosure bar.

Relator Richard Mark filed a *qui tam* suit against his former employer, Shamir USA, Inc., and its affiliates, for engaging in an alleged kickback scheme in violation of the FCA. Mark asserted that Shamir knew that government insurance plans reimbursed optical lenses based on the purported invoice price. Using this knowledge, Shamir's rewards program offered discounts to eyecare professionals to lower the prices, but the invoices Shamir submitted to the government used the pre-discount prices. The district court dismissed Mark's suit as barred by the FCA's public disclosure bar because Shamir previously posted announcements publicizing the rebates offered through its rewards program.

On appeal, the Ninth Circuit reasoned that if a public disclosure of "problems" or even some "generalized fraud" could bar a *qui tam* action, the government would be deprived of whistleblower information that could lead to recovery and prevent further fraud. The court concluded that the information in disclosures was so innocuous that there was no public disclosure of a transaction or allegation of fraud. Thus, the public disclosure bar was not triggered.

***Roe v. Stanford Health Care,*** **No. 20-55874, 2022 WL 796798 (9th Cir. Mar. 15, 2022)**

Ninth Circuit joined the majority of circuits in holding that materials released by a government agency under the Freedom of Information Act (FOIA) can trigger the public disclosure bar.

Relator Emily Roe brought this FCA action alleging that Stanford Health Care and others engaged in fraudulent Medicare billing. The district court dismissed Roe's second amended complaint with prejudice, relying on the FCA's public disclosure bar.

The Ninth Circuit agreed with the district court that Roe's second amended complaint was almost entirely premised on publicly disclosed Medicare data Roe obtained through FOIA requests. Therefore, the Ninth Circuit held that materials released by a government agency under FOIA can trigger the public disclosure bar of the FCA.

The court also ruled that Roe's operative complaint was not saved by the FCA's original source exception, which allows private suits by someone with "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions" (31 U.S.C. § 3730(e)(4)(B)). Neither Roe's specialized expertise, the allegedly fraudulent billing to a private insurer she personally observed, nor the other information she points to materially added to the Medicare data obtained through Roe's FOIA requests.

***U.S. ex rel. Silbersher v. Allergan, Inc.,*** **46 F.4th 991 (9th Cir. Aug. 25, 2022)**

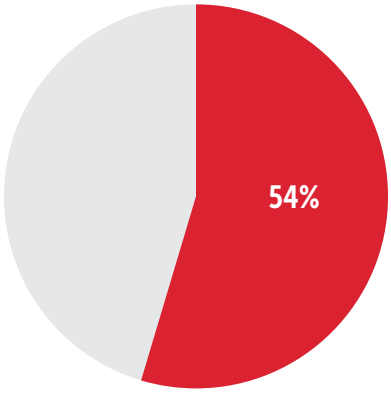
*Ex parte* patent prosecution is an "other federal hearing" where publicly disclosed information may bar an FCA action.

Relator alleged that the defendant pharmaceutical company fraudulently obtained patents on drugs, thus preventing competitors from entering the market and allowing the company to charge Medicare-inflated prices. All of the key factual information in the complaint was publicly disclosed and found on government websites, including for the Patent and Trademark Office (PTO). Though the district court found that the public disclosure bar did not apply, the Ninth Circuit reversed. It found that the *ex parte* patent prosecution proceedings that take place when inventors submit applications to the PTO are an "other Federal . . . hearing" as contemplated in 31 U.S.C. § 3730(e)(4)(A)(ii), sufficient to trigger the public disclosure bar. The Ninth Circuit remanded the case back to the district court to determine whether the relator was an "original source" of the disclosure.

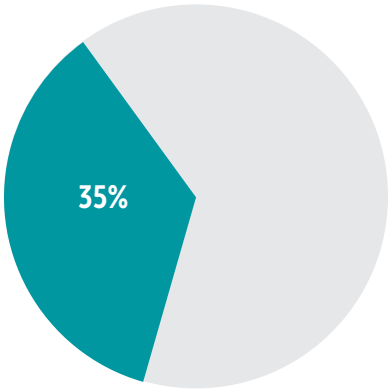
***U.S. ex rel. CKD Project, LLC v. Fresenius Med. Care Holdings, Inc.,*** **No. 21-2117, 2022 WL 17818587 (2d Cir. Dec. 20, 2022)**

SEC filings describing material elements of the alleged fraud constitute public disclosure barring relator's complaint.

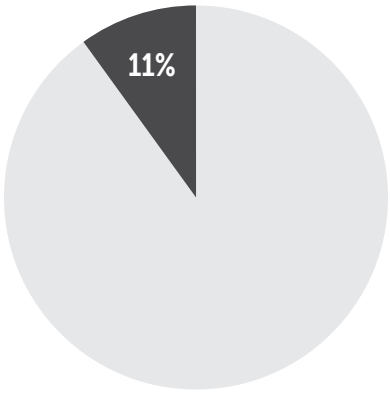
CKD, a professional whistleblower company, made several allegations regarding the structure of joint ventures the defendant entered into with dialysis centers, claiming the arrangements violated the AKS. Applying the "material elements" test, the court found that all of the material elements of the joint ventures were disclosed in the company's SEC filings. Because the court found that each of the facts that CKD alleged were described in the SEC filings, CKD's claims were barred.




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




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




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

## GOVERNMENT ACTION BAR

The FCA's government action bar prevents relators from bringing *qui tam* actions "based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the government is already a party" (31 U.S.C. § 3730(e)(3)).

***U.S. ex rel. Vt. National Tel. Co. v. Northstar Wireless, LLC,* 34 F.4th 29 (D.C. Cir. May 17, 2022)**

D.C. Circuit declines to apply the government action bar where an administrative proceeding does not impose civil monetary penalties and finds materiality sufficiently pleaded where the conduct had the potential to affect the government's decision.

In an FCC auction for wireless spectrum licenses, two small businesses, Northstar and SNR, successfully won a large percentage of licenses. As an element of the bidding process, the FCC explained that small businesses would be eligible to receive bidding credits entitling them to a discount on their winning bids. Several companies petitioned the results of this auction, arguing that Northstar and SNR were ineligible for the small business credits because those businesses were effectively controlled by a much larger business, DISH Network, that itself was ineligible for the credits. The FCC agreed and concluded that Northstar and SNR were ineligible for bidding credits. Following this decision, Northstar and SNR selectively defaulted on several of their obligations to buy the licenses they were awarded. FCC levied a fine ("default payment") because of these defaults. Amidst the fallout of the FCC's bidding credits decision, relator Vermont Telephone brought an FCA claim against Northstar and SNR, alleging that the small businesses provided false certifications and manipulated the FCC's auction rules to secure fraudulent bidding credits. The district court dismissed Vermont Telephone's suit on two independent grounds: (1) that the government action bar foreclosed an FCA claim based on transactions that were the subject of an administrative civil money penalty; and (2) that Vermont Telephone failed to satisfy the act's materiality standard.

The D.C. Circuit reversed on appeal. First, the court declined to apply the government action bar because the FCC's licensing proceeding was separate from its proceeding to assess default payments. The FCC's proceeding to assess default payments arose later, after Northstar and SNR chose to selectively default on their obligations to pay for some of their winning bids. "It would make no sense" for the court to conclude that the FCC's decision to impose default payments could retroactively transform the licensing proceedings into a civil monetary penalty proceeding. Second, the court held that Vermont Telephone adequately pled that Northstar's and SNR's failure to disclose its relationship with DISH Network was material. Vermont Telephone alleged several behaviors, which, if properly disclosed, would have had the potential to affect the FCC's eligibility determinations regarding the bidding credits.

## 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. Tracy v. Emigration Improvement Dist.,*** **No. 21-4059, 2022 WL 16570934 (10th Cir. Nov. 1, 2022)**

Ten-year statute of repose begins to run upon filing of claims as opposed to when government pays the claim.

The Tenth Circuit affirmed dismissal of an untimely filed FCA suit based on the 10-year statute of repose in 31 U.S.C. § 3731(b)(2). In reaching this conclusion, the Tenth Circuit held that the limitations period begins running on the date that "the defendant submits a false claim, not when the government pays the claim." The court explicitly rejected an opinion by the Court of Federal Claims in *Jana, Inc. v. United States,* 41 Fed. Cl. 735 (1998), which had previously held that the 10-year period begins to run at different times depending on whether a suit seeks only civil penalties or actual damages (*Tracy*, 2022 WL 16570934, at *3). The court further distinguished between the three-year statute of limitations that begins to run "when the government knew or should have known about the fraud" and a statute of repose that traditionally begins to run when a specific event occurs – often the last culpable act or omission of the defendant.

## STATUTORY DAMAGES

***U.S. v. Honeywell Int'l Inc.,*** **No. 21-5179, 47 F.4th 805 (D.C. Cir. Aug. 30, 2022)**

D.C. Circuit finds that the *pro tanto* approach to calculating settlement offsets applies in FCA cases.

In 2008, the government filed FCA suits against Honeywell International Inc. and other defendants for allegations related to the creation of faulty Z Shield bulletproof vests. The government sought a total of roughly $35 million in damages.

After other defendants reached settlements totaling $36 million, Honeywell asked the district court to apply *pro tanto* damages to offset the settlements, which would result in Honeywell owing $0. The government argued that the proportionate share approach should apply, which would require Honeywell to be responsible for its proportionate share of the $35 million in damages, regardless of settlements reached with other parties. On June 18, 2021, D.C. District Court Judge Paul Friedman certified for an interlocutory appeal the question of whether the *pro tanto* approach or the proportionate share approach was the appropriate method for calculating damages offsets for FCA defendants.

On August 30, 2022, the D.C. Circuit issued its opinion finding that the *pro tanto* rule is the appropriate approach to calculate settlement credits under the FCA. The D.C. Circuit reasoned that the *pro tanto* approach was similar to joint and several liability, which courts have often applied in FCA cases with multiple parties that cause the same indivisible harm to the government. While the court acknowledged that *pro tanto* damages could result in a non-settling party not paying any damages if the government fully recovers its losses from other defendants, it explained that "consistent with the FCA, the *pro tanto* rule leaves the government in the driver's seat to pursue and punish false claims according to its priorities."

## ATTORNEYS' FEE AWARDS

***U.S. ex rel. Bryant v. Cmty. Health Sys., Inc.,*** **24 F.4th 1024 (6th Cir. Jan. 25, 2022)**

Sixth Circuit finds that the FCA's first-to-file and public disclosure rules do not bar groups of whistleblowers, who uncovered multiple independent parts of the same complex scheme, from recovering attorneys' fees.

Various relators sued, among others, Community Health Systems (CHS). The relators alleged that CHS submitted fraudulent claims to Medicaid and Medicare for medically unnecessary hospital admissions. The government intervened in these cases, which were consolidated, and counsel for relators performed thousands of hours of work assisting the government. The relators, the government, and CHS entered into a settlement agreement that disposed of the underlying claims in all the cases; however, the settlement did not address the allocation of attorneys' fees under the FCA. CHS subsequently took the position that the relators were not entitled to attorneys' fees, claiming that the relators' claims were barred by the first-to-file and public disclosure rules.

The Sixth Circuit, reversing the decision of the Tennessee district court, held that CHS could not rely on those provisions of the FCA after reaching a global settlement that was the result of a collaborative process between the government and relators' counsel. The court reasoned that the FCA's first-to-file and public disclosure rules act as counterbalances to the FCA's provisions that allow the relator to share in the government proceeds when the government successfully litigates or settles the claim the relator originally brought. The purpose of these counterbalances is to discourage opportunistic plaintiffs from bringing parasitic lawsuits.

After first concluding that the relators satisfied the FCA's prerequisites (receiving a portion of the proceeds of a successful settlement and government intervention), the court held that rejecting the application of the statutory bars was consistent with both the statutory text and the legislative intent. The court, emphasizing the low risk of opportunism, concluded that barring recovery of attorneys' fees in these circumstances (where the defendant had already settled with the relators and the government) would be fundamentally inconsistent with Congress's goal of encouraging collaboration between the government and public to uncover fraud. The court, therefore, reversed and remanded the case to the district court to determine an award of reasonable attorneys' fees to relators' counsel.

***U.S. ex rel. Lovell v. AthenaHealth, Inc.,*** **56 F.4th 152 (1st Cir. Dec. 21, 2022)**

First Circuit strikes a blow to private agreements between relators finding that in intervened matters settled by the government only relators who receive a relator's share in the government's settlement agreement should receive attorneys' fee awards.

This matter involved a dispute over relators' entitlement to attorneys' fees in two *qui tam* actions involving multiple relators. After intervening on some of the claims in both *qui tam* actions, the government entered into a settlement agreement that identified one relator ("the first-to-file relator") as the party to receive a relator's share. The agreement noted that two other relators ("secondary relators") had reached their own agreement with the first-to-file relator on the amount they would receive directly from the first-to-file relator. The settlement agreement did not resolve the question of relators' attorneys' fees, resulting in all three relators making claims for attorneys' fee awards.

The district court denied the secondary relators' request for fees because neither relator was the first-to-file, and the two secondary relators appealed. The first to file relator also appealed his award for failure to include fees for work associated with a non-intervened claim.

The First Circuit affirmed the district court's denial of fees to the secondary relators but declined to address whether attorneys' fee awards are categorically restricted to first-to-file relators in matters where a government settlement agreement provides for shares to multiple relators. Instead, the First Circuit held that payments exchanged between relators under a private agreement ancillary to a government settlement agreement do not meet the definition of "relator's share" under the FCA. Where a person fails to receive a relator's share, that person does not meet the requirements for receipt of an attorneys' fees award in an intervened case.

The First Circuit also affirmed the district court's denial of the first-to-file relator's claim for fees on a claim in which the government did not intervene. Because the intervened cause of action and declined cause of action were not substantially interconnected, the district court properly declined to award fees for the declined claim.

*Commentary*

## 2022 CYBERSECURITY ENFORCEMENT INCREASED & 2023 WILL BE WORSE

The government's announcement of renewed emphasis on cybersecurity enforcement spawned million-dollar enforcement actions in 2022. Continued government attention on cybersecurity promises a treacherous enforcement environment in 2023 and beyond.

Several government initiatives in 2021 and 2022 have focused on cybersecurity enforcement. In October 2021, DOJ announced a Civil Cyber-Fraud Initiative to use the FCA to hold companies and individuals accountable for 1) deficient cybersecurity; 2) misrepresentations of cybersecurity; and/or 3) insufficient monitoring or reporting of cybersecurity incidents. The Cyber Incident Reporting for Critical Infrastructure Act of 2022 now requires the Cybersecurity and Infrastructure Security Agency to develop and implement regulations requiring covered entities to report covered cybersecurity incidents. The Safeguards Rule now requires non-banking financial institutions, including mortgage brokers and automobile dealerships, to develop, implement, and maintain a comprehensive cybersecurity program to protect customer information. The deadline for compliance with the Safeguards Rule has been extended to June 2023. All 50 states now have data breach notification laws that include requirements to report certain cybersecurity incidents to the attorney general of the relevant state. Government entities, both state and federal, are increasing their enforcement actions under laws, rules, regulations, and common industry practices. In 2021, President Biden issued an Executive Order focused on improving the entire nation's cybersecurity by ordering government entities to increase cybersecurity and to influence private sector change.

Cybersecurity requirements are common when companies and individuals do work for government entities. The government often requires companies and individuals to certify that they have requisite cybersecurity, represent that cybersecurity procedures are being enforced, have insurance protection for cybersecurity incidents, and that cybersecurity incidents will be monitored and reported in a specific manner. Companies and individuals need to be absolutely aware of any cybersecurity requirements for doing work with the government, how compliance is certified, and how to monitor and report any cybersecurity incident. Often organizations may not even be aware of what they have agreed to. An employee may receive an email link from a government customer and click the boxes certifying compliance in order to earn the work. Many companies may not be prepared for the consequences of such certifications.

In July 2022, DOJ announced the Comprehensive Cyber Review (CCR) and a $9 million Aerojet settlement to resolve cybersecurity fraud claims under the FCA. The Aerojet settlement involved a former employee acting as a whistleblower, who was the senior director of Cyber Security, Compliance, and Controls for Aerojet. The whistleblower claimed that Aerojet had federal contracts that mandated specific cybersecurity standards, and even though Aerojet knew their systems did not meet these standards, Aerojet had fraudulently obtained the contracts while not meeting those cybersecurity standards (see *United States ex rel. Brian Markus v. Aerojet Rocketdyne Holdings Inc., et al.,* 2:15-cv-02245-WBS-AC (E.D. Cal.)).

In March 2022, DOJ announced the just-under $1 million settlement with Comprehensive Health Services for civil cybersecurity fraud claims under the FCA. The principal deputy assistant attorney general for DOJ's Civil Division specifically stated, "This settlement demonstrates the department's commitment to use its civil enforcement tools to pursue government contractors that fail to follow required cybersecurity standards, particularly when they put confidential medical records at risk. We will continue to ensure that those who do business with the government comply with their contractual obligations, including those requiring the protection of sensitive government information." This high-ranking government official previously stated, "As they have in many other aspects of False Claims Act enforcement, we expect whistleblowers to play a significant role in bringing to light known failures and misconduct in the cyber arena." FCA settlements in 2022 demonstrate the government's commitment to make good on its promise of increased enforcement in this space.

2023 promises to be an even more active year for cybersecurity enforcement. DOJ's CCR specifically commented that many of the cybersecurity standards for government contractors were insufficiently rigorous and volunteered to collaborate with other government entities to update cybersecurity contract terms. The CCR specifically promised that when contractual cybersecurity standards were not satisfied, the government would attempt to utilize the FCA to enforce cybersecurity fraud claims. Additionally, certain cybersecurity requirement deadlines are coming up in 2023, which will only increase the pressure on companies and opportunities for potential whistleblowers.

## SERVING THE COMPLAINT

***U.S. ex rel. Sy v. Oakland Physicians Med. Ctr., LLC,* 44 F.4th 565 (6th Cir. Aug. 12, 2022)**
Sixth Circuit upholds dismissal of relators' complaint for failure to effectuate service of summons, even though refiling was barred by the statute of limitations.

Relators Mohamed Sy and Doshuan Edwards filed this *qui tam* suit against their former employer Oakland Physicians Medical Center, LLC. The government declined to intervene, and soon after, the district court unsealed the complaint and directed Sy and Edwards to serve the complaint on Oakland within the 90-day period as set forth in Federal Rule of Civil Procedure 4(m). Within the 90-day period, Sy and Edwards amended their complaint and sent it to Oakland via certified mail without attaching a summons. After the 90-day period expired, Sy and Edwards requested a summons to be issued and then served Oakland the amended complaint with a summons. Upon Oakland's motion, the district court dismissed the relators' amended complaint under Rule 12(b) for insufficient service, finding there was no good cause for the relators' delay in effectuating proper service on Oakland.

On appeal, Sy and Edwards did not argue that there was good cause for their delay, but instead argued that the district court should have used its discretion to grant an extension under Federal Rule of Civil Procedure 4 because the statute of limitations would bar them from re-filing their claims. The Sixth Circuit affirmed the dismissal and set forth a seven-factor balancing test when determining whether a district court should grant a discretionary extension of time to effectuate service in the absence of good cause for the delay.

## WHISTLEBLOWER RETALIATION

***El-Khalil v. Oakwood Healthcare, Inc.,* 23 F.4th 633 (6th Cir. Jan. 10, 2022)**

Sixth Circuit determined that the tolling period for a retaliation claim began when the healthcare company decided not to renew an employee's privileges, not when the employee found out about that decision five days later.

In *Oakwood Healthcare, Inc.,* the First Circuit affirmed the district court's motion for summary judgment because the plaintiff's claim was time barred by the statute of limitations. Ali El-Khalil, a podiatrist at Oakwood, alleged in a report to the government that he saw Oakwood employees submit fraudulent Medicare claims. The Oakwood Medical Executive Committee (MEC) required physicians to regularly reapply for staff privileges for up to two years at a time. In 2015, MEC rejected El-Khalil's application to renew his staff privileges. Despite commencing a series of appeals, he was ultimately issued a final, non-appealable decision by Oakwood's Joint Conference Committee (JCC).

On September 22, 2016, after deliberating into the night, the JCC decided to affirm the denial of El-Khalil's staff privileges. El-Khalil had already gone home for the evening, but members of the JCC noted that their decision was "final." The JCC informed El-Khalil of their decision on September 27, 2016. Three years later, on September 27, 2019, El-Khalil sued Oakwood for violating the whistleblower provision of the FCA, 31 U.S.C. § 3730(h), based on JCC's action. Oakwood moved for summary judgment, arguing that the claim was untimely because JCC's decision became final when it voted on September 22, 2016. The district court agreed that the claim was time barred and granted summary judgment to Oakwood.

On appeal, the Sixth Circuit agreed with the district court and affirmed summary judgment based on the date JCC made its final decision. In its reasoning, the court noted that in FCA retaliation cases, the limitations period commences when the retaliation actually happened. From the record, the court found that it was clear that the retaliation occurred when JCC voted to affirm the denial of El-Khalil's staff privileges. The court found that actual or constructive notice of the denial was not necessary because the text of § 3730(h) does not have a notice requirement. Indeed, the court concluded that El-Khalil had a ripe cause of action, triggering the limitations period, as soon as JCC made its decision that night. The court noted that using El-Khalil's approach of waiting until a plaintiff knows of facts giving rise to a claim would directly contradict the text of 31 U.S.C. § 3730(h)(3), which "starts the clock when the 'retaliation occurred,' not when it was discovered."

***Lam v. Springs Window Fashions, LLC,* 37 F.4th 431 (7th Cir. June 16, 2022)**

Appellate court affirmed summary judgement in favor of Springs Window Fashions holding that executives did not retaliate or fire plaintiff after she reported company owed higher tariffs.

In April 2020, Jennifer Lam sued her former employer, Springs Window Fashions, for allegedly retaliating against her in violation of the FCA over her opinion that the company owed additional tariffs on fabric blankets. The lower court determined that Lam did not identify any specific comments to her by executives and the isolated incidents of frustration described could not support a retaliation claim. The court also determined Lam did not show she was fired in retaliation for addressing the tariff issue, as the complaint did not allege specific facts to show this, and other evidence suggested that Lam's performance-related issues were addressed by the company in specific instances. The court granted summary judgment in favor of the company.

Noting that the Supreme Court had clarified that a "simple lack of good manners" would not deter a reasonable employee from reporting an FCA violation, the Seventh Circuit determined Lam's generic descriptions of the comments made to her did not rise to the standard for retaliation. Additionally, the Seventh Circuit determined that the evidence presented by Lam was insufficient to show that the company fired her because she informed them of their obligation to pay higher tariffs.

***Casias v. Raytheon Co.,* No. 21-1195, 2022 WL 2824256 (10th Cir. July 20, 2022)**

Change of employee's assignment can constitute an adverse employment action even though salary and benefits are not changed.

In July 2022, the Tenth Circuit affirmed a $1 million jury verdict against defendant government contractor based on the Defense Contractor Whistleblower Protection Act. The Tenth Circuit upheld a jury verdict even though the whistleblower's title, salary, and benefits stayed the same after the reassignment, holding that the jury could infer the reassignment of the whistleblower from supervising dozens of employees to supervising only two employees was an adverse employment action because a "change in responsibilities, combined with a decrease in reputation and job prospects, can constitute an adverse employment action."

***Crosbie v. Highmark, Inc.,* 47 F.4th 140 (3rd Cir. Aug. 26, 2022)**

Employee's whistleblowing under the FCA does not shield the employee from termination for separate misconduct.

Discharged employee Alastair Crosbie sued his former employers, Gateway Health Plan and Highmark Inc., a health insurance company, for unlawful retaliation under the FCA. Gateway initially hired Crosbie to investigate fraud in Highmark's network of doctors. In 2017, Crosbie's audit of Highmark's doctors gave rise to compliance concerns, such as doctors lacking required Medicaid licenses and having prior convictions based on opioid prescription sales. Crosbie reported these concerns to his managers at Gateway, including manager Jim Burgess. The Gateway managers decided not to investigate these issues. In October 2018, Crosbie's coworker claimed that Crosbie called her "Miss Piggy" and "oinked at her." Others witnessed this encounter, and Gateway fired Crosbie two days later. Crosbie's coworker discussed these harassment issues with Burgess. Crosbie sued Gateway and Highmark under the FCA for retaliation. The district court granted the employers' motion for summary judgment and found that the employers' stated reason for terminating Crosbie for harassment was not mere pretext.

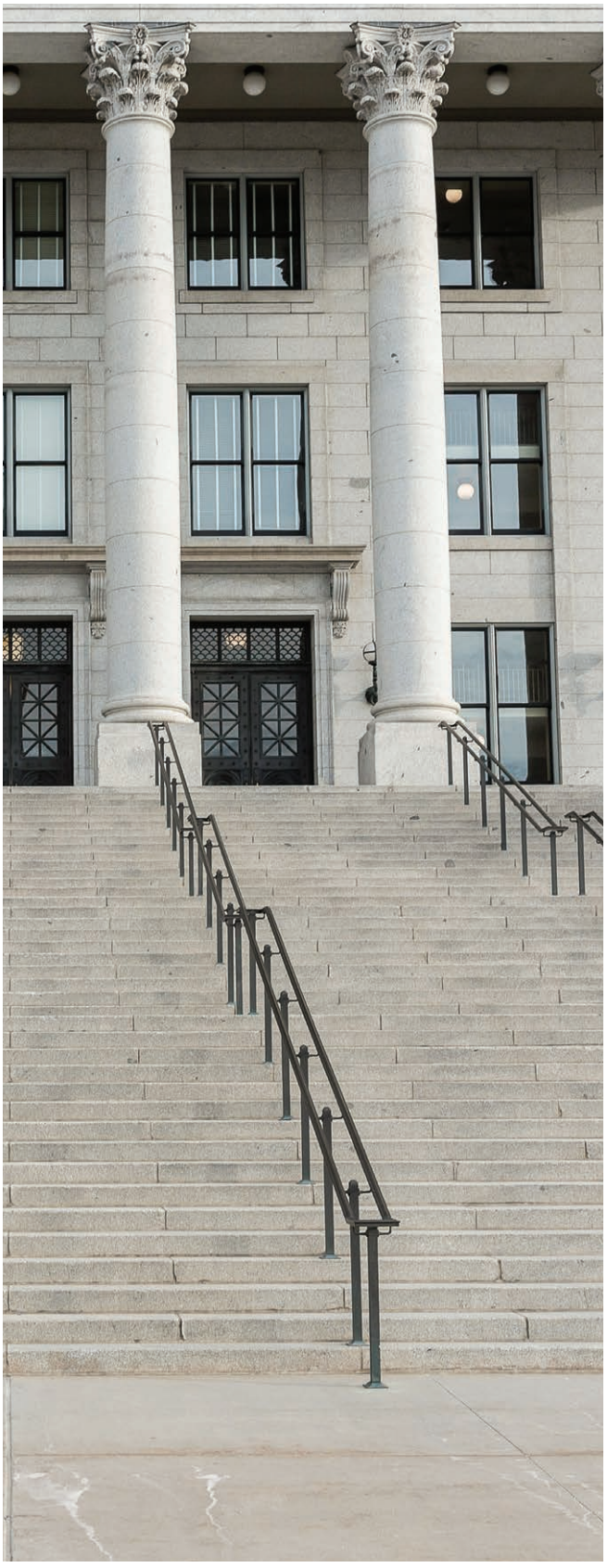
The Third Circuit affirmed. The court ruled that Crosbie failed to show that Gateway's reason for firing Crosbie was "a pretext for discrimination" or retaliation. First, the court stated that Crosbie's suspicions of improper behavior neither disproved his employers' explanation for his dismissal such that a jury could find it "unworthy of credence" nor showed directly that retaliation "was more likely than not a motivating or determinative" reason for his firing. The court reasoned that any administrative flaw in the harassment investigation and Burgess giving an interview for Crosbie's investigation was not enough to establish mere pretext. Second, Crosbie had no evidence of Burgess's desire to retaliate and could not show that Burgess communicated with Gateway to cause Gateway to fire Crosbie. Thus, the court found the whistleblowing and harassment events were separate, and Crosbie failed to show that the harassment investigation "was a sham."

***Simon ex rel. Fla. Rehab. Assocs., PLLC v. HealthSouth of Sarasota Ltd. P'ship,* No. 21-11618, 2022 WL 3910607 (11th Cir. Aug. 31, 2022)**

Eleventh Circuit held that relators must have an objectively reasonable belief that their employer violated the FCA in order to establish a prima facie claim for FCA retaliation.

Relator Emese Simon — a physiatrist who held admitting privileges at HealthSouth Sarasota Hospital — alleged that HealthSouth encouraged her and other physicians to diagnose patients with disuse myopathy so that HealthSouth could meet a threshold requirement to be classified as an inpatient rehabilitation facility and thus receive Medicaid funding. Simon, who believes disuse myopathy is a nonexistent medical condition, complained to HealthSouth that this practice amounted to fraud. In retaliation, HealthSouth allegedly limited Simon's admitting privileges and constructively discharged her.

The Eleventh Circuit affirmed HealthSouth's summary judgment victory. To make a prima facie case for FCA retaliation, Simon needed to have an objectively reasonable belief that HealthSouth violated the FCA. Although Simon subjectively believed that HealthSouth committed fraud by using a fabricated diagnosis, this belief was not objectively reasonable. Other doctors testified that disuse myopathy is a valid medical condition, and Simon herself admitted to diagnosing her patients with it. "Simon's medical opinion that disuse myopathy is not a legitimate diagnosis does not establish that the judgments of other doctors who diagnosed disuse myopathy — or any claims based on those doctors' judgments — were false for the purposes of the FCA."



***U.S. ex rel. Ascolese v. Shoemaker Constr. Co.*, 55 F.4th 188 (3rd Cir. Nov. 30, 2022)**

Third Circuit found that the anti-retaliation provision of the FCA prohibits employers from retaliating against employees who undertake lawful efforts to stop a violation of the FCA, even if the employer is not on notice of the distinct possibility that the employee was contemplating filing an FCA action. In so holding, the court departed from its own prior precedent that suggested that the "distinct possibility" standard would remain in place following the 2010 amendments to the FCA.

In 2014, the United States Department of Housing and Urban Development (HUD) awarded a $30 million grant to the Philadelphia Housing Authority (PHA) for the construction of public housing in north Philadelphia. PHA hired Shoemaker Construction for the project, and Shoemaker subcontracted with McDonough Bolyard Peck (MBP) to handle quality control for the project. The relator Don Ascolese worked for MBP as the quality assurance/quality control manager for the project. In this role, Ascolese was tasked with detecting and reporting deficiencies with the project's design, specifications and building codes. Over the course of the project, Ascolese outlined project deficiencies and initially brought his concerns to MBP and Shoemaker. He told them that it would be "wrongful" and "fraudulent" for the project to receive government funds and that certification of their contract compliance to obtain payments would "necessarily be false and fraudulent." When neither MBP nor Shoemaker acted in response to his internal complaints, Ascolese broke his chain of command and informed PHA engineers of the deficiencies. Shortly thereafter, Ascolese was fired.

Following his termination, Ascolese filed a *qui tam* action under the FCA, alleging that MBP and Shoemaker defrauded the government by falsely certifying their compliance with safety requirements and MBP illegally retaliated against him for trying to stop the fraud. MBP filed a motion to dismiss Ascolese's retaliation claim, which the district court granted. The district court denied Ascolese's motion to amend his complaint, applying the pre-2010 FCA amendment standard and noting that such amendment would be futile because Ascolese failed to show that MBP was on notice that he was contemplating filing an FCA action. Ascolese appealed. The Third Circuit reversed and clarified that the relevant inquiry was whether Ascolese pled facts that plausibly showed MBP was on notice that Ascolese had tried to stop the alleged FCA violations. The court further noted that this question has two prongs: first, whether an employee was engaging in protected conduct, and second, whether the employer had notice of this conduct.

Finding that Ascolese had alleged that he engaged in protected conduct, the court noted that while an employee must do more than their job responsibilities to trigger FCA protection, Ascolese's reporting of the project deficiencies to PHA was over and above his normal duties as a compliance officer, which amounted to an "effort to stop one or more violations" of the FCA. Similarly, Ascolese satisfied the notice prong with both his internal reporting and communications up the chain of command to PHA.

# WHAT TO WATCH IN 2023

## SUPREME COURT TO DECIDE STANDARD FOR GOVERNMENT MOTIONS TO DISMISS

***U.S. ex rel. Polansky v. Exec. Health Res., Inc.,*** **No. 21-1052**

Supreme Court granted certiorari to decide the question of whether the government can dismiss a *qui tam* relator lawsuit after declining to litigate and, if so, what the government must show for the motion to dismiss to be granted.

Relator Jesse Polansky filed the initial suit in 2012, alleging that defendant Executive Health Resources (EHR) improperly billed for inpatient services that should have been provided on an outpatient basis. The government investigated EHR's billing practices for two years before declining to intervene. Polansky proceeded with the suit for several years until 2019, when the government moved to dismiss under § 3730(c)(2)(A). The district court granted the motion to dismiss, and Polansky appealed.

On appeal, the Third Circuit affirmed. It addressed two main questions. First, regarding intervention, it joined the Sixth and Seventh circuits in holding that the government must intervene in order to exercise its dismissal authority. By contrast, the D.C., Ninth, and Tenth circuits have held that intervention is not necessary before the government can move to dismiss.

Second, the court addressed the standard for dismissal, which also resulted in a circuit split. Joining the Seventh Circuit, the court held that the government's motion to dismiss was governed by Fed. R. Civ. P. 41(a)'s requirements for voluntary dismissal. Other circuits have applied different standards: The D.C. Circuit held that the government had an "unfettered right" to dismiss, while the Ninth and Tenth circuits required the government to show a "rational relation" to a valid purpose for dismissal. And the First Circuit recently held that "the government must provide its reasons for seeking dismissal" but that the district court should allow dismissal unless "the government is transgressing constitutional limitations or perpetrating a fraud on the court."

The Supreme Court granted certiorari over the government's objection to decide (1) whether the government waives its right to dismiss by declining to intervene at the outset and (2), if not, what standard courts should apply when evaluating such a motion. The court heard oral argument on December 6, 2022. The questioning at the argument suggested the justices' general skepticism about limits on the government's dismissal authority and fairly low standard to justify such dismissal.

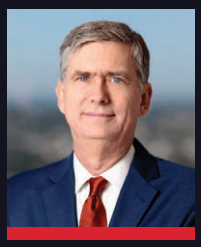
## SUPREME COURT TO DECIDE WHETHER ACTING WITH A REASONABLE INTERPRETATION OF AMBIGUOUS REGULATION CONSTITUTES ACTING "KNOWINGLY"

***U.S. ex rel. Schutte v. SuperValu Inc.,*** **No. 21-1326;** ***U.S. ex rel. Proctor v. Safeway, Inc.,*** **No. 22-111**

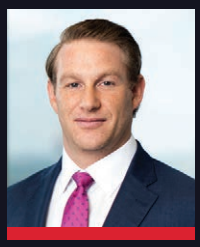
Supreme Court granted certiorari in a pair of Seventh Circuit cases to decide a key issue of FCA scienter.

The issue presented to the court is "whether and when a defendant's contemporaneous subjective understanding or beliefs about the lawfulness of its conduct are relevant to whether it 'knowingly' violated the False Claims Act." See further discussion of this issue on pages 10-11.

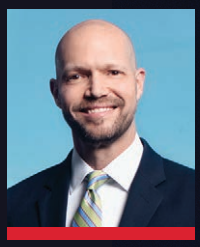
# BRADLEY'S GOVERNMENT ENFORCEMENT & INVESTIGATIONS PRACTICE GROUP

**A. Lee Bentley III**
Partner, Tampa
lbentley@bradley.com
813.559.5524

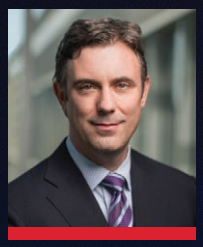


**Gene R. Besen**
Partner, Dallas
gbesen@bradley.com
214.257.9758

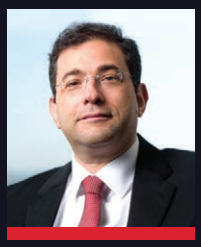


**Jonathan H. Ferry**
Partner, Charlotte
jferry@bradley.com
704.338.6011

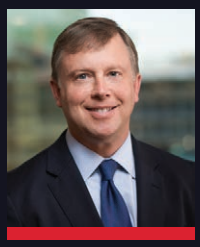
**Daniel J. Fortune**
Partner, Birmingham
dfortune@bradley.com
205.521.8048



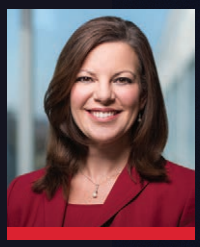
**Ty E. Howard**
Partner, Nashville
thoward@bradley.com
615.252.2376



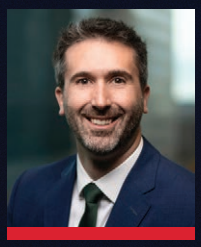
**Elisha J. Kobre**
Partner, Dallas
ekobre@bradley.com
214.257.9785



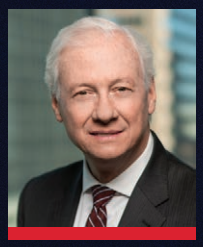
**Gregory G. Marshall**
Partner, Washington, D.C.
gmarshall@bradley.com
202.719.8207



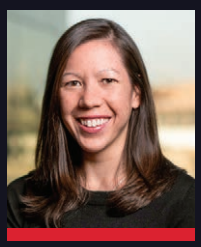
**Scarlett Singleton Nokes**
Partner, Nashville
snokes@bradley.com
615.252.3556



**Brad Robertson**
Partner, Birmingham
brobertson@bradley.com
205.521.8188



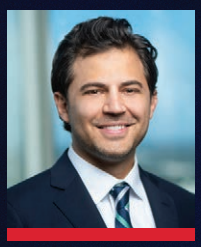
**Jack W. Selden**
Partner, Birmingham
jselden@bradley.com
205.521.8472



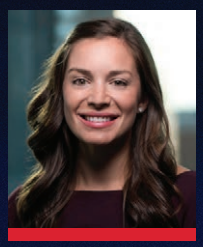
**Erin K. Sullivan**
Partner, Washington, D.C.
esullivan@bradley.com
202.719.8208

**Matthew W. Bedan**
Senior Attorney, Tampa
mbedan@bradley.com
813.559.5577

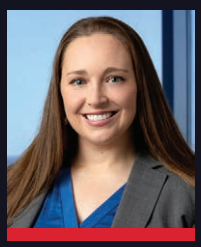
**Tara S. Sarosiek**
Senior Attorney, Nashville
tsarosiek@bradley.com
615.252.3522



**Giovanni P. Giarratana**
Associate, Tampa
ggiarratana@bradley.com
813.559.5558

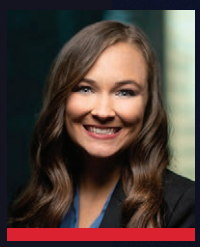


**Anna M. Lashley**
Associate, Washington, D.C.
alashley@bradley.com
202.719.8273



**Lyndsay E. Medlin**
Associate, Charlotte
lmedlin@bradley.com
704.338.6131

**Ocasha O. Musah**
Associate, Nashville
omusah@bradley.com
615.252.3544



**Cara Rice**
Associate, Tampa
crice@bradley.com
813.559.5520

**Courtlyn Ward**
Associate, Dallas
cward@bradley.com
214.257.9813

**Virginia C. Wright**
Associate, Birmingham
vwright@bradley.com
205.521.8876