HAYNES BOONE

False Claims Act

2022 Year in Review

Clients and friends,

In 2022, the government continued to build upon the previous year's enforcement efforts to address various forms of fraud—many of which have seen unprecedented proliferation in the shadow of the COVID-19 pandemic. The False Claims Act, 31 U.S.C. §§ 3729 *et seq.* ("FCA"), remains one of the government's most important weapons in those efforts.

This Review highlights key developments from 2022 related to the FCA, including:

- The recovery by the government of more than $2.2 billion in settlements and judgments in FCA cases in fiscal year 2022—less than half the previous fiscal year's recovery.
- The government prioritizing the detection, investigation, and prosecution of fraud related to cybersecurity and COVID-19 relief programs like the Paycheck Protection Program.
- The government continuing to emphasize individual accountability and adopting policies to incentivize voluntary self-disclosure.
- Continued judicial efforts to interpret the substantive elements of an FCA claim, including what it means for a claim to be "material" after the U.S. Supreme Court's landmark 2016 decision in *Escobar*.
- Significant judicial decisions regarding the standard the government must meet to dismiss an FCA case, the types of allegations sufficient to satisfy Rule 9(b)'s heightened pleading standard, what it means for a defendant to act "knowingly," and whether the FCA imposes an objective scienter standard, among many other issues.

In 2022, Haynes Boone represented healthcare providers, defense contractors, and individuals in FCA investigations and lawsuits. We successfully resolved matters before lawsuits were filed, negotiated favorable settlements at all stages, and defended our clients in active litigation and appeals. We also advised many healthcare providers and contractors regarding FCA compliance and other related issues.

If you have any questions about the issues covered in this Review, please let us know. We look forward to working with our friends and clients in 2023.

Stacy Brainin, Bill Morrison, Taryn McDonald, and Neil Issar

This paper is for informational purposes only. *It is not intended to be legal advice. Transmission is not intended to create and receipt does not establish an attorney-client relationship. Legal advice of any nature should be sought from legal counsel.*

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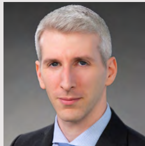

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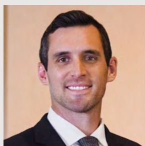

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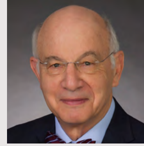

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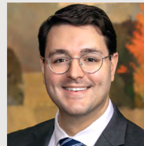

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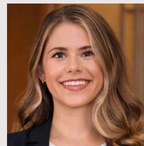

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2022: A LOOK AT THE NUMBERS

The False Claims Act is the government's main civil enforcement tool for fighting fraud. It broadly prohibits anyone from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment if the claim will be paid directly or indirectly by the federal government. 31 U.S.C. § 3729(a)(1)(A). It also broadly prohibits anyone from knowingly making, using, or causing to be made or used, a false record or statement that is material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(B).

The government can also bring criminal charges for knowingly making or presenting a false, fictious, or fraudulent claim to the government or a government agency or department. 18 U.S.C. § 287.

During fiscal year 2022, the government recovered over $2.2 billion in settlements and judgments in FCA cases. This is a noticeable decline from the previous fiscal year's recovery of $5.7 billion and is the lowest recovery since fiscal year 2008. But total recoveries since 1986—the year Congress significantly strengthened the FCA—now exceed $72 billion.

The Department of Justice ("DOJ") further reported:

- Of the $2.2 billion recovered, over $1.7 billion came from the healthcare industry.
- Relators (a.k.a. whistleblowers) filed 652 new "*qui tam*" actions in fiscal year 2022.
- Of the $2.2 billion recovered, nearly $2 billion related to cases filed by private whistleblowers, with whistleblowers receiving nearly $489 million for their share of the rewards.

NOTABLE SETTLEMENTS

1. VIOLATIONS OF THE ANTI-KICKBACK STATUTE AND THE STARK LAW

Some of the largest settlements in 2022 reflected DOJ's traditional focus on violations of the Anti-Kickback Statute ("AKS") and the Stark Law, which can render a claim for government payment "false or fraudulent" and thereby form the basis for an FCA action. Many such cases involved pharmaceutical companies.

For example, the year's largest settlement involved a Massachusetts-based pharmaceutical company agreeing to pay $900 million to resolve allegations that it violated the FCA and the AKS by paying kickbacks to physicians to induce them to prescribe the company's drugs.[1] Over the course of five years, the pharmaceutical company allegedly held programs through which it offered and paid remuneration—including outsized "speaker honoraria, speaker training fees, consulting fees and meals"—to health care professionals who spoke at or attended such programs to induce them to prescribe the company's drugs.

Similarly, a New Jersey-based pharmaceutical company agreed to pay $260 million to resolve allegations that it violated the FCA by using a foundation as a conduit to pay illegal copay subsidies in violation of the AKS, and by underpaying Medicaid rebates due to the large price increases of its drug.[2]

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[1] Release available at https://www.justice.gov/usao-ma/pr/biogen-inc-agrees-pay-900-million-settle-false-claims-act-allegations-related-improper.

[2] Release available at https://www.justice.gov/usao-edpa/pr/mallinckrodt-agrees-pay-260m-settle-false-claims-act-lawsuit-alleging-payment-illegal.

2. VIOLATIONS OF THE "PAYER OF LAST RESORT" LAW

Another notable settlement involved a state-created birth-related neurological injury compensation program agreeing to pay $51 million to resolve allegations that it violated the FCA by requiring program participants to first submit their healthcare claims to Medicaid instead of drawing from the program's fund.[3] This requirement violated federal law, which established Medicaid as a "payer of last resort" for any and all healthcare claims. In essence, the healthcare program was improperly shifting the payment of claims to a federally funded program.

3. FALSE CLAIMS MADE TO THE DEPARTMENT OF DEFENSE

There were also several notable settlements involving false claims made to the Department of Defense ("DoD"). For example, a Texas-based company and its affiliates agreed to pay $13.67 million to settle allegations that they violated the FCA and the AKS and breached a government contract.[4] The company had contractually agreed to provide logistics support to U.S. Army forces and relied on subcontractors to fulfill its obligations under the contract.

The government alleged that the company employees in charge of the subcontracts rigged the bidding process and received kickbacks for doing so. The government further alleged that the subcontract prices were inflated and that the company sought reimbursement from the DoD on the inflated costs.

Also, a Kansas-based transportation company agreed to pay $6.85 million to resolve allegations that it violated the FCA by systematically

overcharging for freight carrier services and making false statements to hide their misconduct.[5] The transportation company contracted with the DoD to ship military freight across the country and was paid, in part, on a shipment's weight. The government alleged the company fraudulently billed for delivery charges based on higher weights when, after reweighing the shipments, they knew that the actual weights were lower.

In another case, a textile manufacturer agreed to pay $3 million to resolve allegations that it violated the FCA by knowingly selling military-grade fabrics to the U.S. military that failed to meet certain performance specifications set by the military.[6] The company also entered into an agreement with the Defense Logistics Agency to ensure that it remains in compliance with testing requirements going forward.

Finally, a manufacturing company agreed to pay $500,000 to resolve alleged violations of the FCA for failing to conduct contractually required testing and falsifying test results for parts used in military aircrafts.[7]

[3] Release available at https://www.justice.gov/opa/pr/florida-birth-related-neurological-injury-compensation-plan-and-association-pay-51-million.
[4] Release available at https://www.justice.gov/opa/pr/kbr-defendants-agree-settle-kickback-and-false-claims-allegations.
[5] Release available at https://www.justice.gov/opa/pr/freight-carriers-agree-pay-685-million-resolve-allegations-knowingly-presenting-false-claims.
[6] Release available at https://www.justice.gov/usao-wdva/pr/united-states-attorney-chris-kavanaugh-announces-3000000-settlement-false-claims-act
[7] Release available at https://www.justice.gov/opa/pr/aircraft-parts-foundry-agrees-settle-false-claims-act-allegations-failure-conduct-testing-and

4. FAILURE TO COMPLY WITH CYBERSECURITY REQUIREMENTS

Last year also saw an uptick in investigations pursuant to the DOJ's Civil Cyber-Fraud Initiative. The Initiative, launched in October 2021, aims to combine the department's expertise in civil fraud enforcement, government procurement, and cybersecurity to combat new and emerging cyber threats to the security of sensitive information and critical systems.[8]

In the first settlement under the Cyber Fraud Initiative, announced in March 2022, a Florida-based medical services provider agreed to pay $930,000 to resolve allegations that it failed to disclose to the State Department and the U.S. Air Force that it had not complied with contract requirements to consistently store patients' medical records in a secure electronic medical record system.[9] The provider also allegedly failed to properly provide certain controlled substances that complied with FDA approvals and manufacturing standards.

Another settlement announced in July 2022 involved a California-based defense and aerospace contractor agreeing during trial to pay $9 million to resolve allegations it misrepresented compliance with specific cybersecurity requirements imposed by certain federal government contracts.[10]

5. PAYCHECK PROTECTION PROGRAM FRAUD

In last year's Review, we reported the first civil settlements involving allegations of fraud against the Paycheck Protection Program ("PPP"), a loan program for small businesses impacted by the COVID-19 pandemic.

2022 saw several similar settlements as well as the first-ever FCA settlement involving a PPP lender. A regional bank with branches throughout Texas and Oklahoma agreed to pay $18,673.50 to resolve allegations it improperly processed a $213,400 PPP loan for a customer it knew was facing criminal charges related to prescribing opioids.[11] The criminal charges would normally render one ineligible for a PPP loan. But the bank processed the application anyway to receive a processing fee of $10,670 from the Small Business Administration ("SBA"), the agency responsible for administering the PPP.

We expect fraud related to the PPP and other COVID-19 relief programs to remain a focus of government enforcement in 2023.

LEGISLATIVE AND ENFORCEMENT UPDATE

1. DOJ MADE ITS ANNUAL INFLATION ADJUSTMENT TO THE CIVIL MONETARY PENALTY AMOUNTS.

While the FCA states that a person who violates the statute is liable "for a civil penalty of not less than $5,000 and not more than $10,000," the penalty amounts are adjusted annually for inflation pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990.

On May 8, 2022, DOJ announced its final rule increasing the civil monetary penalty amounts that can be assessed for violations of the FCA to a minimum of $12,537 per false claim and a maximum of $25,076.

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[8] Release available at https://www.justice.gov/opa/pr/deputy-attorney-general-lisa-o-monaco-announces-new-civil-cyber-fraud-initiative
[9] Release available at https://www.justice.gov/opa/pr/medical-services-contractor-pays-930000-settle-false-claims-act-allegations-relating-medical
[10] Release available at https://www.justice.gov/opa/pr/aerojet-rocketdyne-agrees-pay-9-million-resolve-false-claims-act-allegations-cybersecurity
[11] Release available at https://www.justice.gov/usao-sdtx/pr/first-ever-false-claims-act-settlement-received-paycheck-protection-program-lender

2. NEW "MONACO MEMO" UPDATED DOJ'S CORPORATE CRIMINAL ENFORCEMENT POLICIES

While the FCA is a civil statute, the government's criminal enforcement policies are relevant because false claims can implicate criminal penalties under 18 U.S.C. § 287 and because those policies can trickle down to civil FCA investigations and settlements.

In September 2022, Deputy Attorney General Lisa Monaco issued a 15-page memorandum that introduced several new enforcement policies or initiatives applicable to corporate criminal matters.[12] Some of the most notable include:

- A continued focus on individual accountability and a company's history of prior misconduct.
- Adoption of policies to incentivize voluntary self-disclosure of corporate wrongdoing, similar to such policies already in place with respect to the Foreign Corrupt Practices Act ("FCPA") and antitrust enforcement. DOJ notably intends not to seek a guilty plea if a corporation voluntarily self discloses, cooperates with DOJ's investigation, and remediates the underlying misconduct.
- An increased emphasis on timely document production by cooperating companies, to enable prosecutors to promptly initiate related proceedings against implicated individual defendants. What qualifies as "timely" in this context is likely to be an issue of significant discussion and potential disagreement between DOJ prosecutors and cooperating companies.
- A commitment to the continued use of independent compliance monitors in connection with the resolution of corporate criminal cases, together with initiatives designed to increase transparency in the appointment, terms of reference, and oversight of those monitors.
- Directing companies to implement executive compensation models that reward good compliance governance and, potentially more radically, require companies to clawback compensation from executives found to have participated in, or contributed to, corporate criminal offenses.

In a keynote address on September 20, 2022, Principal Associate Deputy Attorney General Marshall Miller reiterated the new policies, including the "new and enhanced premium on voluntary self-disclosure" and the expectation that "cooperating companies [will] produce hot documents or evidence in real time."[13]

3. DOJ BROUGHT MORE NON-*QUI TAM* CASES.

Private citizens (a.k.a. whistleblowers or "relators") can file FCA cases on behalf of government. These relator-initiated cases are called "*qui tam*" actions. Relators are entitled to receive between 15% and 25% of the amount recovered by the government through the *qui tam* action if the government intervenes. 31 U.S.C. § 3730(d)(1). The relator's share is increased to between 25% and 30% if the government declines to intervene. 31 U.S.C. § 3730(d)(2).

But the last fiscal year was marked by an increase in cases brought by the government itself without a relator (i.e., non-*qui tam* cases). There were 296 such cases—the most in any one fiscal year since 1993. This increase aligns with Principal Deputy Assistant Attorney General Brian

[12] Memorandum available at https://www.justice.gov/opa/speech/file/1535301/download.
[13] Remarks available at https://www.justice.gov/opa/speech/principal-associate-deputy-attorney-general-marshall-miller-delivers-live-keynote-address.

Boynton's announcement in February 2021 that DOJ would "continue to expand its own efforts to identify potential fraudsters, including its reliance on various types of data analysis."[14]

4. PRIVATE EQUITY FIRMS REMAIN IN THE CROSSHAIRS.

In June 2020, then-Principal Deputy Assistant Attorney General Ethan Davis said that private equity firms investing in healthcare or life science companies that "take[] an active role in illegal conduct by the acquired company" are exposing themselves to FCA liability.[15] FCA liability may indeed apply to any person or entity that "causes" a false claim to be submitted, and not just to those that submit claims themselves. *See* 31 U.S.C. § 3729(a)(1).

So, unsurprisingly, we have seen several investigations and lawsuits against private equity firms—even where they had little involvement in the underlying alleged conduct. As an example, on March 24, 2022, a California federal district court unsealed a *qui tam* complaint in which the relator had named several specialty pharmacies and their private equity firm owners as defendants. *See United States ex rel. Webster v. BioMatrix Holdings, LLC, et al.*, No. 2:18-cv-09333 (C.D. Cal.).

The relator's only allegations against the private equity firms were that they were aware of the pharmacies paying kickbacks to individual hemophilia patients to recruit and refer family members and friends with hemophilia to the pharmacies to fill prescriptions for costly hemophilia drugs, and then fraudulently charge federal healthcare programs and private insurers for the tainted prescription purchases. Although these kinds of complaints may be subject to early dismissal, private equity firms should be aware of the risk of being named in FCA complaint based only on alleged knowledge of fraud by their portfolio companies.

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[14] Remarks available at https://www.justice.gov/opa/speech/acting-assistant-attorney-general-brian-m-boynton-delivers-remarks-federal-bar.

[15] Remarks available at https://www.justice.gov/civil/speech/principal-deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-false-claims.

5. FINTECH LENDERS EMERGING AS LATEST TARGET.

A more recent target of government scrutiny, particularly as it applies to the PPP, are financial technology companies (a.k.a. fintechs). On December 1, 2022, the House Select Subcommittee on the Coronavirus Crisis issued a report alleging that fintechs "facilitat[ed] a disproportionately high rate of fraudulent and otherwise ineligible loans through the [PPP]" and "handled 75 percent of the approved PPP loans that had been connected to fraud by [DOJ]."[16]

The report highlighted several fintech lenders under investigation and recommended that DOJ investigate those lenders for violations of the FCA.

The report and the aforementioned settlement with a PPP lender indicate that DOJ and the SBA will investigate and hold accountable not just loan recipients but also financial institutions that processed loans under COVID-19 relief programs. False representations and loan eligibility are likely to be key areas of attention in 2023 and beyond.

SIGNIFICANT JUDICIAL DECISIONS

1. THE SEAL REQUIREMENT

At the outset of a case, the FCA requires that the complaint "be filed in camera," "remain under seal for at least 60 days," and "not be served on the defendant until the court so orders." 31 U.S.C. §3730(b)(2). The 60-day seal requirement is generally designed to allow the government time to investigate the allegations and determine whether it wishes to intervene and proceed with the action.

a. Violations of the seal requirement do not necessarily mandate dismissal of an FCA action.

In 2016, the U.S. Supreme Court held that the FCA does not necessarily mandate dismissal of the lawsuit where the relator violates the seal requirement. *See State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 580 U.S. 26, 34–37 (2016). In general, the seal requirement protects the federal government's interest in *qui tam* actions. Rather than adopting a strict rule requiring dismissal for every seal violation, the Supreme Court concluded that remedy should be left to the discretion of the district court based on a number of factors, including the government's interest.

In 2022, the federal bankruptcy court for the Western District of Texas provided an example of a court exercising that discretion. *See In re GDC Technics, LLC*, 643 B.R. 417, 432 (Bankr. W.D. Tex. 2022). The relator in that case brought an FCA challenge against several companies for allegedly exchanging kickbacks so that one of the companies would be selected as a subcontractor on various "heads of state aircraft projects," despite knowing that the company was not qualified to fulfill the contract obligations. *Id*. at 422.

The federal government declined to intervene. The relator continued with the action and filed new FCA claims in an addendum to the complaint. But unlike the original complaint, the addendum was not filed under seal. Relying on the Supreme Court's 2016 *Rigsby* decision, the district court held the government's interests in protecting information were served in this case, as it had previously declined an opportunity to intervene in the original lawsuit filed under seal. So, the court would consider the addendum

[16] Report available at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.12.01%20How%20Fintechs%20Facilitated%20Fraud%20in%20the%20Paycheck%20Protection%20Program_0.pdf.

despite the relator's failure to adhere to the seal requirement.

b. Requests to extend the seal beyond dismissal of an FCA action will likely be denied.

In 2022, district courts in three different jurisdictions ruled that an FCA case should not remain under seal after dismissal. *See United States v. Amador*, No. 2:20-cv-01840, 2022 WL 594548 (D. Nev. Feb. 25, 2022); *United States ex rel. Powell v. Aerocare Holdings, Inc.*, No. 3:18-cv-00286, 2022 WL 829497 (W.D. Ky. Mar. 18, 2022); *United States ex rel. Dunn v. Merck & Co., Inc.*, No. 3:13-cv-01723, 2022 WL 890037 (D.N.J. Mar. 24, 2022).

The relators in those cases sought to maintain their anonymity after voluntary dismissal of the lawsuit out of fear of retaliation. But the courts all held that the strong public interest in and presumption of public access to the judicial record outweighed a relator's desire for anonymity.

2. GOVERNMENT MOTIONS TO DISMISS

a. The circuit split regarding the appropriate dismissal standard for government motions to dismiss remains entrenched—for now.

When a *qui tam* action is filed, the government has three options: (i) intervene in the litigation and take over the case; (ii) decline intervention and allow the relator to litigate the case on its own; or (iii) move for dismissal of the case over the objections of the relator.

To exercise the third option, the FCA requires the government to notify the relator that it is filing a motion to dismiss, and the court must provide the relator an opportunity for a hearing on the motion. 31 U.S.C. § 3730(c)(2)(A). But a circuit split has developed over the years regarding the standard the government must meet to obtain dismissal over the objections of the relator and when the government is permitted to exercise that authority. In late 2022, the U.S. Supreme Court heard arguments in a case that will likely clarify some of those issues before the end of this term.

The Ninth and Tenth Circuits use a two-part "rational relation" standard, under which the government must identify (i) a "valid government purpose" to be served by the dismissal, and (ii) a "rational relation between dismissal and accomplishment of the purpose." *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998); *Ridenour v. Kaiser-Hill Co.*, 397 F.3d 925, 936 (10th Cir. 2005).

Conversely, the D.C. Circuit uses a more deferential "unfettered right" standard, under which courts do not review the grounds for the government's motion to dismiss and instead view the FCA as giving the government an "unfettered right" to dismiss an action. *Swift v. United States*, 318 F.3d 250, 252–53 (D.C. Cir. 2003).

More recently, the Third, Seventh, and Eleventh Circuits held that the Federal Rules of Civil Procedure should apply as they would to any party, allowing the government to rely on Rule 41(a)(1)(A)(i) to "dismiss an action without a court order" by serving a notice of dismissal any time "before the opposing party serves either an answer or a motion for summary judgment." *United States ex rel. CIMZNHCA, LLC v. UCB, Inc.*, 970 F.3d 835, 839 (7th Cir. 2020).

One distinction between those three circuits is that the Third Circuit required the government to intervene in a case before it can move to dismiss it, but the Third Circuit also clarified that the government can seek leave to intervene at any point with a showing of good cause. *Polansky v. Executive Health Res. Inc.*, 17 F.4th 376, 385 (3d Cir. 2021).

The Eleventh Circuit, in contrast, declined to impose a good-cause intervention requirement, viewing intervention as needed only if the government intends to actually proceed with the litigation—not when the government is only

stepping in for the purpose of ending the case. *See United States v. Republic of Honduras*, 21 F.4th 1353, 1357 (11th Cir. 2021). Note, however, that the Eleventh Circuit granted *en banc* review last year to potentially reconsider the issue. *See United States v. Republic of Honduras*, 26 F.4th 1252 (11th Cir. 2022).

b. The First Circuit added a new "constitutional infirmity or fraud" standard to the split.

Early in 2022, the First Circuit added to the circuit split by rejecting the other circuits' approaches and instead requiring the government to provide some sort of reason for seeking dismissal so that the relator has a formal opportunity or hearing to persuade the government not to end the case. *See Borzilleri v. Bayer Healthcare Pharm., Inc.*, 24 F.4th 32, 42 (1st Cir. 2022). If the relator fails to convince the government not to pursue dismissal, then the district court should grant the government's motion unless the relator can show that "the government's decision to seek dismissal of the *qui tam* action transgresses constitutional limitations or that, in moving to dismiss, the government is perpetrating a fraud on the court." *Id.*

c. The Supreme Court appears poised to resolve the four-way split in 2023.

The U.S. Supreme Court heard argument on December 6, 2022, in a case regarding which standard applies when the government moves for dismissal and whether the government has the authority to move for dismissal after initially declining to intervene in an FCA lawsuit. *See United States ex rel. Polansky v. Exec. Health Res. Inc.*, No. 21-1052, 142 S. Ct. 2834 (Jun. 21, 2022).

So, it is likely we will have clarity or resolution of the circuit split sometime in 2023 when the Supreme Court issues its decision in that case. At least one district court has stayed proceedings in which a government motion to dismiss is pending until the Supreme Court issues its decision. *See* Order Granting Motion to Stay Proceedings Pending U.S. Supreme Court Decision, *United States ex rel. Jefferson v. Roche Holding AG, et al.*, No. 1:14-cv-03665 (D. Md. Nov. 16, 2022), Dkt. No. 147.

The *Polansky* case before the Supreme Court represents a rare instance of alignment between the government and potential FCA defendants, with both warning that limits on the government's authority to dismiss FCA lawsuits will lead to whistleblowers proceeding with meritless lawsuits and burdening both government and defendant resources.

3. THE PUBLIC DISCLOSURE BAR AND ORIGINAL SOURCE EXCEPTION

Other than the government's ability to dismiss a *qui tam* action over the objection of the relator, the FCA contains several statutory "bars" to prevent a relator's case from proceeding.

The FCA's public disclosure bar prohibits *qui tam* suits if "substantially the same allegations or transactions" of fraud as alleged in the suit were previously disclosed in (i) a federal criminal, civil, or administrative hearing in which the government or its agent was a party; (ii) a congressional, Government Accountability Office, or other federal report, hearing, audit, or investigation; or (iii) the news media. 31 U.S.C. § 3730(e)(4)(A).

For a relator's case to survive the public disclosure bar, the relator must show that (i) the public disclosure bar does not apply; or (ii) if it does apply, the relator is an "original source." An "original source" means an individual who either (i) prior to a public disclosure has voluntarily disclosed to the government the information on which allegations or transactions in a claim are based, or (ii) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the government before filing an FCA action. 31 U.S.C. § 3730(e)(4)(B).

The requirements for both the public disclosure bar and the original source exception are common sources of litigation, as courts attempt to strike the congressionally intended balance between discouraging parasitic lawsuits and properly incentivizing true whistleblowers.

a. ***The Ninth Circuit held that a patent prosecution hearing before the Patent Trademark Office counts as a federal hearing.***

In 2022, the Ninth Circuit concluded that a patent prosecution before the Patent Trademark Office constitutes a "federal hearing" for purposes of the FCA's public disclosure bar. *See United States v. Allergan, Inc.*, 46 F.4th 991, 997 (9th Cir. 2022).

In *Allergan*, a patent attorney filed an FCA lawsuit, alleging that defendants fraudulently obtained patents to protect their brand-name drugs from price competition by generic drug competitors. The case turned on whether an *ex parte* patent prosecution at which the key factual information underlying the relator's claims was discussed is a "hearing" under Section 3730(e)(4)(A)(ii). The Ninth Circuit reasoned that Congress's use of the adjective "other" in the statute demonstrates an intent for the public disclosure bar to apply broadly, including to hearings before the Patent Trademark Office.

b. ***The Fourth Circuit held that a public disclosure must include information specifically related to the alleged fraud.***

On the other hand, the Fourth Circuit rejected the argument that a relator's FCA lawsuit was barred by a federal report that publicly disclosed the basis of her claims. *See United States ex rel. Taylor v. Boyko*, 39 F.4th 177, 189 (4th Cir. 2022). In *Taylor*, the relator alleged that defendants knowingly submitted false claims to Medicare and engaged in a fraudulent medical upcoding scheme to bill Medicare at inflated rates.

The district court concluded, and the Fourth Circuit agreed, that the federal report the defendants cited as the purported public disclosure solely focused on deficiencies in medical care provided by the defendants and did not disclose any information related to billing or the alleged fraud. Thus, the report did not implicate the public disclosure bar.

c. ***The Second Circuit held that an original source must have direct knowledge and provide more than just "detail or color."***

The Second Circuit reviewed a case in which a relator-entity alleged violations of the AKS and FCA when certain healthcare entities paid physician-owners of dialysis centers far beyond fair market value to acquire controlling interests in the centers in exchange for the physicians referring patients back to the center. *See United States ex rel. CKD Project, LLC v. Fresenius Med. Care Holdings, Inc.*, No. 21-2117, 2022 WL 17818587, at *3–4 (2d Cir. Dec. 20, 2022).

The district court dismissed the relator's claims under the public disclosure bar, finding the defendants had disclosed the material elements of their dialysis center acquisitions and the corresponding risk of AKS scrutiny in public SEC filings. The Second Circuit affirmed, holding that the relator's complaint "merely supplied additional details." *Id*. at *3.

The Second Circuit also held that the relator was not an "original source." As an entity formed solely for litigation, the relator could not possess direct knowledge of the information on which its allegations were based. Also, the relator provided only "detail or color to previously disclosed elements of an alleged scheme," which does not count as a material addition. *Id*. at *4 (quoting *United States ex rel. Winkelman v. CVS Caremark Corp*., 827 F.3d 201, 213 (1st Cir. 2016)).

4. THE FIRST-TO-FILE BAR

The FCA's first-to-file bar provides that "no person other than the government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5).

Generally speaking, the rule prohibits an individual from bringing a *qui tam* action if there is already another pending action based on the same essential facts. The goal of the first-to-file bar is "to discourage opportunistic plaintiffs from bringing parasitic lawsuits whereby would-be relators merely feed off a previous disclosure of fraud." *Walburn v. Lockheed Martin Corp*., 431 F.3d 966, 970 (6th Cir. 2005).

a. *The first-to-file bar does not preclude an award of attorneys' fees where multiple relators assisted the government and received a relator's share of the recovery or settlement.*

In 2022, the Sixth Circuit held that the first-to-file bar does not necessarily preclude an award of attorneys' fees where multiple relators assisted the government's investigation of the alleged fraud. *See United States ex rel. Bryant v. Cmty. Health Sys., Inc*., 24 F.4th 1024, 1039 (6th Cir. 2022). In that case, seven relators filed multiple lawsuits against the same defendant-health system, and they all worked together to assist the government in its investigation and prosecution of claims against the health system. The government eventually settled all the cases in 2014 for $97 million. In 2020, after several proceedings, the district court held that the FCA's first-to-file bar and public-disclosure bar precluded the claims for attorneys' fees by all the relators except the relator that filed the first complaint.

The Sixth Circuit reversed, reasoning that nothing in the text of the FCA mandated the application of the first-to-file bar to the issue of attorney fees. The court also held the relators were not "opportunistic plaintiffs," but instead were plaintiffs who spent significant time and effort assisting the government. *See id*. at 1035. So, the award of attorneys' fees would be consistent with Congress's intent to encourage collaboration between the government and the public to prosecute fraudulent conduct. *See id*. at 1046, 1039.

The First Circuit recently cited the Sixth Circuit's decision to explain that only persons who received a relator's share of the government's recovery or settlement are entitled to recover attorneys' fees. *See United States ex rel. Lovell v. AthenaHealth, Inc*., 56 F.4th 152, 158 (1st Cir. 2022). So, if a relator reaches a private sharing agreement with another relator regarding the allocation of any funds paid by the government to the latter, then the former did not actually receive a relator's share within the meaning of the FCA and is not entitled to recover attorney's fees. *See id*. at 159.

b. *The Eleventh Circuit explained that the first-to-file analysis takes effect the moment the original complaint is filed.*

The Eleventh Circuit also recently addressed a question of statutory interpretation of § 3730(b)(5) and affirmed a dismissal under the

FCA's first-to-file bar on the grounds that the plain language of the statute indicates the first-to-file analysis takes effect the moment the original complaint is filed. *Cho v. Surgery Partners, Inc.*, 30 F.4th 1035, 1040 (11th Cir. 2022). In other words, the Eleventh Circuit held that a "first-to-file defect" cannot be cured by the filing of an amended complaint.

This aligns with previous holdings by the Second and D.C. Circuits, but not all circuits agree. *Compare United States ex rel. Wood v. Allergan, Inc*., 899 F.3d 163, 172 (2d Cir. 2018) ("[A]n amended or supplemental pleading cannot change the fact that [the relator] brought an action while another related action was pending, as is prohibited by the first-to-file bar.") *with United States ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1, 6 (1st Cir. 2015) (concluding a supplemental pleading can be used to cure a jurisdictional defect such as a first-to-file defect).

5. THE GOVERNMENT ACTION BAR

Another FCA provision aimed at discouraging duplicative *qui tam* actions is the government action bar, which prohibits relators from bringing a *qui tam* action "based upon allegations or transactions which are the subject of a civil suit or an administrative civil money proceeding in which the Government is already a party." 31 U.S.C. § 3730(e)(3).

a. *The D.C. Circuit adopted a narrow interpretation of the phrase "administrative civil money proceeding."*

In 2022, the D.C. Circuit adopted a narrow interpretation of the phrase "administrative civil money proceeding." The district court had dismissed an FCA action under the government action bar based on an FCC licensing proceeding. But the court of appeals rejected that interpretation of the statutory phrase. *See United States ex rel. Vt. Nat'l Tel. Co. v. Northstar Wireless, LLC*, 34 F.4th 29, 35 (D.C. Cir. 2022). The court reasoned that the FCC had no authority to assess civil money penalties during its licensing proceeding; its authority was limited to evaluating the parties' licensing applications. So, the licensing proceeding was not an "administrative civil money proceeding" and thus did not trigger the government action bar as an impediment to the relator's lawsuit.

6. THE HEIGHTENED PLEADING STANDARD OF RULE 9(B)

The submission of a false or fraudulent claim to the government is essential to an FCA violation. And because it involves allegations of fraud, any FCA complaint must satisfy the heightened pleading standard of Rule 9(b) of the Federal Rules of Civil Procedure. That is, a party "must state with particularity the circumstances constituting fraud." FED. R. CIV. P. 9(b).

While Rule 9(b) requires that a plaintiff plead the "who, what, when, where, and how" of the alleged fraud in all cases, circuit courts have been split for years over how exactly Rule 9(b) applies to FCA claims specifically—and the Supreme Court again declined to resolve the split.

a. *The Sixth, Seventh, Eighth, and Eleventh Circuits require allegations of specific false claims actually submitted to the government.*

The Sixth, Seventh, Eighth, and Eleventh Circuits appear to favor—and in some cases have required—detailed allegations of a specific false claim that was actually submitted to the government.

For example, in 2022, the Sixth Circuit explained that it imposes a "clear and unequivocal requirement that a relator allege specific false claims" and that "[t]he identification of at least one false claim with specificity is an indispensable element of a complaint that alleges a False Claims Act violation." *United States ex rel. Owsley v. Fazzi Assocs., Inc.*, 16 F.4th 192, 196 (6th Cir. 2021), *cert. denied*, 143 S. Ct. 362 (2022); *see also United States ex rel. USN4U, LLC v. Wolf Creek Fed. Servs., Inc.*, 34 F.4th 507, 514

(6th Cir. 2022) ("If a relator alleges a widespread fraud, then 'a single adequately pled claim of this nature would allow relators to satisfy Rule 9(b)'s pleading requirement and proceed to discovery on the entire scheme.'") (citation omitted).

Likewise, the Seventh Circuit stated that "specific representative examples" of false submissions are required. *See United States ex rel. Sibley v. Univ. of Chicago Med. Ctr*., 44 F.4th 646, 656 (7th Cir. 2022) (citation omitted); *see also Lanahan v. Cty. of Cook*, 41 F.4th 854, 862 (7th Cir. 2022) ("Rule 9(b) demands Relator 'allege . . . specific facts demonstrating what occurred at the individualized transactional level' to maintain a claim. This 'includes the identity of the person making the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated to the [defendant].'") (citation omitted).

As an example, a relator alleging that defendants received Medicare reimbursement for uncollectible patient debt must allege "specific examples of patient debts" that were unlawfully included in the defendants' cost reports. *Sibley*, 44 F.4th at 656. Failure to do so will result in dismissal of the relator's claims.

b. *The Fourth Circuit requires allegations of specific false claims actually submitted <u>or</u> a pattern of conduct that would necessarily have led to submission of false claims..*

In contrast, the Fourth Circuit issued opinions in 2022 explaining that it is satisfied with detailed allegations of a specific false claim that was actually submitted to the government, <u>or</u> a "pattern of conduct that would '*necessarily* have led to submission of false claims' to the government for payment." *See United States ex rel. Nicholson v. MedCom Carolinas, Inc*., 42 F.4th 185, 194 (4th Cir. 2022) (emphasis in original); *United States ex rel. Taylor v. Boyko*, 39 F.4th 177, 196 (4th Cir. 2022) (emphasis in original).

Though this standard is less stringent, the Fourth Circuit explained that "inherently speculative" assertions about claim submission are still insufficient, and it is not enough for a relator to allege without factual grounds that fraudulent claims "*must* have been submitted, were *likely* submitted or *should* have been submitted to the government." *Taylor*, 39 F.4th at 196 (emphasis in original).

c. *Other circuits require only details of a scheme to submit false claims plus indicia of reliability that false claims were actually submitted.*

Since details of specific false claims or claim submissions may be difficult for relators to obtain, most other circuits generally require only (i) particular details of a scheme to submit false claims to the government, combined with (ii) indicia of reliability that false claims were actually submitted.

For example, last year the Ninth Circuit reiterated that a relator was not required to identify particular invoices, but rather "it was enough to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *UPPI LLC v. Cardinal Health, Inc*., No. 21-35905, 2022 WL 3594081, at *3 (9th Cir. Aug. 23, 2022) (citation omitted).

In that case, the Ninth Circuit held that the relator did enough by identifying the specific contracts at issue, alleging that fraudulently certified invoices were issued pursuant to those contracts, contending the government paid the defendants under those contracts, and describing the alleged false certifications contained in those invoices. *See id*.

"Reliable indicia" will be case-specific, but may include information such as "dates that services were fraudulently provided or recorded, by whom, and evidence of the . . . standard billing procedure." *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 189 (5th Cir. 2009).

The D.C. Circuit went a step further in favor of relators, requiring a relator to simply plead "detailed allegations regarding the 'time, place, and manner' of the fraudulent scheme." *United States ex rel. Vermont Nat'l Tel. Co. v. Northstar Wireless, LLC*, 34 F.4th 29, 39 (D.C. Cir. 2022).

d. The Supreme Court declined to resolve the circuit split.

On October 17, 2022, the Supreme Court declined to review cases out of the Sixth, Seventh, and Eleventh circuits regarding what is needed to satisfy Rule 9(b) in FCA claims. *See Johnson v. Bethany Hospice & Palliative Care LLC*, 143 S. Ct. 351 (2022); *Molina Healthcare of Illinois, Inc. v. Prose*, 143 S. Ct. 352 (2022); *United States ex rel. Owsley v. Fazzi Assocs., Inc.*, 143 S. Ct. 362 (2022). So, the circuit split will continue in 2023.

7. *ESCOBAR* AND MATERIALITY

The FCA imposes liability where a person "knowingly makes, uses, or causes to be made or used, a false record or statement ***material*** to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B) (emphasis added). The statute defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

The U.S. Supreme Court construed the materiality requirement to mean that "[a] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision." *Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 181 (2016). *Escobar* reasoned that this requirement, like scienter, must be "rigorous" to ensure that the FCA does not become "a vehicle for punishing garden-variety breaches of contract or regulatory violations" or "minor or insubstantial" non-compliance with government contracts. *Id.* at 192, 194.

Escobar also explained that the materiality inquiry may be influenced by non-exclusive factors such as whether the alleged non-compliance goes to the "essence of the bargain," whether the non-compliance is significant (as opposed to "minor or insubstantial"), and

whether the government has taken action in response to similar, known violations (e.g., consistently refusing to pay claims in similar circumstances or continuing to pay in full despite actual knowledge of the alleged violation). *See id*. at 194–95.

Some courts use the non-exclusive factors listed in *Escobar* as the test for materiality. *See, e.g.*, *United States ex rel. Lee v. N. Metro. Found. for Healthcare, Inc*., No. 21-2155, 2022 WL 17366627, at *1 (2d Cir. Dec. 2, 2022). But most courts view the materiality analysis as a “holistic,” “totality-of-the-circumstances” examination where no one factor is determinative.

Some of the key decisions issued in 2022 concerning materiality are summarized below.

a. ***The Ninth Circuit and D.C. Circuit held that bid eligibility requirements and key contract compliance requirements are material.***

The Ninth Circuit clarified that it “interpret[s] *Escobar* as creating a ‘gloss’ on the analysis of materiality that requires a court to consider three factors:

i) whether the government’s ‘payment was conditioned on compliance with the [statutory, regulatory, or contractual requirement,’

ii) the government’s ‘past enforcement activities,’ i.e., ‘how [it] has treated similar violations,’ and

iii) the magnitude of the violation.”

UPPI, 2022 WL 3594081, at *3 (citing *United States ex rel. Rose v. Stephens Inst*., 909 F.3d 1012, 1020 (9th Cir. 2018)).

In that case, the relator alleged that two service-disabled veteran-owned small businesses (“SDVOSBs”) exploited the preferential treatment SDVOSBs receive in bidding on government contracts by failing to disclose that the majority of the work under contracts awarded to them would be performed by a large third-party enterprise. *Id*. at *1. The large enterprise would not otherwise be eligible to bid for the contracts, and SDVOSB contracts include restrictions on subcontracting a majority of the work.

The district court dismissed the complaint because the government allegedly had actual knowledge of the large enterprise’s involvement, rendering any falsities immaterial. But the Ninth Circuit reversed, holding that its three-factor test above weighed in favor of finding materiality.

Specifically, the court held that compliance with the subcontracting requirement was material to the government’s payment decision and observed that the government had terminated contracts or prosecuted similar violations in the past. The court also held that the noncompliance at issue was not minor or insubstantial since the large enterprise “performed the vast majority of the work and kept the majority of the revenue, while the SDVOSBs took only a small cut for doing some nominal invoicing.” *Id*.

Similarly, the D.C. Circuit held that allegations regarding the failure to comply with eligibility requirements to participate in FCC auctions were sufficient to plead materiality under the FCA. *See United States ex rel. Vermont Nat’l Tel. Co. v. Northstar Wireless, LLC*, 34 F.4th 29, 36–38 (D.C. Cir. 2022).

In *Vermont Nat’l Tel.*, a telecommunications company sued its competitors for alleged misrepresentations in their applications to participate in an FCC auction for exclusive licenses to use certain radio frequencies, such as those used to provide television, cell phone, and wireless internet services. *Id.* at 31. Specifically, the relator alleged that the defendants misrepresented themselves as “very small businesses” with less than $15 million in revenue so as to be eligible for a 25% bidding credit.

The district court held that the alleged misrepresentations were not material because, upon a post-auction review, the FCC denied bidding credits to the defendants anyway. But the

D.C. Circuit reversed, holding that the defendants' misrepresentations were material because they not only affected their eligibility for bidding credits, but also implicated their eligibility to participate in the FCC's auction bidding in the first place. *Id.* at 38.

b. *The Ninth Circuit also held that use of a certification code that triggered automatic payment was material to the government's payment decision.*

The Ninth Circuit also reviewed a case in 2022 in which a medical device manufacturer was alleged to have falsely certified compliance with requirements that its device caused "progressive wound healing" during each month for which the manufacturer sought payment from Medicare. *See United States ex rel. Hartpence v. Kinetic Concepts, Inc.*, 44 F.4th 838, 841 (9th Cir. 2022). The relator alleged that the defendant fraudulently used a billing code certifying its compliance with this requirement even though healing was not occurring in every month.

The district court granted the defendant's motion for summary judgment, holding that the relator had not introduced sufficient evidence to create a triable issue over whether the defendant's false certifications were material to the government's payment decisions. But the Ninth Circuit reversed.

The Ninth Circuit held that a jury could conclude that the defendant's use of a billing code certifying compliance with payment criteria would be material to the government's payment decision. Under Medicare's "coverage determination system" for the defendant's device, the defendant's use of the certification code usually triggered an automatic payment with no further review. *See id*. at 841, 846–47.

On the other hand, if the defendant had not used the certification code, it would have triggered a denial of the claim that could be reviewed in case-specific appeals. That two-track review system, the court held, showed that the government treated a provider's use of the certification code as important to its payment decisions since the government would not have paid the defendant's claims if case-specific review were occurring. *See id*. at 846–50.

c. *In contrast, the Ninth Circuit held that the use of a noncompliant supply chain was not material to the government's decision to pay for delivery.*

In another case, the Ninth Circuit affirmed a district court's dismissal of relators' FCA claims upon finding that the relators failed to allege materiality. *See McElligott v. McKesson Corp.*, No. 21-15477, 2022 WL 728903, at *2 (9th Cir. Mar. 10, 2022). In that case, the relators alleged that the defendant violated the FCA by making "implied" false certifications about its delivery of medical supplies to the government.

But the court held that the defendant's "failure to disclose that the supplies were delivered through a noncompliant supply chain did not render misleading the representation that the supplies were delivered." *Id*. at *1. Further, the Court concluded that relators failed to allege a material implied misrepresentation because "nothing in the complaint gives rise to a reasonable inference that the security of [the] supply chain was material to the government's decision to pay for medical supplies that [the defendant] actually delivered." *Id*. at *2.

d. *The Second Circuit held that adulteration of drugs was not material where the FDA approved the drugs and did not withdraw approval even after learning of the adulteration.*

The Second Circuit reviewed a case in which a pharmaceuticals manufacturer was alleged to have made false representations to the FDA regarding its drugs' manufacturing practices to secure FDA approval. *See United States ex rel. Yu v. Grifols USA, LLC*, No. 22-107, 2022 WL 7785044, at *3 (2d Cir. Oct. 14, 2022). Specifically, the relator alleged that the manufacturer's drugs were adulterated. But the district court dismissed the claims and the

Second Circuit affirmed dismissal because the manufacturer's contracts with the government did not expressly require that the drugs be unadulterated or that they comply with any specific manufacturing processes.

The Second Circuit also held that the allegations lacked materiality because the FDA declined to withdraw its approval of the defendant's drugs even after learning that the drugs were adulterated. In particular, the Second Circuit concluded that the relator's failure to "point to anything to suggest that [the defendants'] alleged violations have resulted in 'significant financial cost to the government,' or demonstrate that the violations go to the 'heart of the bargain,' . . . weighs against a finding of materiality." *Id*. at *5.

e. *The Tenth Circuit held that a naked assertion of a statutory violation does not satisfy Escobar's materiality requirement.*

In 2022, the Tenth Circuit affirmed dismissal of a relator's claims in a lawsuit that alleged the defendant violated the Davis-Bacon Act by failing to pay its employees minimum wage for construction services on a federal transportation project. *See United States ex rel. Sorenson v. Wadsworth Bros. Constr. Co.*, 48 F.4th 1146, 1153–54 (10th Cir. 2022). Because the defendant was required to certify its compliance with the Davis-Bacon Act as a prerequisite for payment under its construction contract, the relator alleged that the defendant had violated the FCA. *Id*. at 1154–55.

But the Tenth Circuit noted that the FCA "is not simply some 'all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations.'" So, the Tenth Circuit reasoned that the relator must allege more than "a naked Davis-Bacon violation" in order to state an actionable claim under the FCA. *Id*. at 1157–58 (quoting *Escobar*, 579 U.S. at 194).

The Tenth Circuit further opined that allowing any instance of statutory or contractual non-compliance to result in FCA liability would "make a mockery" of the Supreme Court's decision in *Escobar*. *Id*. at 1158. Because the relator failed to allege that Davis-Bacon violations were a substantial factor in the government's decision to pay or not pay the defendant for construction services, the Tenth Circuit affirmed the district court's dismissal of the lawsuit.

f. *The Fourth Circuit held that a company's failure to maintain its corporate charter was "bureaucratic rather than material."*

The Fourth Circuit reviewed a case in which the relator alleged an emergency room staffing company knowingly continued to bill Medicare for medical services after the state of West Virginia revoked its corporate charter and the West Virginia Board of Medicine then automatically revoked its certificate of authorization for a medical corporation. *See United States ex rel. Taylor v. Boyko*, 39 F.4th 177, 186 (4th Cir. 2022). The charter was revoked simply because the defendant failed to submit an annual report and $25 fee for maintaining its charter, as required for all corporations by the West Virginia Secretary of State.

The relator argued, however, that billing without a corporate charter was like a physician practicing medicine without a license. The Fourth Circuit rejected this argument, and instead concluded that failure to maintain its corporate charter was "bureaucratic rather than material" because the defendant could have its charter reinstated retroactively by submitting its annual report and $25 fee. *Id*. at 194. So, the Fourth Circuit affirmed dismissal of the relator's FCA claim because the relator failed to show the revocation of the corporate charter was material to the government's decision to pay.

g. *The Sixth Circuit held that declining to intervene and continuing to contract with a defendant are not dispositive, but contract requirements that go "to the very essence of the bargain" are strong evidence of materiality.*

The Sixth Circuit reviewed a case involving allegations that a contractor fraudulently inflated project estimates and caused the government to overpay for its construction services. *See United States ex rel. USN4U, LLC v. Wolf Creek Fed. Servs., Inc*., 34 F.4th 507, 510 (6th Cir. 2022). In that case, the relator alleged that a construction contractor's employees intentionally inflated estimates of how many labor hours were required for various construction projects for NASA, and that NASA paid the face value of the estimates in reliance on those misrepresentations.

The district court dismissed the relator's lawsuit, concluding that the inflated labor estimates were not material to NASA's decision to pay because (i) the government declined to intervene, and (ii) NASA continued to contract with that same defendant even after becoming aware of the relator's fraud allegations. *Id*. at 513.

The Sixth Circuit reversed, reasoning that while the Government's decision to intervene in a *qui tam* action can be evidence that the misrepresentation was material, the opposite is not necessarily true. The Sixth Circuit explained that "[t]he very fact that the FCA allows private relators to enforce the Act . . . implies a recognition that the Government may have limited resources or may choose to focus its enforcement efforts elsewhere." *Id*. at 518. In other words, declining to intervene or continuing to contract with a defendant were not each dispositive on the issue of materiality. Instead, the Sixth Circuit concluded that "gross overcharging for work not done goes inherently 'to the very essence of the bargain,'" and thus held that the relator had sufficiently pleaded materiality to avoid dismissal. *Id*. at 516–17.

8. SCIENTER

The FCA "is not intended to punish honest mistakes or incorrect claims submitted through mere negligence." *United States ex rel. Skibo v. Greer Labs., Inc.*, 841 F. App'x 527, 531 (4th Cir. 2021) (citation omitted); *see also United States ex rel. Jacobs v. Walgreen Co.*, No. 21-20463, 2022 WL 613160, at *1 (5th Cir. Mar. 2, 2022) (allegations of fraud that do not amount to "anything more than innocent mistake or negligence" are insufficient), *cert. denied*, 143 S. Ct. 104 (2022). Rather, FCA liability requires that a defendant acted "knowingly." *See* 31 U.S.C. § 3729(a)(1).

The terms "knowing" and "knowingly" are defined by the FCA to "mean that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A).

a. Courts continue to follow the two-part test outlined in Safeco v. Burr.

To evaluate scienter, courts often rely on the holding in *Safeco Ins. Co. of America v. Burr*, 551 U.S. 47 (2007), which set forth a two-step analysis in determining whether a defendant has acted in reckless disregard of the law. Under *Safeco*, a court first asks whether defendant's interpretation of the relevant statute or regulation was "objectively reasonable." If so, the court then determines whether "authoritative guidance" might nonetheless have warned defendant away from that interpretation.

While *Safeco* was a non-FCA case, courts often rely on it in the FCA context because the "FCA defines 'knowingly' as including actual knowledge, deliberate ignorance, and reckless disregard" and *Safeco* likewise "interpreted 'willfully' to include both knowledge and recklessness." *United States ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 348 (4th Cir. 2022).

In 2022, both the Fourth and Seventh Circuits issued opinions following the *Safeco* standard that appear headed toward Supreme Court review and resolution.

b. The Fourth Circuit and the Eleventh Circuit held that a defendant does not act knowingly if it acted on an objectively reasonable interpretation of an ambiguous regulation.

In January 2022, the Fourth Circuit issued an opinion in a case in which the relator alleged drug manufacturers engaged in a fraudulent price reporting scheme under the Medicaid Drug Rebate Statute, which requires a manufacturer to report its "best price" to the Centers for Medicare & Medicaid Services ("CMS") so that CMS can calculate the amount of rebates owed to states by the manufacturer. *See United States ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 343 (4th Cir. 2022). Federal payments to each state are reduced by the rebates that the state receives from manufacturers.

The relator alleged that the defendants gave different discounts to different customers but failed to aggregate those discounts when calculating its "best price," resulting in lower rebates defendants had to pay to the states and the government, in turn, paying $680 million more to states than if the discounts were aggregated.

The district court dismissed the relator's lawsuit on scienter grounds, holding that the Medicaid Drug Rebate Statute "may be susceptible to multiple interpretations" and that the defendants' interpretation that discount aggregation was unnecessary was not objectively unreasonable. *See United States ex rel. Sheldon v. Forest Labs., LLC*, 499 F. Supp. 3d 184, 212 (D. Md. 2020).

The Fourth Circuit affirmed dismissal, concluding that the defendants' "reading of the Rebate Statute was not only objectively reasonable but also the most natural." *Sheldon*, 24 F.4th at 351. The Fourth Circuit later vacated its opinion but,

after rehearing *en banc*, affirmed dismissal again without issuing a new opinion. 49 F.4th 873, 874 (4th Cir. 2022) (en banc).

The Fourth Circuit also reviewed another case in which the relator alleged certain adult care homes were billing for reimbursement for personal care services based on census rather than based on the actual number of hours spent providing services, in violation of the rules of the state Medicaid program. *See United States ex rel. Gugenheim v. Meridian Senior Living, LLC*, 36 F.4th 173, 177–78 (4th Cir. 2022).

As in *Sheldon*, the Fourth Circuit affirmed dismissal, concluding that the applicable Medicaid regulation was ambiguous as to whether adult care homes were required to track and bill by number of hours, and thus the defendant's interpretation of relevant regulations and agency guidance to bill by census instead of by number of hours was reasonable. As a result, the relator failed to show the defendants knowingly submitted false claims.

Similarly, the Eleventh Circuit affirmed dismissal in a case in which the relator alleged that the defendants were providing mail-order diabetic testing supplies without obtaining required assignment-of-benefit forms from patients. *See Olhausen v. Arriva Med., LLC*, No. 21-10366, 2022 WL 1203023, at *1 (11th Cir. Apr. 22, 2022). In that case, the Eleventh Circuit concluded that the defendants' interpretation of the Medicare rules concerning when an assignment-of-benefit form is needed was objectively reasonable; thus, the relator could not show that the defendants had the requisite scienter.

c. The Seventh Circuit held that guidance is "authoritative" if it comes from a source with interpretive authority.

The Seventh Circuit reviewed a case in which the relator alleged that for nearly ten years the defendant knowingly submitted false claims to government health programs when it reported its "retail" price for certain drugs as its "usual and customary" price, even though many customers paid much less than the retail price due to discount programs. *See United States ex rel. Proctor v. Safeway, Inc.*, 30 F.4th 649, 652–54 (7th Cir. 2022).

The Seventh Circuit reaffirmed the two-step scienter standard set forth in *Safeco*, and explained that in the second step, guidance is "authoritative" if it "come[s] from a source with authority to interpret the relevant text." *Safeway*, 30 F.4th at 660. At a minimum, such guidance "must come from a governmental source." *Id*. The Seventh Circuit also considered whether such guidance was sufficiently specific to put a defendant on notice that its conduct was unlawful. *Id*.

The relator in *Safeway* pointed to a footnote in the CMS Manual as guidance that should have warned the defendant away from its interpretation of how to report drug pricing. But the Seventh Circuit ultimately held that a CMS Manual footnote was not "authoritative guidance" and was "insufficiently specific" and that the risk of treble damages under the FCA should not "hinge on a single footnote in a lengthy manual that CMS can, and did, revise at any time." *Id*. at 662.

d. The Supreme Court will review the scienter standard in 2023.

On January 13, 2023, the U.S. Supreme Court agreed to hear the *Safeway* case and another 2021 Seventh Circuit case dealing with the correct standard for FCA scienter. The government seeks to have the two-part *Safeco* test deemed inapplicable to the FCA, characterizing the test as one that allows defendants "to prevail merely by showing that its unlawful conduct can be shoehorned (after the fact) into an 'objectively reasonable' interpretation of the relevant legal requirement that has not been specifically foreclosed by authoritative guidance." Reply Brief for Petitioner at 1, *United States ex rel. Proctor v. Safeway, Inc.*, No. 22-111 (U.S. Nov. 22, 2022).

In contrast, defendants have argued that immunizing "objectively reasonable" interpretations of Medicare and Medicaid regulations is necessary because they are "unclear and complex" and have been described by lower courts as "among the most completely impenetrable texts within human experience." Respondents' Brief in Opposition at 3, *United States ex rel. Schutte v. Supervalu Inc.*, No. 21-1326 (U.S. June 12, 2022) (citation omitted).

Oral argument in the case is set for April 18, 2023, and we will likely have clarity regarding the FCA scienter standard by the end of the Court's current term.

9. FALSITY

The terms "false" and "fraudulent" are not defined in the FCA, so the governing standards have developed through caselaw. A circuit split on a facet of falsity emerged over the past three years, and courts provided additional guidance in 2022.

a. *The circuit split regarding whether an objective falsehood is needed remains.*

In 2019, the Eleventh Circuit held that the FCA's falsity element requires proof of an "objective falsehood," and that "in order to show objective falsity . . . the government must show something more than the mere difference of reasonable opinion" between physicians. *See United States v. AseraCare, Inc.*, 938 F.3d 1278, 1297 (11th Cir. 2019).

In 2020, two appellate courts rejected that view and created a circuit split. The Ninth Circuit held that "the FCA does **not** require a plaintiff to plead an 'objective falsehood'" and a physician's "subjective opinion or an expression of clinical judgment"—such as a physician's Medicare certification that inpatient hospitalization is medically necessary—can be false or fraudulent. *See Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1119 (9th Cir. 2020). An example of when that might be the case is when allegations are made or evidence is presented that a medical necessity opinion is not honestly held or if it implies the existence of facts that do not exist.

The Third Circuit likewise rejected the objective-falsehood requirement, finding that a subjective dispute among physician experts about the certification of patients for hospice care was sufficient evidence of falsity to defeat summary judgment. *See United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 95 (3d Cir. 2020).

In 2022, the Ninth Circuit issued an opinion that again explained that a "false statement need not deal with purely objective facts, but rather can involve a subjective opinion or an expression of clinical judgment." *See Holzner v. DaVita Inc.*, No. 21-55261, 2022 WL 726929, at *1 (9th Cir. Mar. 10, 2022) (citation omitted). But in that case, the Ninth Circuit found that the complaint did not contain sufficient facts to state a plausible claim of false or fraudulent billing because the allegations instead "show[ed] no more than a disagreement in clinical judgment." *Id*. In other words, there were no allegations or evidence that the disagreement was a result of an opinion not honestly held or based on facts that did not exist.

b. *The Sixth Circuit held that reliance on industry standards to allege falsity is sufficient to survive dismissal.*

In 2022, the Sixth Circuit held that a relator's lawsuit could survive dismissal even though the relator relied on "industry standards" as a comparison to allege that the defendant's quotes for work to the government were inflated. *See United States ex rel. USN4U, LLC v. Wolf Creek Fed. Servs., Inc.*, 34 F.4th 507, 515 (6th Cir. 2022).

c. *The Seventh Circuit held that a relator must allege certifications were false at the time they were made.*

In 2022, the Seventh Circuit held that a relator cannot infer a certification was false at the time it was made by relying on conduct that took place months after the certification. *See Lanahan v. Cty.*

of Cook, 41 F.4th 854, 864 (7th Cir. 2022). The FCA requires the relator to "allege the certifications were false at the time they were made." *Id*.

10. RETALIATION AGAINST WHISTLEBLOWERS

To protect whistleblowers, the FCA has an anti-retaliation provision that imposes liability on an employer if an employee is "discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee . . . in furtherance of an [FCA] action . . . or other efforts to stop one or more violations of this subchapter." 31 U.S.C. § 3730(h)(1).

a. In the absence of direct evidence of retaliation, most courts continue to use a three-step framework to assess FCA retaliation claims.

Courts have generally held that when there is no direct evidence of retaliation, an FCA retaliation claim can be analyzed by the three-step, burden-shifting framework of *McDonnell Douglas Corp. v. Green*, 411 U.S. 792, 802–03 (1973).

Under the framework's first step, an employee must prove that (i) she was engaged in a protected activity; (ii) her employer had knowledge of this conduct; and (iii) the employer retaliated against the employee because of this conduct. *See, e.g.*, *Harrington v. Aggregate Indus. Ne. Region, Inc.*, 668 F.3d 25, 31 (1st Cir. 2012) (citations omitted). If the employee proves these three elements, then the second step involves the burden of proof shifting back to the employer to provide a legitimate, non-retaliatory explanation for its allegedly retaliatory action. *See id*. The framework's third step shifts the burden back to the employee to demonstrate that the employer's proffered explanation is a pretext calculated to mask retaliation. *See id*.

The Tenth Circuit and Eleventh Circuit recently framed the test more simply, requiring FCA retaliation plaintiffs to satisfy only the first step of the framework. *See United States ex rel. Sorenson v. Wadsworth Bros. Constr. Co.*, 48 F.4th 1146, 1159–60 (10th Cir. 2022); *Simon ex rel. Florida Rehab. Assocs., PLLC v. Healthsouth of Sarasota Ltd. P'ship*, No. 21-11618, 2022 WL 3910607, at *5 (11th Cir. Aug. 31, 2022).

b. The Eleventh Circuit held that a plaintiff must have an objectively reasonable belief that a false claim was submitted.

To satisfy the first step of the retaliation analysis, the Eleventh Circuit held that "engag[ing] in protected activity" requires an "objectively reasonable belief that her employer violated the FCA." *Simon*, 2022 WL 3910607, at *6. And because the Eleventh Circuit is one of the circuits that requires "a specific false claim" for an FCA case to satisfy the heightened pleading standard of Rule 9(b), an FCA retaliation claim likewise requires an objectively reasonable belief "that a false claim for payment was submitted to the government." *Id*. at *7.

c. The Third Circuit held that a compliance employee going outside of his chain of command and making specific complaints about fraud was sufficient to plead protected activity and notice.

Also relevant to the first step of the retaliation analysis, the Third Circuit recently held that a compliance employee—for example, one whose normal job responsibilities include investigating regulatory deficiencies—"must do more than his job responsibilities" to be considered to be "engag[ing] in protected activity." *United States ex rel. Ascolese v. Shoemaker Constr. Co.*, 55 F.4th 188, 195 (3d Cir. 2022). This may include "acting outside [his] normal job responsibilities [or] notifying a party outside the usual chain of command." *Id*. (citations omitted).

In that case, the relator was the quality assurance and control manager for a subcontractor hired by the manager of a federally funded construction project. When the subcontractor and manager failed to act in response to his complaints of project deficiencies, the relator informed the government agency overseeing the project. He was subsequently fired by his employer, the subcontractor. The district court dismissed the relator's FCA retaliation claim.

But the Third Circuit reversed, holding that the relator sufficiently pleaded that he engaged in protected conduct because "[i]n addition to internal reports of fraud, [he] went outside of his chain of command" by contacting the government agency "and continued to document fraudulent project deficiencies despite being told not to do so." *Id*. at 196.

In addition, the Third Circuit held that the relator sufficiently pleaded that his employer was on notice of his protected activity because he complained to management on numerous occasions, including directly advising "that receiving government funds for the Project was fraudulent under the circumstances since there were dozens of project deficiencies . . . and, consequently, certifications of their contract compliance to obtain payments would necessarily be false and fraudulent." *Id*.

d. The Tenth Circuit held that merely informing an employer about statutory noncompliance does not put the employer sufficiently on notice.

In contrast to the Third Circuit case above, the Tenth Circuit rejected the relator's proposition that "merely informing an employer it is not complying with a statutory, regulatory, or contractual requirement—whether through ignorance, by accident, or with intent—is enough to establish a nexus to the FCA." *United States ex rel. Sorenson v. Wadsworth Bros. Constr. Co.*, 48 F.4th 1146, 1160 (10th Cir. 2022).

In that case, the relator had informed his bosses that the company was not paying employees wages consistent with the Davis-Bacon Act. But the court held that simply making inquiries about wages without specifically relating them to potential violations of the FCA (as the relator in the Third Circuit case above did) was not enough. *See id*. ("Under the rule posited by [the relator], the anti-retaliation provisions of the FCA would be, in effect, incorporated into the entire body of the federal statutory and regulatory code. [*United States ex rel. Reed v. KeyPoint Gov't Sols.*, 923 F.3d 729 (10th Cir. 2019)] clearly, and quite properly, rejects such an approach . . .").

e. The Third Circuit held that pretext is evidenced by a plainly wrong non-retaliatory explanation or by a high likelihood of retaliation.

To satisfy the third step of the retaliation analysis, the Third Circuit held that there are two ways to show that an employer's allegedly non-retaliatory explanation is pretextual: (i) by "so thoroughly disproving his employers' explanation for firing him that a jury could find it unworthy of credence" or "so plainly wrong that it cannot have been the employer's real reason," or (ii) by showing directly that retaliation "was more likely than not a motivating or determinative reason for his firing." *Crosbie v. Highmark Inc*., 47 F.4th 140, 144 (3d Cir. 2022) (citations omitted). The Third Circuit explained that "[b]ald assertion[s]" and "mere suspicions of shady behavior" are insufficient to show pretext. *Id*. at 144, 146.

f. The Seventh Circuit held that generic allegations of scolding or berating did not constitute "harassment."

The Seventh Circuit found that "generic descriptions of hostility," a company executive appearing "frustrated and visibly irritated," being berated or scolded, "summary descriptions of yelling," and "unspecified intimidation" are not examples of "harassment" for purposes of 31 U.S.C. § 3730(h)(1). *See Lam v. Springs Window Fashions, LLC*, 37 F.4th 431, 438 (7th Cir. 2022).

The court explained that under an analogous anti-retaliation standard outlined by U.S. Supreme Court precedent, none of these activities would deter a reasonable worker from reporting. *See id.* (citing *Burlington N. & Santa Fe Ry. Co. v. White*, 548 U.S. 53, 67–68 (2006) ("[For] actionable retaliation . . . a plaintiff must show that a reasonable employee would have found the challenged action materially adverse, which in this context means it well might have dissuaded a reasonable worker from making or supporting a charge of discrimination.")). Because the employee did not include at least "facts describing the words used" or "the context of the statements" made against her, the Seventh Circuit affirmed summary judgment dismissal of the retaliation claim.

g. The Sixth Circuit held that the statute of limitations begins to run when the retaliation occurs, not when the plaintiff learns of it.

The FCA states that a retaliation action "may not be brought more than 3 years after the date when the retaliation occurred." 31 U.S.C. § 3730(h)(3). The Sixth Circuit rejected the application of a discovery rule to this provision, holding that the statute of limitations for an FCA retaliation claim begins to run when the retaliatory conduct occurs, not when the plaintiff learns of the conduct. *See El-Khalil v. Oakwood Healthcare, Inc.*, 23 F.4th 633, 634 (6th Cir. 2022). While it left open the possibility that a particularly long delay could allow for equitable tolling, the Sixth Circuit's opinion notes the plain text of the FCA statute tells courts to apply "the standard rule" regarding limitations periods. *Id.* at 635.

h. Courts remain split on whether the anti-retaliation provision applies to former employees with post-termination claims.

As covered in our last Review, the Sixth and Tenth Circuits disagree on whether former employees can assert post-termination retaliation claims. Specifically, the circuits are split on whether the term "employee" in 31 U.S.C. § 3730(h)(1) includes someone who is no longer an employee when the alleged retaliation takes place. *Compare United States ex rel. Felten v. William Beaumont Hosp.*, 993 F.3d 428, 430 (6th Cir. 2021) (concluding former employees can bring anti-retaliation claims) *with Potts v. Center for Excellence in Higher Educ., Inc.*, 908 F.3d 610, 618 (10th Cir. 2018) (concluding the FCA "unambiguously excludes" anti-retaliation claims by former employees).

Early last year, the U.S. Supreme Court declined to review the Sixth Circuit case. *See William Beaumont Hosp. v. United States ex rel. Felton,* 142 S. Ct. 896 (Jan. 24, 2022). So the circuit split will continue in 2023. At least one district court has since adopted the Sixth Circuit's position. *See Smith v. Athena Constr. Grp., Inc.*, No. 1:18-cv-2080, 2022 WL 888188, at *18 (D.D.C. Mar. 25, 2022) ("This court finds the Sixth Circuit's interpretation to be more persuasive than the Tenth Circuit's. It therefore rejects [the defendant]'s contention that Relator's retaliation claim must be dismissed merely because the alleged retaliation occurred after he left [the defendant]'s employment."), *cert. denied*, 2022 WL 2513500 (D.D.C. May 27, 2022).

11. THE ANTI-KICKBACK STATUTE

The AKS prohibits knowingly and willfully offering, paying, soliciting, or receiving any remuneration (including any kickback, bribe, or rebate) to induce or reward referrals for items or services reimbursable under a federal healthcare program. 42 U.S.C. § 1320a-7b(b).

Under a 2010 amendment to the FCA, "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for the purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). This amendment meant plaintiffs no longer had to prove that compliance with the AKS was material to the government's decision to pay any specific claims in an FCA case; materiality was assumed.

a. *The Eighth Circuit created a circuit split regarding the causation standard for FCA claims premised on AKS violations.*

In most jurisdictions, it is an open question whether the government or a relator, when pursuing an AKS claim, must prove that a defendant would not have included particular items or services in a claim "but for" the unlawful kickback.

Prior to 2022, the Third Circuit held that the phrase "resulting from" in the AKS did **not** impose a "but for" causal standard, and that neither the FCA nor the AKS "require[d] a plaintiff to show that a kickback directly influenced a patient's decision to use a particular medical provider." *See United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 96 (3d Cir. 2018).

In 2022, however, the Eighth Circuit created a circuit split by openly disagreeing with the Third Circuit's interpretation. *See United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 836 (2022). The Eighth Circuit reasoned that the phrase "resulting from" unambiguously suggests "but for" causation—meaning that plaintiffs asserting FCA claims premised on violations of the AKS "must prove that a defendant would not have included particular items or services but for the illegal kickbacks." *Id*.

The Eighth Circuit characterized its ruling as "narrow." *Id*. Correspondingly, a district court in the Eighth Circuit recently explained that it would apply "but for" causation only to FCA claims specifically brought under the 2010 amendment—that is, when a plaintiff seeks to establish falsity or fraud by the mere existence of an AKS violation. *See United States ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, No. 0:13-cv-3003, 2023 WL 36174, at *2 (D. Minn. Jan. 4, 2023). But if a plaintiff can establish that an AKS violation was material to the government's decision to pay a claim (as was required before the 2010 amendment), then the plaintiff does not also have to show "but for" causation. *See id*. at *3, *17 ("[T]his Court concludes that but-for causation need not be proven so long as Plaintiffs proceed exclusively on their material-falsity theory.").

Note that a district court in the Fourth Circuit, which has not weighed in on the circuit split, rejected the Eighth Circuit's "but for" causation standard and agreed with the earlier Third Circuit decision. *See United States ex rel. Fitzer v. Allergan, Inc.*, No. 1:17-cv-00668, 2022 WL 3599139, at *10 (D. Md. Aug. 23, 2022).

b. *The Second Circuit held that AKS violations do not require corrupt intent.*

The Second Circuit reviewed a case in which a pharmaceutical manufacturer sued the U.S. Department of Health and Human Services Office of Inspector General ("OIG"). The manufacturer sought to implement a program that would cover patients' Medicare copays for one of its cardiomyopathy drugs. *See Pfizer, Inc v. United States Dep't of Health & Human Servs*., 42 F.4th 67, 69 (2d Cir. 2022), *cert. denied*, No. 22-339, 2023 WL 124415 (U.S. Jan. 9, 2023). OIG issued an advisory opinion concluding the proposed program would violate the AKS because it might "operate as a *quid pro quo*—[the manufacturer] would offer remuneration . . . to the beneficiary in return for the beneficiary purchasing" the manufacturer's drug. *See Pfizer Inc. v. United*

States Dep't of Health & Human Servs., No. 1:20-cv-04920, 2021 WL 4523676, at *4 (S.D.N.Y. Sept. 30, 2021). But the manufacturer challenged the agency's interpretation of the AKS, arguing that an AKS violation requires a "corrupt" intent.

The district court granted OIG's motion to dismiss, and the Second Circuit affirmed, holding that neither the phrases "any remuneration . . . to induce," "including any kickback, bribe, or rebate," or "willfully," nor the fact that an AKS violation can create FCA liability, created any obligation to show corrupt intent. 42 F.4th at 74–80.

12. OTHER NOTABLE DECISIONS

a. *The D.C. Circuit held that FCA damages are offset by other defendants' settlement amounts.*

Courts have historically applied joint and several liability without a right of contribution to FCA cases involving a single, indivisible harm caused by multiple parties. *See, e.g.*, *United States v. TDC Mgmt. Corp.*, 288 F.3d 421, 429 (D.C. Cir. 2002).

But in other contexts, courts reduce a joint tortfeasor's potential liability when another joint tortfeasor settles. There are two approaches to reducing liability. Under a "*pro tanto*" reduction, common damages are reduced dollar for dollar by the amount of any settlements. But under a "*pro rata*" or "proportionate share" approach, the court assigns liability based on the non-settling parties' proportion of fault without regard to the amount of any settlements. Whether and how to reduce a joint tortfeasor's liability following another party's settlement was a question of first impression answered by the D.C. Circuit in 2022. *See United States v. Honeywell Int'l Inc.*, 47 F.4th 805, 810 (D.C. Cir. 2022).

The D.C. Circuit reversed the district court's adoption of the *pro rata* rule and held that the FCA's text and structure called for application of the *pro tanto* rule as the appropriate measure of settlement offsets when calculating damages under the FCA. *Id*. at 817–19. In that case, the government argued that the district court was correct to apply a *pro rata* approach, under which the defendant would have been liable for its share of $35 million of damages based on its fault for misrepresentations related to sale of defective bulletproof vests to the government. *Id*. at 810–11. The *pro tanto* rule, on the other hand, reduced the defendant's liability to $0 because

other parties' settlements exceeded the defendant's potential liability. *Id*. at 811.

The D.C. Circuit explained that unlike the *pro rata* rule, the *pro tanto* approach affords the government greater certainty with regard to the amount of potential damages available after a settlement and allows the government to tailor its settlement strategy with knowledge of any settlement's effect on funds ultimately returned to the U.S. treasury. *Id*. at 816–17.

b. The Eleventh Circuit held an association administering a state-created compensation plan was a "person" subject to FCA liability, not an "arm of the state."

Under the FCA, liability may be imposed upon "[a]ny person" who defrauds the government. 31 U.S.C. § 3729(a). The U.S. Supreme Court has previously held that a state or agency acting as an arm of the state is not a "person" for purposes of FCA liability. *Vt. Agency Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 788 (2000).

In 2022, the Eleventh Circuit reviewed a *qui tam* action brought against the Florida Birth-Related Neurological Injury Compensation Association, which was tasked with administering the Florida Birth-Related Neurological Injury Compensation Plan. Relators alleged the association engaged in improper payment practices that caused Medicaid to shoulder more financial responsibility for certain claims. *See United States ex rel. Arven v. Fl. Birth-Related Neurological Injury Compensation Ass'n*, No. 20-13448, 2022 WL 1180142, at *1–2 (11th Cir. Apr. 21, 2022). Florida had created the plan as an alternate compensation system for claims arising from birth-related neurological injuries in babies. The association argued that it was not a "person" under the FCA because the Florida legislature envisioned that it would be an arm of the state.

But the Eleventh Circuit held otherwise. It found that the state had limited control over the association, there was no ongoing funding from the state, and the state would not bear responsibility for any judgment against the association. *See id.* at *3–7. In other words, the association only had superficial ties to the state and was therefore not an "arm of the state" to avoid liability under the FCA.

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