HAYNES BOONE

False Claims Act

2023 Year in Review

Clients and friends,

The False Claims Act continues to be one of the most commonly used weapons in the government's enforcement arsenal to address various forms of fraud. This review highlights key developments from 2023 related to the FCA, including:

- The recovery by the government of nearly $2.7 billion in settlements and judgments in FCA cases in fiscal year 2023—$450 million more than the previous fiscal year's recovery but over $3 billion less than the recovery in 2021.
- The government continuing to prioritize the detection, investigation, and prosecution of fraud related to private equity investment in healthcare, cybersecurity requirements for government contractors, and COVID-19 relief programs like the Paycheck Protection Program.
- The government maintaining its traditional focus on targeting fraudulent billing schemes, holding the individuals behind corporate fraud accountable, and adopting policies to incentivize voluntary self-disclosure and cooperation.
- 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 2023, 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 2024 and beyond.

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

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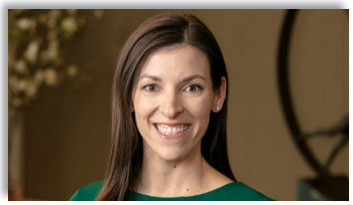

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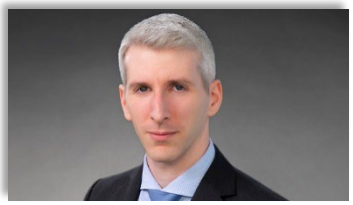

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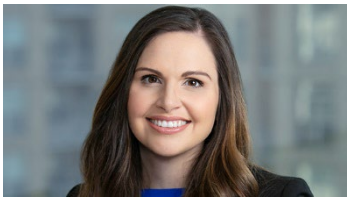

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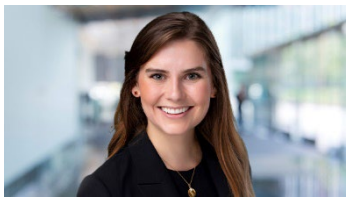

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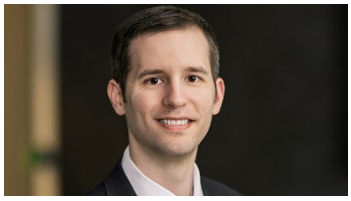

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INTRODUCTION

The False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, is the government's main civil enforcement tool for fighting fraud. It was enacted during the Civil War in response to rampant fraud by private contractors billing the government for goods that were not actually delivered.

The FCA imposes liability on any individual or entity that "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," or "conspires to commit a violation of [the FCA]." 31 U.S.C. § 3729(a)(1)(A)–(C).

The government can also bring criminal charges for knowingly making or presenting a false, fictious, or fraudulent claim to the government. 18 U.S.C. § 287. In addition, the Program Fraud Civil Remedies Act ("PFCRA"), 31 U.S.C. §§ 3801–3812, was enacted in 1986 to give agencies the ability to initiate administrative proceedings on false, fictitious, or fraudulent claims with a value of $150,000 or less—that is, "small" claims that the Department of Justice ("DOJ") may elect not to pursue under the FCA.

During fiscal year 2023, the government recovered nearly $2.7 billion in settlements and judgments in FCA cases.[1] This is an increase from the previous fiscal year's recovery of $2.2 billion but is significantly lower than the $5.7 billion recovered in 2021,[2] and it constitutes one of the lower annual recoveries since fiscal year 2008. Nonetheless, total recoveries since 1986—the year Congress significantly strengthened the FCA—now exceed $75 billion.

DOJ further reported:

- Of the nearly $2.7 billion recovered, $1.8 billion came from the healthcare industry.
- Relators (a.k.a. whistleblowers) filed 712 new "*qui tam*" actions in fiscal year 2023.
- Of the nearly $2.7 billion recovered, over $2.3 billion related to cases filed by private whistleblowers, with whistleblowers receiving nearly $350 million for their share of the rewards (including $82 million in cases where the government declined to intervene).

NOTABLE SETTLEMENTS

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

DOJ's enforcement efforts often target violations of the Anti-Kickback Statute ("AKS") and the Stark Law (a.k.a. the Physician Self-Referral Law), which DOJ argues can render a claim for government payment "false or fraudulent" and thereby form the basis for an FCA action. *See* 42 U.S.C. § 1320a-7b(g). 2023 was no different.

The largest recovery involved a $487 million judgment against Cameron-Ehlen Group, Inc. d/b/a Precision Lens and its owner Paul Ehlen after a jury concluded they violated the FCA and the AKS by paying kickbacks—including paying for private jet flights and luxury vacations—to

[1] Release available at https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023.

[2] Note that nearly half of 2021's high recovery was due to a single global resolution of criminal and civil investigations against an opioid manufacturer. Release available at https://www.justice.gov/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid.

ophthalmic surgeons to induce their use of the reimbursed by Medicare.[3]

The AKS and the Stark Law were also implicated in many other announced settlements of FCA actions. For example, an Indiana non-profit health network agreed to pay $345 million to resolve allegations that it violated the FCA and the Stark Law by knowingly submitting Medicare claims for services referred by hundreds of physicians to whom the health network paid salaries that were well above fair market value or bonuses based on the number of their referrals.[4] This settlement was DOJ's largest ever FCA settlement based on Stark Law violations.

Also, a Delaware-based specialty pharmacy agreed to pay $20 million to resolve allegations that it violated the FCA by paying kickbacks to patients in the form of waived copayments and to physicians in the form of gifts, dinners, and free administrative and clinical support services to induce them to purchase and refer the pharmacy's drugs and infusion services.[5]

In another case, a Michigan-based regional hospital system agreed to pay over $69 million to resolve allegations that it violated the FCA when it established financial relationships with eight physicians that improperly made referrals to it (in violation of the Stark Law) and that it forgave rental payments for office space rented to a physician in exchange for referrals from that physician (in violation of the AKS).[6]

As a final example, a health system in South Carolina agreed to pay $36.5 million to resolve

allegations that it violated the FCA by paying millions in illegal bonuses to orthopedic surgeons over a 14-year period based on the volume of referrals the surgeons made to the health system, which violated the AKS's and Stark Law's prohibitions against buying and selling patient referrals.[7]

2. FAILURE TO COMPLY WITH CYBERSECURITY REQUIREMENTS

In 2021, DOJ launched the Civil Cyber-Fraud Initiative, which combined 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] Since then, there has been an increasing number of settlements of FCA actions initiated due to entities' failure to comply with cybersecurity requirements.

[3] Release available at https://www.justice.gov/usao-mn/pr/court-enters-487-million-judgment-against-precision-lens-and-owner-paul-ehlen-paying.

[4] Release available at https://www.justice.gov/opa/pr/indiana-health-network-agrees-pay-345-million-settle-alleged-false-claims-act-violations.

[5] Release available at https://www.justice.gov/opa/pr/united-states-settles-kickback-allegations-biotek-remedys-inc-chaitanya-gadde-and-dr-david.

[6] Release available at https://www.justice.gov/usao-edmi/pr/covenant-healthcare-system-and-physicians-pay-over-69-million-resolve-false-claims-act.

[7] Release available at https://www.justice.gov/usao-sc/pr/st-francis-pay-united-states-365-million-settle-allegations-under-false-claims-act.

[8] Release available at https://www.justice.gov/opa/pr/deputy-attorney-general-lisa-o-monaco-announces-new-civil-cyber-fraud-initiative.

For example, an internet design firm and its manager agreed to pay $293,771 to resolve allegations that their failure to comply with cybersecurity obligations resulted in FCA violations.[9] The firm had been hired to create and maintain a HIPAA-compliant website for an entity established by the State of Florida to offer federally funded children's health insurance. But contrary to representations it made in agreements and invoices, the firm failed to secure applicants' personal information as required by HIPAA, which resulted in a breach of data from a cyberattack. According to the government, the firm's misrepresentations constituted false claims for federal funds paid out through the firm's contract with the state-created entity.

As another example, a Virginia-based telecommunications company agreed to pay over $4 million to resolve allegations that it failed to follow required cybersecurity standards in violation of the FCA.[10] The company discovered that its service to provide federal agencies with secure connections to the public internet and other external networks did not meet certain cybersecurity controls required under federal government contracts.

Finally, a Delaware-based electronic health record ("EHR") technology vendor agreed to pay $31 million to resolve allegations that it violated the FCA by misrepresenting the capabilities of certain versions of its EHR software, which in reality lacked critical functionality and thus caused providers who used the software to falsely attest to compliance with government requirements necessary to receive Medicare payments.[11] The government also alleged the vendor provided unlawful remuneration to its users to induce them to recommend its software (in violation of the AKS).

3. PAYCHECK PROTECTION PROGRAM FRAUD

Since 2021, we have reported on civil settlements involving allegations of fraud against the Paycheck Protection Program ("PPP"), a forgivable loan program established to assist small businesses impacted by the COVID-19 pandemic. In 2023, the government continued to investigate and prosecute fraudulent schemes involving the PPP, including false certifications regarding loan eligibility and misuse of loan funds.

For example, a Florida-based automotive management company and a Texas-based commercial roofing contractor each agreed to pay $9 million in separate settlements to resolve allegations they violated the FCA by knowingly providing false information in support of PPP loan and loan forgiveness applications they submitted.[12]

Both companies certified they were small businesses with fewer than 500 employees. In reality, the automotive management company shared common operational control with dozens of car dealerships across the country and had more than 3,000 employees in total. Likewise, the roofing contractor was part of a national network of affiliated companies with more than 500 employees in total. These facts rendered the companies ineligible for PPP loans.

As another example, two resort management companies in Florida agreed to pay $272,000 to resolve allegations they violated the FCA because one of the two companies sought forgiveness of

[9] Release available at https://www.justice.gov/opa/pr/jelly-bean-communications-design-and-its-manager-settle-false-claims-act-liability.

[10] Release available at https://www.justice.gov/opa/pr/cooperating-federal-contractor-resolves-liability-alleged-false-claims-caused-failure-fully.

[11] Release available at https://www.justice.gov/opa/pr/electronic-health-records-vendor-nextgen-healthcare-inc-pay-31-million-settle-false-claims.

[12] Releases available at https://www.justice.gov/opa/pr/victory-automotive-group-inc-agrees-pay-9-million-settle-false-claims-act-allegations and https://www.justice.gov/usao-ndtx/pr/national-roofing-company-settles-ppp-fraud-allegations-9-million.

its PPP loan by certifying it used part of the loan to pay the wages of its employees when in fact some of those employees were solely employed by the other company.[13]

Like cybersecurity, we expect fraud related to the PPP and other COVID-19 relief programs to remain a focus of government enforcement in 2024.

4. FRAUDULENT BILLING SCHEMES

Perhaps the most common allegation underlying an FCA action is participation in some form of fraudulent billing scheme, such as overbilling, underpaying, or billing for worthless services, medically unnecessary services, or services that were not provided. Those types of actions led to some of the largest settlements and judgments in 2023.

A. Overbilling

A Virginia-based government contractor agreed to pay $377 million to resolve allegations that it violated the FCA by knowingly overcharging the government over a 10-year period.[14] Specifically, the company allegedly allocated indirect costs associated with its commercial and international business to its government contracts and subcontracts that either had no relationship to those contracts and subcontracts or were improperly allocated to those contracts and subcontracts in disproportionate amounts.

Similarly, an Alaska-based telecommunications company agreed to pay $40.2 million to resolve allegations that it violated the FCA by knowingly inflating its prices and violating Federal Communications Commission ("FCC") competitive bidding regulations in connection with the company's participation in the FCC's Rural Health Care Program ("RHCP").[15] In particular, the company allegedly engaged in several schemes that violated FCC regulations, including entering an artificially increased bid for a contract when it learned it was the only bidder; underreporting its revenues to avoid paying into an FCC fund; and overselling bandwidth to RHCP customers and misreporting its prices for

[13] Release available at https://www.justice.gov/opa/pr/florida-resorts-agree-pay-325000-settle-false-claims-act-allegations-relating-false.

[14] Release available at https://www.justice.gov/opa/pr/booz-allen-agrees-pay-37745-million-settle-false-claims-act-allegations.

[15] Release available at https://www.justice.gov/opa/pr/gci-communications-corp-pay-more-40-million-resolve-false-claims-act-allegations-related-fcc.

purposes of receiving greater subsidy payments from the FCC than it was entitled to.

Finally, a California-based laboratory testing company agreed to pay $32.5 million to resolve allegations that it violated the FCA by improperly billing Medicare for genomic testing in violation of Medicare's "14-day rule," which prohibits laboratories from separately billing Medicare for covered tests if a physician ordered the test within 14 days of a patient's discharge from a hospital stay in an inpatient or outpatient setting.[16]

B. Underpaying

The counterpart to overbilling the government is underpaying money owed to the government. For example, a Texas-based energy company agreed to pay $16 million to resolve allegations it violated the FCA by knowingly underpaying royalties it owed on natural gas produced from federal and tribal lands.[17] Companies leasing federal or tribal lands for the production of natural gas must put the gas in marketable condition at no cost to the government.

But the company at issue allegedly deducted from its reports payments to third parties for gas transportation and processing that included costs to place the gas in marketable condition. This reduced the reported value of the gas produced and, in turn, reduced the amount of federal royalties the company was obligated to pay.

C. Billing for Services Not Ordered or Performed

A Kentucky businessman and several laboratory testing companies he owned were ordered to pay more than $370 million to resolve allegations that they violated the FCA by billing Medicare for expensive molecular tests that were not ordered by a physician or other licensed provider.[18] The case was brought by the defendants' former operations manager, who learned that the defendants were ordering the tests that were reimbursed at the highest amounts by Medicare regardless of what kind of tests were actually ordered, unbeknownst to both the patients and ordering providers.

As another example, a vascular surgeon agreed to pay $43 million to resolve allegations he violated the FCA by submitting claims for the placement of vascular stents and for thrombectomies that he did not actually perform.[19] The surgeon was also ordered to pay $19.5 million in restitution and was sentenced to 80 months in prison.

D. False Reporting

As a final example, a Connecticut-based company that owns and operates Medicare Advantage organizations agreed to pay $172 million to resolve allegations that it violated the FCA by submitting inaccurate diagnoses on behalf of its members, and then falsely certifying that its submitted diagnosis data was accurate, complete, and truthful, in order to qualify for larger regular payments from Medicare.[20]

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[16] Release available at https://www.justice.gov/opa/pr/genomic-health-inc-agrees-pay-325-million-resolve-allegations-relating-submission-false.

[17] Release available at https://www.justice.gov/opa/pr/xto-agrees-pay-16-million-resolve-natural-gas-royalty-underpayments-united-states.

[18] Release available at https://www.justice.gov/usao-mdfl/pr/united-states-obtains-more-370-million-judgments-against-kentucky-businessman-and-his.

[19] Release available at https://www.justice.gov/opa/pr/michigan-vascular-surgeon-sentenced-80-months-prison-health-care-fraud-conviction-and-agrees.

[20] Release available at https://www.justice.gov/opa/pr/cigna-group-pay-172-million-resolve-false-claims-act-allegations.

UPDATE ON LEGISLATION AND ENFORCEMENT TRENDS AND POLICIES

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 January 30, 2023, DOJ announced its final rule increasing the civil monetary penalty amounts that can be assessed for violations of the FCA to a minimum of $13,508 per false claim and a maximum of $27,018 per false claim. *See* 88 Fed. Reg. 5,776, 5,778 (Jan. 30, 2023). For 2024, these amounts will increase to a minimum of $13,946 per false claim and a maximum of $27,894 per false claim. *See* 89 Fed. Reg. 9,764, 9,766 (Feb. 12, 2024).

2. SENATOR CHUCK GRASSLEY SPONSORED BILLS TO EXPAND THE FCA.

In 2023, Senator Chuck Grassley—a long-time proponent of the government's use of the FCA to combat fraud—reintroduced a bill entitled the False Claims Amendments Act of 2023, which failed to pass in 2021.[21] The proposed bill seeks to amend the FCA in order to strengthen the government's anti-fraud enforcement power as well as whistleblowers' rights under the statute.

First and foremost, the bill would lessen the rigor of the FCA's materiality requirement (discussed in Section IV.D.5 of the Review) by clarifying that the government's decision to pay a claim despite actual knowledge of the fraud or falsity at issue is not dispositive evidence of a lack of materiality if there may have been "other reasons" for the government to do so.

Second, the bill would extend the FCA's anti-retaliation protections for whistleblowers (discussed in Section IV.D.6 of the Review) to current and former employees, such that whistleblowers who report unlawful conduct of their former employers would also be legally protected against retaliation or harassment.

Finally, the bill would require the Government Accountability Office to submit a report to Congress describing "the benefits and challenges of enforcement efforts under the FCA" and the amounts recovered under the FCA.

Also, in March 2023, the Senate passed a Senator Grassley-sponsored bill entitled the Administrative False Claims Act of 2023 ("AFCA"). The AFCA amends the PFCRA to raise the maximum amount of a fraud claim that may be handled administratively from $150,000 to $1 million, allow for inflation adjustments to that maximum amount (in the same manner penalty amounts are adjusted), and allow the government to recoup costs for investigating and prosecuting administrative actions.[22] Grassley said the AFCA was intended to "improve the process for smaller claims" since "[f]raud of any size should not be tolerated."[23]

3. DOJ OFFERS GREATER INSIGHT ON COOPERATION CREDIT.

In 2019, DOJ announced a formal policy related to cooperation credit for targets of FCA violations.[24] The policy stated that a company could be eligible for cooperation credit if they

[21] Text of the bill available at https://www.congress.gov/118/bills/s2466/BILLS-118s2466is.pdf.

[22] Text of the bill available at https://www.congress.gov/118/bills/s659/BILLS-118s659es.pdf.

[23] Release available at https://www.grassley.senate.gov/news/news-releases/bipartisan-fraud-fighting-bill-unanimously-passes-senate.

[24] Release available at https://www.justice.gov/opa/pr/department-justice-issues-guidance-false-claims-act-matters-and-updates-justice-manual.

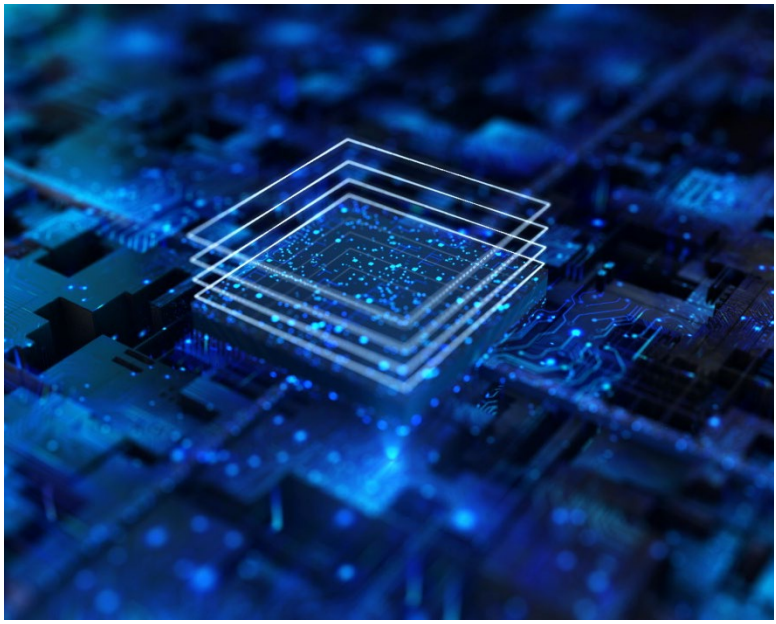
voluntarily disclosed misconduct unknown to the government and cooperated in the government's investigation, which could take the form of actions like preserving relevant documents and information, identifying individuals involved, and taking corrective action related to the unlawful conduct under investigation.[25]

Historically, the government has not always disclosed which settling individuals or companies benefitted from cooperation credit. But in 2023, DOJ began to memorialize how and why cooperation factored into FCA settlement agreements in several notable press releases.

For example, in June 2023, DOJ announced a settlement agreement in which the defendant billing company explicitly received cooperation credit under the aforementioned policy because the company "perform[ed] and disclos[ed] the results of an internal investigation, provid[ed] information relevant to potential misconduct by other individuals and entities, and admit[ted] liability."[26]

In another example, the government announced that a settling telecommunications company received cooperation credit for "identifying individuals involved in or responsible for the issues; preserving, collecting, and disclosing relevant documents and information relating to the issues; disclosing facts gathered during its independent investigation, including rolling disclosures of relevant information; and assisting in the determination and recovery of the losses caused by the issues."[27]

These settlement agreements indicate a trend towards DOJ providing a more transparent and reliable framework for cooperation credit in FCA actions, which could assist the FCA defense bar in advising clients about the possible benefits and risks of cooperation.



4. NEW PROPOSED RULES MAY FURTHER ENHANCE THE GOVERNMENT'S FOCUS ON CYBERSECURITY REQUIREMENTS.

In October 2023, the Federal Acquisition Regulatory Council[28] published two proposed rules that would impose new cybersecurity obligations for government contractors. *See* 88 Fed. Reg. 68,055 (Oct. 3, 2023); 88 Fed. Reg. 68,402 (Oct. 3, 2023). The proposed rules would require contractors to, among other things, "immediately and thoroughly" investigate "all indicators that a security incident may have occurred" and submit information to the Cybersecurity and Infrastructure Security Agency ("CISA") within eight hours of discovery. Contractors would then provide updates to CISA every 72 hours until all eradication or remediation activities are complete. Importantly, the definition of "security incident" includes an

[25] *See* DOJ Justice Manual § 4-4.112, https://www.justice.gov/jm/jm-4-4000-commercial-litigation#4-4.112.

[26] Settlement agreement available at https://www.justice.gov/d9/press-releases/attachments/2023/06/16/settlement_agreement_-_vitalaxis_-_signed_redacted.pdf.

[27] Settlement agreement available at https://www.justice.gov/opa/file/1313011/dl?inline.

[28] Additional information about the Federal Acquisition Regulatory Council may be found at https://www.acquisition.gov/far-council.

"actual or potential" occurrence of certain cyber-related events, including those that pose "actual or imminent jeopardy" to information or information systems.

The proposed rules also outline standardized cybersecurity policies, procedures, and requirements for contractors that develop, implement, operate, or maintain a Federal Information System, which is defined as "an information system used or operated by an executive agency, by a contractor of an agency, or by another organization, on behalf of an agency."

In other words, the government is attempting to both expand and harmonize the cybersecurity requirements imposed on its contractors in order to limit the negative impact of cybersecurity incidents and vulnerabilities. This will almost certainly lead to increased scrutiny of government contracts involving information and communications technology and a rise in cybersecurity-related enforcement actions.

SIGNIFICANT JUDICIAL DECISIONS

1. THE SEAL REQUIREMENT

The FCA requires that a 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 primary purpose of this seal requirement is to allow the government time to investigate the allegations and determine whether it will intervene in the case before the defendant is notified of the action. *See State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 580 U.S. 26, 34–35 (2016).

The seal requirement ultimately seeks to strike a balance between encouraging private parties to initiate more false claims litigation and the needs of the government to properly evaluate the claims for itself. *See, e.g.*, *United States ex rel. Lujan v. Hughes Aircraft Co.*, 67 F.3d 242, 245 (9th Cir. 1995).

A. Amended complaints with new but related or "substantially similar" allegations do not violate the seal requirement.

The U.S. Supreme Court has established that the FCA does not necessarily mandate dismissal of the lawsuit if a relator violates the seal requirement. *See Rigsby*, 580 U.S. at 34–37. Instead of adopting a bright-line rule, the Supreme Court concluded that district courts should determine the appropriate remedy based on case-specific factors like the government's interest, the nature of the violation, and the relator's state of mind.

Since the 2016 *Rigsby* decision, several courts have held that a complaint can be amended without being sealed again so long as the amended complaint is "substantially similar" to the original complaint, since the government would already have had a sufficient opportunity to investigate in those cases. *See, e.g.*, *United States v. Walgreen Co.*, No. 2:09-cv-01293, 2017 WL 10591756, at *3 (C.D. Cal. May 1, 2017). In 2023, two district courts further clarified when dismissal may be warranted where an amended complaint violates the seal requirement.

In *United States ex rel. Williams v. Landmark Hospital of Athens, LLC*, the U.S. District Court for the Middle District of Georgia dismissed two counts of relators' amended complaint that it found not to be "substantially similar" to the original complaint for violating the FCA's seal requirement. No. 3:21-cv-00036, 2023 WL 3097948, at *8 (M.D. Ga. Apr. 26, 2023). The relators' original complaint was properly filed under seal and alleged false or fraudulent claims for payment by Medicare and Medicaid related to COVID-19 testing. *See id*. at *2–*5. The

government declined to intervene. Subsequently and in response to the defendants' motion to dismiss, the relators filed an unsealed amended complaint that included two new claims alleging violations of the PPP and the presentation of additional false claims to the government related to medication, laboratory, treatment, and equipment charges. *See id*. at *1.

The court weighed three factors: (1) whether and to what extent the seal violation harmed the government; (2) the nature of the violation; and (3) whether the violation was willful or made in bad faith. Based on these factors, the court concluded that the two new claims were not related to the original claims and that "the Government was not afforded an opportunity to conduct a confidential review of these claims prior to declining intervention." *Id.* at *9. Accordingly, the two claims were dismissed for violation of the seal requirement.

In contrast, in *United States ex rel. Miller v. ManPow, LLC*, the U.S. District Court for the Central District of California granted the relators' motion for leave to file an amended complaint that did not comply with the seal requirement. No. 2:21-cv-05418, 2023 WL 2661182, at *1 (C.D. Cal. Feb. 28, 2023). The relators' original complaint was properly filed under seal and alleged that the defendant fraudulently obtained PPP loans. *Id*. After the government declined to intervene, the relators moved for leave to file an unsealed amended complaint to include newly discovered information. *Id*.

The court granted the motion and found that the seal requirement does not prevent filing of an amended complaint with new allegations so long as those allegations relate to the same unlawful conduct alleged in the original complaint and "merely add details" without creating new or altering previous theories of liability. *Id.* at *3.

These two cases suggest that to avoid dismissal for violation of the FCA's seal requirement, amended complaints should not include new

claims that are unrelated to claims in the original complaint or that refashion the theory of liability.

2. GOVERNMENTAL DISMISSAL & HEARING REQUIREMENT

The FCA authorizes the government to dismiss an action over a relator's objections so long as the government notifies the relator of its motion to dismiss and the court provides the relator with an opportunity for a hearing on the matter. 31 U.S.C. § 3730(c)(2)(A).

Litigants have long agreed that this provision allows the government to dismiss an action in which it intervened at the outset. But it remained

an open question whether the government could exercise this option when it declined to intervene during the seal period.

In 2023, the U.S. Supreme Court addressed the question in *United States ex rel. Polansky v. Executive Health Resources, Inc.*, 599 U.S. 419 (2023). The Court held that the government may seek dismissal if it intervened "sometime in the litigation," whether during the seal period or after. *Id.*

In *Polansky*, the relator, a doctor who worked for a company that assisted hospitals with Medicare-covered billing services, filed a *qui tam* action against his employer. The government declined to intervene during the seal period. After a protracted seven years of litigation, the government filed a motion to dismiss under Section 3730(c)(2)(A). The relator contended that the government could not move to dismiss the case because it declined to intervene during the seal period. The government countered that Section 3730(c)(2)(A) gives it *carte blanche* authority to dismiss a *qui tam* action, irrespective of its intervention in the matter.

The Supreme Court rejected both arguments, ultimately holding that the FCA's text indicates that Section 3730(c)(2)(A) authorizes the government to seek dismissal only when it has, in fact, intervened, but does not place a limit on when that can happen.

The intervention requirement, however, lacks some teeth. In *Polansky*, the government—who had not previously intervened—successfully dismissed the case because the lower court construed its motion to dismiss as both a motion to intervene and dismiss. This is because a request for dismissal may "itself establish[] good cause to intervene." *Polansky*, 599 U.S. at 428–29 & n.2.

Polansky further clarified that the standard for dismissal is similar to that of voluntary dismissal under Rule 41(a) of the Federal Rules of Civil Procedure, with two caveats. First, as statutorily mandated, the court must give the relator an opportunity for a hearing. Second, the court must consider the relator's interest in dismissal. Even so, Rule 41(a) imposes a low bar, and it will be met "in all but the most exceptional cases." *Id*. at 437. Because the injury asserted in an FCA case is "exclusively to the Government," the government's own assessment that an action will not vindicate its interests will generally suffice. *See id*. at 425, 437.

As for the hearing requirement, the interplay between Rule 41(a) and Section 3730(c)(2)(A) may render an oral or evidentiary hearing unnecessary. Under Rule 41(a)(1), a plaintiff may unilaterally dismiss an action before a motion for summary judgment. At this stage, the district court typically "has no adjudicatory role." *Id*. at 436 n.4. Thus, a Section 3730(c)(2)(A) hearing before summary judgment may either be unnecessary or constrained to an inquiry into whether the dismissal violates the relator's constitutional rights. *Id.*

The Third Circuit in *Brutus Trading, LLC v. Standard Chartered Bank* held that the district court was not required to hold an evidentiary hearing when dismissal is sought prior to summary judgment. No. 20-2578, 2023 WL 5344973, at *2 (2d Cir. Aug. 21, 2023). Indeed, the district court satisfied the FCA's hearing requirement by "carefully considering the parties' written submissions."

In clarifying the standard, the Third Circuit held that the court "must exercise some degree of scrutiny in evaluating the government's motion to dismiss," but this scrutiny may be met, at least prior to summary judgment, by evaluating the arguments on the papers. *See id*. And as *Polansky* and subsequent decisions have made clear, the government will largely succeed in dismissing *qui tam* actions that, in the government's view, are not worth its resources. *See United States ex rel. Carver v. Physicians Pain Specialists of Alabama, P.C.*, No. 22-13608, 2023 WL 4853328, at *6 (11th Cir. July 31, 2023).

3. STATUTORY BARS TO BRINGING AN FCA ACTION

A. Public Disclosure Bar & Original Source Exception

The FCA requires a court to dismiss a relator's action if its allegations were publicly disclosed, unless the relator is an original source. *See* 31 U.S.C. § 3730(e)(4)(A). Allegations are generally considered "publicly disclosed" if "substantially the same allegations or transactions" were disclosed: (1) in a federal criminal, civil, or administrative hearing in which the government or its agent is a party; (2) in a congressional, Government Accountability Office, or other federal report, hearing, audit, or investigation; or (3) from the news media. *Id.*; *see also United States ex rel. Jehl v. GGNSC Southaven, L.L.C.*, No. 22-60209, 2022 WL 17443684, at *2, *5 (5th Cir. Dec. 6, 2022) (resolving the case on other grounds but noting that the defendant "ma[de] a good public disclosure bar argument" against a relator who filed its complaint in reliance on publicly available administrative depositions that he discovered online).

A relator is an "original source" if (1) prior to a public disclosure of the allegations, he or she "voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based," or (2) "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and ... has voluntarily provided the information to the Government before filing an action." 31 U.S.C. § 3730(e)(4)(B).

i. The Ninth Circuit held that the 2010 amendments to the public disclosure bar did not disturb its precedent.

The standard above reflects the FCA public disclosure bar as amended in 2010. Nonetheless, courts are still occasionally having to apply the previous version of the statute in cases involving conduct that occurred before the 2010 amendments. *See Piacentile v. U.S. Oncology, Inc.*, No. 22-00018, 2023 WL 2661579, at *1–2 (2d Cir. Mar. 28, 2023) (affirming dismissal under the pre-2010-amendment public disclosure bar of a defendant that was not named in previous lawsuits involving the same scheme because the pre-amendment standard considers whether the claims were "*based in any part* upon publicly disclosed allegations or transaction") (emphasis added).

Additionally, the Ninth Circuit clarified last year that the post-amendment standard of "substantially the same allegations or transactions," which replaced the pre-amendment standard of allegations "based upon" previously disclosed allegations, leaves Ninth Circuit pre-amendment precedent effectively undisturbed because the Ninth Circuit had always interpreted "based upon" to mean "substantially similar to." *United States ex rel. Silbersher v. Valeant Pharm. Int'l, Inc*., 89 F.4th 1154, 1167 (9th Cir. 2024); *see also United States ex rel. Sam Jones Co., LLC v. Biotronik Inc.*, No. 2:17-cv-01391, 2023 WL 2993409, at *7 (C.D. Cal. Jan. 4, 2023) (holding that under either version of the statute, the public disclosure bar applied where both the complaint and a previous New York Times article "involve[d] [the defendant] as the main actor and set-out the same core charge that [the defendant] hired the family members of physicians to induce those physicians to implant [the defendant's] devices").

ii. The Ninth Circuit held that an IPR review of a patent is not a federal hearing under the public disclosure bar.

The Ninth Circuit also held in the same opinion that an *inter partes* review ("IPR") of a patent—a trial-like proceeding before the Patent and Appeals Board—does not qualify as a federal hearing under subsections (1) or (2) of the public disclosure bar because the government is not a party to an IPR and the IPR's primary function is adversarial and adjudicatory, not investigative. *Silbersher*, 89 F.4th at 1166.

iii. Multiple courts hold that relators do not qualify for the original source exception if they do not have independent knowledge of the conduct.

As to the original source exception, courts repeatedly hold that relators do not qualify for the exception if they do not have independent knowledge of the conduct. *See Piacentile*, 2023 WL 2661579, at *3 (rejecting the original source exception where the "'relators' allegations are based on interviews that one relator conducted with executives at [defendant companies]"); *Sam Jones*, 2023 WL 2993409, at *9 (rejecting the original source exception where neither relator had "'independent' knowledge of the purported fraud prior to the publication of the N.Y. Times article").

B. 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 objective 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).

i. The Eastern District of Pennsylvania held that the first-to-file bar is not implicated if a subsequent action identifies new unrelated defendants.

In 2023, the U.S. District Court for the Eastern District of Pennsylvania held that the first-to-file bar does not preclude a subsequent FCA action where relators allege a substantially similar fraudulent scheme to that of a pending action but simultaneously identify new unrelated defendants that may not have been discovered by the government in the pending action. *See United States v. Select Rehab. Inc.*, No. 2:19-cv-03277, 2023 WL 6341446, at *1 (E.D. Pa. Sept. 29, 2023).

In that case, relators filed a *qui tam* action alleging that the defendants billed Medicare and Medicaid for therapies that patients either did not need or were not provided. *Id*. This was the

second of four *qui tam* actions filed against the primary defendant, a national provider of contract rehabilitation services, but this action added operators of skilled nursing facilities as new defendants. *Id.* at *1. With the government's consent, relators voluntarily dismissed Select, leaving only the new defendants. *Id.*

As a matter of first impression, the court surveyed the precedent of its sister circuits to determine "whether the adding of new defendants in a second *qui tam* action takes the case outside the reach of the first-to-file rule." *Id.* In adopting the reasoning of both the Fifth Circuit (which held the key question was whether the first action alleges enough facts to instigate a government investigation that would lead to the identity of the new defendants) and the Tenth Circuit (which considered a defendant's identity a material element of a fraud claim), the court concluded that "adding unrelated defendants in a later-filed FCA action does not necessarily bar that action under the first-to-file rule." *Id*. at *10. Accordingly, the court held that "a second action is not barred [by the first-to-file rule] when it asserts a new claim based upon similar but different schemes and a separate injury caused by different defendants." *Id.*

ii. The Middle District of Florida held that the first-to-file bar prohibited a subsequent action where the government could have investigated newly named defendants based on the first-filed action.

In contrast to the outcome of *Select Rehab.*, the U.S. District Court for the Middle District of Florida held that the first-to-file bar precluded a later-filed FCA action because "the government would have been equipped to investigate Defendants based on only [the first-filed] complaint." *See United States v. Millennium Physician Grp.*, 2:16-cv-00798, 2023 WL 2022228, at *5 (M.D. Fla. Feb. 15, 2023).

In *Millennium*, the relator filed a *qui tam* action alleging Medicare and Medicaid fraud. In determining whether the first-to-file bar served to prevent the later-filed action, the court explained that "the first-filed and later-filed claims need not be identical; they need only be 'related.'" *Id.* To decide whether the two claims are 'related,' courts are instructed to conduct a side-by-side comparison and consider "whether the later complaint alleges a fraudulent scheme the government already would be equipped to investigate based on the first complaint." *Id.* (quoting *Cho v. Surgery Partners, Inc.*, 30 F.4th 1035 (11th Cir. 2022)).

Applying this standard, the court found the later-filed complaint not only failed to allege a sufficiently different fraudulent scheme to that of the first-filed complaint, but that the two complaints contained a "myriad" of essential facts in common. *Id.* Further, the court reasoned "the government would have been equipped to investigate Defendants based on only [the first-filed] complaint," and correspondingly held that the later-filed complaint was prohibited by the first-to-file bar. *Id.*

C. Government Action Bar

Another statutory bar under the FCA is the government action bar, which forbids relators from bringing a *qui tam* action "based upon allegations or transactions [that] 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).

One aim of the government action bar is to protect FCA defendants from future relators where the government has previously settled related conduct, even if the conduct at issue was not part of the release. *See United States ex rel. Bennett v. Biotronik, Inc.*, 876 F.3d 1011, 1020 (9th Cir. 2017).

In 2023, the Fifth Circuit reversed a dismissal under the FCA's government action bar. *See United States ex rel. Miniex v. Houston Hous. Auth.*, No. 21-20435, 2023 WL 6174416 (5th Cir. Sept. 22, 2023) (per curiam) (unpublished). A relator alleged the defendant "skirted federal housing regulations" for the procurement of contractors and services. *Id.* at *1. But prior to the relator's action, the U.S. Department of Housing and Urban Development Office of Inspector General had conducted an audit of the defendant's "procurement practices" and concluded that the defendant "repeatedly had failed to conduct federally-required cost estimates before procuring contractors and services." *Id.*

On the defendant's motion, the district court dismissed the action, finding that the audit qualified as a "requisite government action" for invoking the government action bar. *Miniex*, 2023 WL 6174416, at *3. The Fifth Circuit disagreed on appeal, however, and found that an "OIG audit is plainly not a civil action or a 'administrative civil money penalty proceeding.'" *Id.* at *3. Therefore, "the government action bar does not apply and the district court was incorrect to dismiss the . . . claims based on that exception." *Id.*

4. SUBSTANTIVE ELEMENTS OF AN FCA CLAIM

A. Rule 9(b) Particularity

Claims brought under the FCA are subject to heightened pleading standards under Rule 9(b). Rule 9(b) requires a complaint to "state with particularity the circumstances constituting fraud." FED. R. CIV. P. 9(b). Most courts have held that in order for a complaint to survive a motion to dismiss under this heightened standard, the complaint must identify, at a minimum, the "who, what, when, where, and how" of the alleged fraud.

But circuit courts have been split for years over what allegations actually satisfy Rule 9(b) for FCA claims. Some circuits, including 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. Most other circuits take a less stringent approach, requiring only particular details of a scheme to submit false claims to the government combined with indicia of reliability that false claims were actually submitted. However, consistent with years past, there are specific nuances amongst the different jurisdictions.

i. Eleventh Circuit precedent requires a claimant to plead particularity of both the circumstances constituting fraud and the fraudulent submission to the government.

In addition to the base requirement that an FCA action plead "the who, what, where, when, and how of improper practices," the Eleventh Circuit also requires the "who, what, where, when, and how of fraudulent submissions to the Government." *United States v. Landmark Hosp. of Athens, LLC*, No. 3:21-cv-00036, 2023 WL 3097948, at *6 (M.D. Ga. Apr. 26, 2023) (quoting *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005)).

Relying on this precedent, the U.S. District Court for the Middle District of Georgia dismissed a relator's claim when the complaint failed to allege who submitted the requests for payment to the government, when the requests were made, what the defendant sought payment for, what documentation was presented in support of the claims, or information regarding whether the government rendered payment for those services. *Id*. at *10.

In addition, a claimant may be required to successfully link the improper practices to the specific improper conduct by the named defendants. For example, in *Millennium Physician Group*, a relator filed a claim alleging that their former employer violated the FCA through fraudulent testing schemes and by submitting false records to Medicare and Medicaid. 2023 WL 2022228, at *1.

The U.S. District Court for the Middle District of Florida found the complaint filed by the relator failed to meet the pleading requirements of Rule 9(b) because the complaint did not provide sufficient details as to how the false records could be linked to the named defendants or describe each defendant's independent involvement in the alleged fraud. *Id.* at *7. Instead, the complaint merely described the conduct of all the defendants generally, which the court held was insufficient to satisfy Rule 9(b). *Id.*

ii. In contrast, the Fifth and Ninth Circuits require only details regarding the circumstances constituting fraud or mistake as well as reliable indicia that false claims were submitted.

Rather than requiring details about specific false claims submitted, the Fifth and Ninth Circuits require a claimant only to (1) state with particularity the circumstances constituting fraud or mistake, including the "who, what, when, where, and how of the misconduct charged," paired with (2) a "reliable indicia that lead to a

strong inference that claims were actually submitted." *Miniex*, 2023 WL 6174416, at *1 (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)); *Gharibian ex rel. United States v. Valley Campus Pharmacy, Inc.*, No. 21-56253, 2023 WL 195514, at * 1 (9th Cir. Jan. 17, 2023). Even under this standard, conclusory and summary allegations will not suffice. *Miniex*, 2023 WL 6174416, at *5; *Gharibian*, 2023 WL 195514, at *1–2.

In *Miniex*, the Fifth Circuit reversed dismissal of a relator's FCA claims concerning failure to comply with procurement regulations where the relator had outlined a defendant's "repeated requests for federal funding and the certifications it made to receive that funding, along with specific details regarding [the defendant]'s fraud via their alleged failure to conduct cost-estimates," as well as "over twenty-five specific transactions that rendered [the defendant]'s certification of compliance false," including the "'time, place, and contents' of those transactions, who was responsible for them, and what was gained out of it." 2023 WL 6174416, at *3. The court held that

these allegations satisfied Rule 9(b) because the relator had "state[d] with particularity the circumstances constituting fraud." *Id*.

In contrast, the relator's claims against other defendants were dismissed where the allegations were "entirely summary, never specifying the properties, contractors, or services procured" by those defendants, and even lacked "detail when the false claims were submitted or when any particular conduct by these entities occurred." *Id*. at *5.

Similarly, in *Gharibian*, the Ninth Circuit dismissed the relator's claim for failure to satisfy Rule 9(b) because the complaint was conclusory. 2023 WL 195514, at *1–2. The relator brought a *qui tam* action alleging the defendants had instructed their employees to misrepresent who their employers were and to falsify patient records in order to procure prior authorizations for prescription medications from insurance providers in violation of the FCA. *Id.* But the relator either only identified private insurers and not any specific government payor, or only made conclusory allegations based on "information and belief." *Id.* Both types of allegations were held to be insufficient under Rule 9(b). *Id.*

iii. The Second Circuit allows a limited exception to the particularity requirement, but it does not enable speculative allegations.

The Second Circuit has stated in order to satisfy the Rule 9(b) particularity requirements, the party alleging fraud must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Doe 1 v. EviCore Healthcare MSI, LLC*, No. 22-530, 2023 WL 2249577, at *2 (2d Cir. Feb. 28, 2023) (quoting *United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017)).

But the Second Circuit has also specified an exception where plaintiffs may not be required to plead the requisite particularity when the allegations are based on facts "peculiarly within the opposing party's knowledge." *Id.* (quoting *Wexner v. First Manhattan Co.*, 902 F.2d 169, 172 (2d Cir. 1990)). However, this is a limited exception and not a "license to base claims of fraud on speculation and conclusory allegations." *Id.*

In *Doe 1*, the Second Circuit held the claimant's allegations failed to meet the heightened pleading standard. *Id.* The relators brought a *qui tam* action under the FCA alleging that their employer instituted interlocking schemes with private health insurance companies to secure high rates of approval for requested medical procedures as opposed to providing the individualized medical necessity review required by regulations. *Id.* at *1. Thus, the relators alleged the defendant caused insurance companies to bill the government for unnecessary and fraudulently approved medical services. *Id.*

The district court granted the defendant's motion to dismiss, finding that the relators failed to satisfy Rule 9(b). *Id.* at *2. The Second Circuit affirmed the district court's dismissal, finding that the relators failed to identify "even a single instance" of a medical procedure that was fraudulent or unnecessary. *Id.* Instead, the relators alleged that the sheer volume of the defendant's approvals made it inevitable fraudulent claims were approved, and that additional details about actual fraud was "peculiarly within the [defendant]'s knowledge." *Id.* at *3. But the Second Circuit held that such "speculative allegations" are insufficient to satisfy Rule 9(b). *Id.*

Regardless of where an FCA claim is brought, a complaint must, at minimum, provide the "who, what, when, where, and how" of the alleged fraud. Conclusory and summary complaints generally will not survive a motion to dismiss

under the heightened pleading standard of Rule 9(b), even in circuits that do not require detailed allegations of a specific false claim that was actually submitted to the government.

B. 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). Instead, 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 (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A).

i. The FCA scienter standard requires inquiry into a defendant's subjective knowledge and belief.

As we previously wrote, in its combined decision in *United States ex rel. Schutte v. SuperValu, Inc.* and *United States et al. ex rel. Proctor v. Safeway, Inc.*, the U.S. Supreme Court unanimously held that the scienter element in an FCA case turns on a defendant's subjective beliefs regarding an ambiguous legal requirement, rather than on what an objectively reasonable person may have believed—rejecting a standard that had been set by the Seventh Circuit and embraced by numerous other circuits. *See United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 749 (2023).

The underlying cases allege that national pharmacy operators SuperValu and Safeway violated the FCA by reporting the full retail price of prescription drugs as their public "usual and customary" price in the process of seeking reimbursement from Medicare and Medicaid. *Id.*

at 744–45. Instead, those drugs were allegedly provided at significantly discounted price to many patients. *Id.* at 745–46. The relators alleged that not only were the pharmacies required to report the discounted price as their "usual and customary" price, but that the pharmacies in fact knew that they should have reported the discounted prices under the applicable federal regulations. *Id.* at 746–47.

The district court granted summary judgment in favor of the defendants, finding that the defendants had not submitted false claims knowingly. *Id.* at 747. The Seventh Circuit affirmed, holding that "[b]ecause SuperValu had an objectively reasonable understanding of the regulatory definition of [usual and customary] price and no authoritative guidance placed it on notice of its error, the Relators have not shown that SuperValu acted knowingly." *United States ex rel. Schutte v. SuperValu Inc.*, 9 F.4th 455, 472 (7th Cir. 2021).

The Supreme Court disagreed with the Seventh Circuit's interpretation of the FCA's knowledge requirement, however, ruling that this view would require a claim "to be objectively unreasonable, as a legal matter, before a defendant could be held liable for 'knowingly' submitting a false claim, no matter what the defendant thought." *Schutte*, 598 U.S. at 748.

The Supreme Court held instead that a defendant's subjective knowledge and beliefs regarding an ambiguous legal requirement are what must be reviewed to determine if the defendant acted "knowingly" under the FCA. *Id.* at 749. Thus, if a defendant "correctly interpreted the relevant phrase and believed their claims were false, then they could have known their claims were false." *Id.* at 743.

The Supreme Court's decision has already forced lower courts to reevaluate prior holdings. *See e.g.*, *United States ex rel. Sheldon v. Allergan Sales, LLC*, 143 S. Ct. 2686 (2023) (remanding "for further consideration in light of *United States ex rel. Schutte v. SuperValu*."); *Olhausen v. Arriva Med., LLC*, 143 S. Ct. 2686 (2023) (same); *United States ex rel. Heath v. Wisconsin Bell, Inc.*, 75 F.4th 778 (7th Cir. 2023) (applying *Schutte* scienter standard and holding genuine issue of material fact existed as to recklessness); *United States ex rel. Aldridge v. Corp. Mgmt., Inc.*, 78 F.4th 727, 739 (5th Cir. 2023) (citing *Schutte* to explain that, "[w]hat matters for an FCA case is whether the defendant knew the claim was false."); *United States ex rel. Miller v. Reckitt Benckiser Group PLC*, No. 1:15-cv-00017, 2023 WL 6849436, at *17 (W.D. Va. Oct. 17, 2023) (staying the case, requiring briefs addressing the impact of *Schutte*, and thereafter finding the relator had sufficiently alleged scienter because under *Schutte* "it is [the defendant]'s subjective knowledge at the time of its submission, not its post hoc rationalizations or an interpretation that is objectively reasonable, that matters").

The decision in *Schutte* potentially increases the burden on defendants to prevail on motions to dismiss or summary judgment on the issue of scienter. Unless companies take protective measures, defense counsel will be required to engage in a fact-specific inquiry to ensure that a defendant's subjective knowledge—including each individual whose "knowledge" could be imputed to the fund-receiving entity—supported submission of the claims at issue.

C. Causation

To establish liability under the FCA, the government or relator must demonstrate "causation"—*i.e.*, that a specific false claim or claims "resulted from" the defendant's fraudulent conduct. This requirement flows from the FCA itself and also from Rule 9(b) of the Federal Rules of Civil Procedure, since the requirement that a plaintiff "state with particularity the circumstances constituting fraud" has been interpreted to require "fairly *show[ing]* the defendants *caused* false claims to be filed." *E.g.*, *United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 914 (6th Cir. 2017) (emphasis added).

In recent years, however, courts have grappled with questions regarding the level of causal connection needed to tie the alleged fraud to the purported claims, the measure of damages available under the FCA depending on the nature of the purported causal nexus alleged, and the types of evidence relators may rely on to demonstrate causation.

Several notable federal court decisions from 2023 shed light on these questions.

i. The Sixth Circuit held that the exacting "but for" causation standard applies even in AKS-based FCA cases—deepening an existing circuit split.

The AKS imposes criminal liability on an individual or entity that knowingly and willfully offers or pays any remuneration to any person to induce such person to (A) refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal healthcare program, or (B) purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal healthcare program. 42 U.S.C. § 1320a-7b(b).

Congress amended the AKS in 2010 to impose FCA liability for certain AKS violations because a "claim that includes items or services *resulting from* a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g) (emphasis added). In other words, claims submitted to federal healthcare programs that result from violations of the AKS are *per se* false or fraudulent for purposes of FCA liability.

In 2023, the Sixth Circuit joined the Eighth Circuit in interpreting the phrase "resulting from" to mean "but for" causation. *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1053 (6th Cir. 2023), *cert. denied sub nom. Martin v. Hathaway*, No. 23-139, 2023 WL 6378570 (U.S. Oct. 2, 2023). It is not enough in the Sixth and Eighth Circuits to show merely a causal link between the claim and the scheme. An FCA plaintiff alleging claims resulting from AKS violations must instead show that an allegedly false or fraudulent claim would not have been submitted "but for" the alleged kickback scheme.

As background, the Third Circuit first addressed the question of what type of causal connection is sufficient to satisfy the "resulting from" language in 2018. *See United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 96–100 (3d Cir. 2018). The Third Circuit reviewed the statutes' legislative history and rejected a "but for" causation standard, which would require showing "direct causation" or that a kickback directly influenced a patient's or medical professional's judgment. *See id*. at 96. This, the court explained, "would dilute the False Claims Act's requirements vis-à-vis the Anti-Kickback Statute, as direct causation would be a precondition to bringing a False Claims Act case but not an Anti-Kickback Statute case." *Id*. at 97. Instead, only a "link" is required. This means a plaintiff must merely show "some connection between a kickback and a subsequent reimbursement claim." *Id*. at 100.

In 2022, the Eighth Circuit created a circuit split by rejecting the Third Circuit's conclusion. *See United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 834 (8th Cir. 2022). Merely showing that (i) a claim failed to disclose an AKS violation or was "tainted" by a kickback, or (ii) that the AKS violation "*may* have been a contributing factor" is not enough. *Id*. at 835 (emphasis in original). Rather, the Eighth Circuit looked at the dictionary definitions of "resulting" and concluded the text "resulting from" meant "a but-for causal relationship." *Id*. at 834.

The Eighth Circuit limited its holding, however, by explaining that not every FCA case "requires a showing of but-for causation." Rather, "but for" causation applies only when a plaintiff seeks to establish falsity or fraud through an AKS violation

pursuant to 42 U.S.C. § 1320a-7b(g). *Id*. at 836. There are of course other ways of showing a claim was false or fraudulent under the FCA.

District courts have since acknowledged this limitation. For example, the U.S. District Court for the Western District of Texas found the Eighth Circuit's holding inapplicable where the plaintiff did not rely exclusively on the AKS to demonstrate falsity and asserted alternative theories of falsity. *See United States ex rel. Hueseman v. Prof'l Compounding Ctrs. of Am., Inc*., No. 5:14-cv-00212, 2023 WL 2669879, at *10 n.4 (W.D. Tex. Mar. 27, 2023).

On the other hand, some district courts have rejected the Eighth Circuit's "but for" causation standard and viewed the Third Circuit's use of legislative history as more persuasive. *See United States ex rel. Fitzer v. Allergan, Inc.*, No. 1:17-cv-00668, 2022 WL 3599139, at *10 (D. Md. Aug. 23, 2022); *see also United States ex rel. Everest Principals, LLC v. Abbott Labs., Inc*., No. 3:20-cv-00286, 2022 WL 3567063, at *8 (S.D. Cal. Aug. 18, 2022) (holding relator had sufficiently pleaded causation by "adequately establish[ing] a 'link' between the kickback and the claim for reimbursement").

Back to the present: the Sixth Circuit's *Martin* decision joined the Eighth Circuit in upholding the "but for" standard of causation. 63 F.4th at 1053. The case involved friction between medical providers in a small town in Michigan. The town's only local option for ophthalmology services was a practice with two ophthalmologists, Dr. Martin and Dr. Hathaway. Likewise, the only local option for surgery was a local hospital. The practice and hospital therefore had a history of referring patients to each other.

In 2018, however, Dr. Martin sought to become employed by the hospital, which could mean the hospital would no longer need to send patients to Dr. Hathaway's practice. In turn, Dr. Hathaway told the hospital he expected to increase his surgical referrals due to a contemplated merger, but he threatened to cease referring to the hospital if it hired Dr. Martin. The hospital gave in and did not hire Dr. Martin. She responded by filing a *qui tam* lawsuit alleging that the hospital's decision not to hire her was "remuneration" to Dr. Hathaway, which tainted all referrals between Dr. Hathaway and the hospital going forward. *See id*. at 1051.

The district court dismissed Dr. Martin's case. On appeal, the Sixth Circuit affirmed and adopted the Eighth Circuit's reasoning as well as the U.S. Supreme Court's reasoning in *Burrage v. United States*, which held that absent strong "textual or contextual indication[s]" to the "contrary," the ordinary meaning of "resulting from" is "but for" causation. 63 F.4th at 1052 (citing *Burrage v. United States*, 571 U.S. 204, 212 (2014)).

As a result, the Sixth Circuit found that Dr. Martin had not identified any claims for reimbursement that would not have occurred but for the hospital's decision not to hire. Instead, the court held the claims at issue all arose from the pre-existing relationship between the hospital and practice that was not altered by the alleged kickback scheme. Thus, Dr. Martin failed to meet the "but for" causation threshold. *Id*. at 1053.

Unlike the Eighth Circuit, the Sixth Circuit did not limit its holding to FCA cases where plaintiffs are attempting to show causation only through an AKS violation pursuant to 42 U.S.C. § 1320a-7b(g). But the Sixth Circuit did not view its decision as raising the bar for plaintiffs too high, as it added that a "faithful interpretation of the . . . 'resulting from' requirement[] still leaves plenty of room to target genuine corruption." *Id.* at 1055.

ii. District courts in the First Circuit are split regarding whether the "but for" causation standard applies in AKS-based FCA cases.

The First Circuit has yet to explicitly weigh in on this issue. *See Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019) (declining to discuss the "full implications" of the AKS provision containing the AKS's "resulting from" language). That silence has prompted a split within the U.S. District Court for the District of Massachusetts, where two decisions within several months of one another reached opposing conclusions. *Compare United States v. Regeneron Pharms., Inc.*, No. 1:20-cv-11217, 2023 WL 6296393, at *11 (D. Mass. Sept. 27, 2023) (siding with the Sixth and Eighth Circuits and adopting the more rigorous "but for" standard)*, motion to certify appeal granted,* 2023 WL 7016900 (D. Mass. Oct. 25, 2023), *with United States v. Teva Pharms. USA, Inc.*, No. 1:20-cv-11548, 2023 WL 4565105, at *5 (D. Mass. July 14, 2023) (holding that "[t]he government need not prove 'but for' causation" and instead adopting the First Circuit's "sufficient causal connection" language (citing *Guilfoile*, 913 F.3d at 190)).

The district court granted motions to pursue an interlocutory appeal in both the *Regeneron* and *Teva* cases to address the question as to the proper causation standard, which the court agreed is "a controlling question of law as to which there is substantial ground of difference of opinion." *Regeneron*, 2023 WL 7016900, at *1 (D. Mass. Oct. 25, 2023); Order, *United States v. Teva Pharm. USA, Inc.*, No. 20-cv-11548 (D. Mass. Aug. 14, 2023), Dkt. No. 235. So, we may gain clarity in 2024 about the standard of causation that applies to AKS-based FCA cases filed in the First Circuit.

iii. The Seventh Circuit clarified plaintiffs' burden to establish causation for FCA claims concerning federally insured mortgages.

In 2023, the Seventh Circuit clarified plaintiffs' burden to establish causation in connection with FCA claims that relate to federally insured mortgages. *See United States ex rel. Calderon v. Carrington Mortg. Servs., LLC*, 70 F.4th 968, 971 (7th Cir. 2023), *cert. denied*, 144 S. Ct. 331 (2023). The relator in that case alleged her former employer, a direct endorsement lender for the U.S. Department of Housing and Urban Development ("HUD"), made false representations to HUD about its underwriting practices in the course of certifying residential mortgage loans for insurance coverage by the Federal Housing Authority ("FHA"). The false representations were allegedly critical because HUD was responsible for covering losses in the event of a loan default.

The Seventh Circuit explained that the causation element under the FCA requires "both actual and proximate cause." *Id*. at *8 (citing *United States v. Luce*, 873 F.3d 999, 1014 (7th Cir. 2017)). At issue was whether the relator had to allege what actually caused defaults of the loans, since the defaults are what would trigger HUD's payment obligations. But the Seventh Circuit "recognize[d] that when [it] adopted the proximate-cause standard in *Luce*, [it] did not explicitly state that proving proximate cause in cases about federal mortgage insurance requires proving the causes of defaults." *Id*. at *8.

However, in *Luce*, the Seventh Circuit relied on decisions from other circuits that had in fact "made explicit statements about the need to prove what caused the defaults." *Id*. Thus, the Seventh Circuit bridged the gap in *Calderon* and held that "[t]o ensure that the false certifications were a substantial factor in bringing about HUD's losses and that the losses were foreseeable to the defendant, the plaintiff must show that the false certifications played some role in causing or increasing the risk of a subsequent default." *Id*.

Applying this standard, the Seventh Circuit affirmed the district court's grant of summary judgment in the defendant's favor, finding that the relator had failed to put forth sufficient evidence that "would permit a reasonable factfinder to determine the cause of default" for any loan upon which the relator had based her claims. *Id*. at *9. Specifically, the relator had failed to provide any evidence that the defendant had a higher-than-average default rate for its federally insured loans, without which a jury could not determine whether the defendant's underwriting practices, reckless or not, had any effect on subsequent loan performance.

iv. The Seventh Circuit left open the possibility that causation need not be proven where a relator seeks civil penalties alone.

Note that the relator in *Calderon* had argued that she should be able to proceed even without sufficient evidence of causation. This argument was based on a minority interpretation of the FCA as a statute that creates "two sorts of liability[,]" with a *first* form of liability—the basic civil penalty—being imposed "regardless of whether the submission of the claim actually causes the government any damages[,]" and a *second* kind of liability in the form of treble damages imposed only "for damages that the government sustains because of the submission of the false claim." *See United States ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 199 (D.C. Cir. 1995). Under this interpretation, whether a relator must prove causation—and the associated standard of proof—depends on the measure of damages sought.

The Seventh Circuit did not consider the possibility of a claim limited to civil penalties because the relator had failed to renew her argument on appeal. *Id.* As such, the Seventh Circuit declined to determine whether *Schwedt* was rightly decided. *Id.*

D. Falsity

As the name implies, the FCA only imposes liability for "false claims"— that is, for presenting a false or fraudulent claim or making a false

record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(A)–(B). A defendant may also be liable under the FCA for a "reverse false claim" if it makes or uses a false record or statement for the purpose of avoiding or decreasing an "obligation" owed to the United States. *See* 31 U.S.C. § 3729(a)(1)(G). The terms "false" and "fraudulent" are not defined in the FCA, so the governing standards have been developed through caselaw.

i. The circuit split about whether an objective falsehood is needed to establish falsity remains.

Over the past three years, a circuit split has developed regarding whether an "objective falsehood" is required to establish falsity. The Eleventh Circuit held in 2019 that clinical disagreement is insufficient to establish falsity because the FCA requires the alleged falsehood to be objectively false. *See United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019).

In 2020, the Ninth Circuit disagreed and held that the FCA does not require a relator to plead an "objective falsehood" and the subjective statements of a medical provider, beyond reasonable disagreement between medical experts, can be false or fraudulent if the medical opinion is not honestly held or if it implies the existence of facts that do not exist. *See Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1119 (9th Cir. 2020).

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).

The Ninth Circuit provided additional guidance in 2022 by holding that disagreement in clinical judgment is insufficient to establish falsity. *See Holzner v. DaVita Inc.*, No. 21-55261, 2022 WL 726929, at *1 (9th Cir. Mar. 10, 2022) (explaining

that a "false statement need not deal with purely objective facts, but rather can involve a subjective opinion or an expression of clinical judgment.").

While the objective falsehood circuit split was not resolved in 2023, courts did provide additional guidance on what information may or may not be sufficient to satisfy the element of falsity.

ii. The Second Circuit held that vague allegations of improperly approved reimbursement requests were not enough to show the requests were actually false.

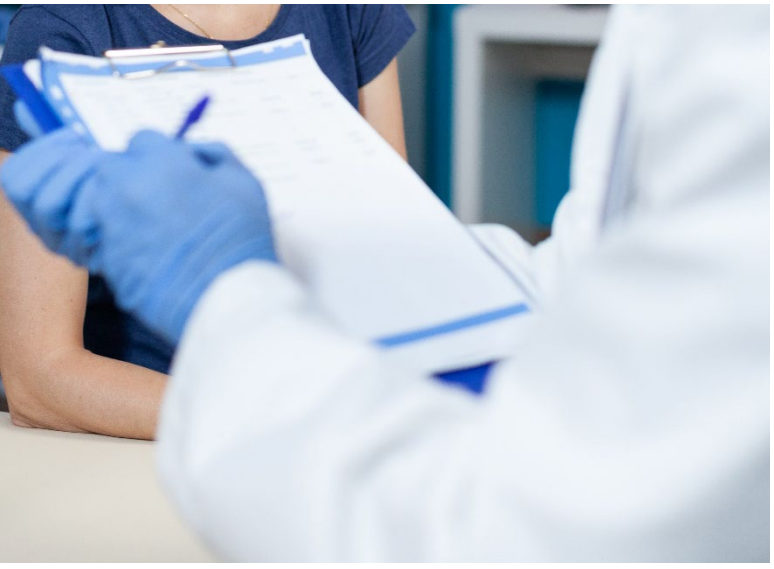
The Second Circuit reviewed a case in which relators alleged the defendants contracted with private health insurance companies to conduct individualized reimbursement determinations for medical services. *See Doe 1 v. EviCore Healthcare MSI, LLC*, No. 22-530, 2023 WL 2249577, at *1 (2d Cir. Feb. 28, 2023). But rather than doing so, the defendants were allegedly auto-approving most reimbursement requests, or they used

artificial intelligence to approve requests without any manual review. In other words, the relators alleged the defendants were providing "worthless" services, which caused the insurance companies to bill Medicare and Medicaid for fraudulently approved services.

The district court dismissed the relators' claims, and the Second Circuit affirmed. *Id*. Both courts held that the relators failed to sufficiently allege that the services were "so worthless that they were the equivalent of no performance at all." *Id*. at *2 (citation omitted). Nor did the relators provide enough details to show that any specific reimbursement request was itself fraudulent. Rather, all plaintiffs alleged was that defendants improperly used auto-approval processes at "various times" for "certain categories" of requests. *Id*. at *3. This was not enough to plead falsity of the reimbursement requests.

iii. The Fifth Circuit held that certifications of compliance with nurse licensure requirements were not rendered false by a nurse's temporary license revocation.

The Fifth Circuit found no falsity for claims submitted by a nursing home while the home was employing a nurse with a temporarily revoked license and was certifying compliance with nurse licensure requirements. *See United States ex rel. Jehl v. GGNSC Southaven, L.L.C.*, No. 22-60209, 2022 WL 17443684, at *4 (5th Cir. Dec. 6, 2022). Under CMS guidance, a nursing license is only invalid when a state governing board determines it invalid in a final adverse action. *See id*. at *3. Because there had been no final adverse action, the nursing home's certifications were not technically false. *Id*. at *4.



E. 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 previously 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 Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 181 (2016). The Court explained that determining materiality must be a "rigorous" and "demanding" fact-based inquiry of whether a noncompliance has a natural tendency to influence, or be capable of influencing, the government's payment decision to ensure that the FCA does not become "a vehicle for punishing garden variety breaches of contract or regulatory violations" or "minor or insubstantial" noncompliance with government contracts. *Id*. at 192, 194.

The materiality inquiry may be influenced by non-exclusive factors such as whether the alleged noncompliance goes to the "essence of the bargain," whether the noncompliance is significant (as opposed to "minor or insubstantial"), and whether the government has taken action in response to similar, known violations. *See id*. at 193–95. For example, in

Escobar, the court held that "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." *Id*. at 195.

Since *Escobar*, numerous district and appellate courts have attempted to interpret what is and is not "material." Some of the key decisions issued in 2023 are summarized below.

i. The Third and Fifth Circuits continue to hold noncompliance that goes to the "essence of the bargain" is material.

The Third and Fifth Circuits both reviewed cases in which the noncompliance at issue was deemed to go to the "essence of the bargain" with the government. In *United States ex rel. Druding v. Care Alternatives*, the relators were former employees of a hospice care provider who brought a *qui tam* action alleging that the provider submitted fraudulent reimbursement claims to Medicare because the patients had inadequate clinical documentation to support their eligibility for hospice care. 81 F.4th 361, 365 (3d Cir. 2023). The district court granted the hospice provider's motion for summary judgment based on lack of materiality. *Id*.

But the Third Circuit reversed, holding that a provider's submission of hospice reimbursement claims based on inadequate documentation of eligibility for hospice care could indeed be a "material" violation of the FCA because (1) the documentation requirement was an express condition of payment, and (2) having documentation to support a physician's determination of hospice necessity was a "foundational part" of Medicare's hospice program to ensure Medicare funds go to those who actually need it. *Id*. at 371. In other words, compliance with the documentation requirement concerned patients' medical need for hospice care and thus went to the "essence of the bargain" with the government. *Id*. at 373.

In *United States ex rel. Aldridge v. Corporate Management, Inc.*, the Fifth Circuit was reviewing a district court's denial of a post-trial motion for judgment as a matter of law in the wake of a $10.9 million jury verdict against a critical access hospital and its corporate owners for overbilling for non-reimbursable, misallocated, and/or inflated costs. 78 F.4th 727, 732 (5th Cir. 2023). On appeal, the Fifth Circuit held there was sufficient evidence to support the jury's finding that the defendants' misrepresentations were material.

The government had continued to reimburse the hospital's costs when the initial allegations of fraud surfaced, but the Fifth Circuit found that this fact was offset by evidence that the government did this to ensure access to care for underserved Medicare beneficiaries, not because it viewed the fraud as immaterial. *See id*. at 737–38. The Fifth Circuit also highlighted evidence that the hospital's owner certified that he was familiar with Medicare regulations and understood that payments were conditioned on compliance with them, that the fraud was substantial, and that the cost reports and statements that the hospital submitted to Medicare went to the "essence of the bargain" because they were the basis for determining reimbursement amounts. *Id*. at 738. All of these suggested the misrepresentations were material.

ii. The Seventh Circuit held that compliance with a pricing rule was material because it was important to a federal program's functioning and thus could influence reimbursement decisions.

In *United States ex rel. Heath v. Wisconsin Bell, Inc*., the relator brought a *qui tam* action against a telecommunication services provider and alleged it fraudulently obtained federal subsidies under the "E-Rate" program, a federal program to keep telecommunication services affordable for schools and libraries in rural and economically disadvantaged areas. No. 22-1515, 2024 WL

217696, at *1 (7th Cir. Jan. 16, 2024). The relator alleged the provider falsely certified compliance with the E-Rate program's "lowest-corresponding-price" rule, which required the provider to deliver services at the lowest rate charged to similarly situated customers. *Id*.

The district court granted summary judgment in favor of the defendant-provider, but the Seventh Circuit reversed on appeal. The Seventh Circuit reasoned that the "lowest-corresponding-price" rule is a necessary mechanism to keep telecommunications services affordable for schools and libraries, which is the primary purpose of the E-Rate program. *See id*. at *7. In other words, the defendant should have understood that "the rule is important to the program's functioning and thus that noncompliance could influence reimbursement decisions." *Id*.

iii. The Fourth Circuit held that false statements about Medicaid eligibility were material because they influenced the government's decision to pay, even if the eligibility requirements were unlawful.

In *United States v. Walgreen Co.*, the government alleged that Walgreens misrepresented that certain patients met Virginia's Medicaid-eligibility requirements for expensive drugs that treat Hepatitis C. 78 F.4th 87 (4th Cir. 2023). The district court dismissed the government's complaint on the grounds that Virginia's eligibility requirements violated the federal Medicaid Act, therefore Walgreen's misrepresentations were immaterial. But the Fourth Circuit vacated and remanded.

The Fourth Circuit explained that under *Escobar*, materiality is determined by whether a false statement influenced the government's decision to pay a claim. Because the government provided evidence that they approved claims only after receiving Walgreen's false statements about meeting the state eligibility requirements, the statements were in fact material. Walgreens' collateral attack on the legality of the state's Medicaid requirements did not permit Walgreens to escape FCA liability.

iv. The Ninth Circuit held that misrepresenting that employees worked for a pharmacy was not material to insurance providers' decision to grant prior authorizations for the pharmacy's prescription medications.

In *Gharibian ex rel. United States v. Valley Campus Pharmacy, Inc.*, a former employee brought a *qui tam* action against her pharmacy employer and a drug manufacturer, alleging that they instructed their employees to misrepresent who they worked for and to falsify patient records in order to procure prior authorizations from insurance providers for their prescription medications. No. 21-56253, 2023 WL 195514, at *1 (9th Cir. Jan. 17, 2023). The district court dismissed the complaint for failure to adequately plead materiality, and the Ninth Circuit affirmed.

The Ninth Circuit explained that the relator failed to sufficiently plead materiality because there were insufficient allegations that the practice of misrepresenting the identity of their employers had any influence on the insurers' decision to grant authorization for prescription medicines, or that the insurers would have refused to pay had they known that the request was from pharmacy employees. *See id*. at *2.

F. Retaliation

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 [the FCA]." 31 U.S.C. § 3730(h)(1).

i. 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 under the three-step, burden-shifting framework established in *McDonnell Douglas Corp. v. Green*, 411 U.S. 792, 802–03 (1973).

Under the first step of the framework, an employee must prove that (1) she was engaged in a protected activity; (2) her employer had knowledge of this conduct; and (3) 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 shifts the burden of proof onto the employer to provide a legitimate, non-retaliatory explanation for its allegedly retaliatory action. *See id*. The third step of the framework shifts the burden back to the employee to demonstrate that the employer's proffered explanation is a pretext calculated to mask retaliation. *See id*.

To qualify as "protected activity" under the first element of step one, many courts require (i) acts in furtherance of an FCA action, or (ii) other "efforts to stop" one or more FCA violations. *See, e.g.*, *Hickman v. Spirit of Athens, Alabama, Inc.*, 985 F.3d 1284, 1288 (11th Cir. 2021) (citing *United States ex rel. Chorches v. Am. Med. Response, Inc*., 865 F.3d 71, 95–98 (2d Cir. 2017)).

But courts continue to differ on what constitutes "acts in furtherance of" an FCA action, whether an FCA lawsuit needs to be a "distinct possibility" at the time of the protected activity, and whether the "efforts to stop" an FCA violation need to be based on "an objectively reasonably belief that violations had occurred."

ii. The Middle District of Florida held that "protected activity" requires that an FCA lawsuit is a distinct possibility or the plaintiff has an objectively reasonable belief that FCA violations occurred.

In *United States v. Millennium Physician Group,* the physician-relator alleged his former employer defrauded the government "by billing Medicare and Medicaid for medically unnecessary testing, by falsifying patient charts, by incentivizing improper referrals, and by improperly inflating their risk management measurements and Accountable Care Organization [] scores and bonuses." 2023 WL 2022228, at *1 (M.D. Fla. Feb. 15, 2023). He also alleged he reported false diagnoses on patient charts to management and attempted to prevent an FCA violation by annotating the falsified charts, but he was told the diagnoses did not matter. *See id*. at *8. His employer then allegedly retaliated against him by "understaffing his office, referring his patients

elsewhere, harassing him, physically intimidating him, [] ignoring his requests for assistance," eventually terminating him, and then interfering with his ability to practice elsewhere independently. *Id*. at *3.

The U.S. District Court for the Middle District of Florida explained that the "protected activity" element of the first step of the retaliation framework requires allegations that raise at least a reasonable inference that the plaintiff "engaged in lawful acts in furtherance of a[n] [FCA] suit when such a suit was a distinct possibility," or (2) "attempted to stop a violation of the [FCA] based on an objectively reasonable belief that violations had occurred." *Id*. at *8 (citations omitted).

Under this standard, the court dismissed the relator's retaliation claim for failing to allege there was a distinct possibility that he or the government would sue the defendants under the FCA and that he acted to further such a lawsuit. *Id*. at *9. The court also held that the relator failed to allege he attempted to stop an FCA violation since he did not allege an FCA violation with the particularity required under Rule 9(b). Further, the court held that even if the relator had sufficiently alleged the elements of a protected activity, he failed to satisfy the other components of a retaliation claim (notice and causation). *See id*.

iii. The Tenth Circuit held that an employer's knowledge of an employee's protected activity does not require the employer to know the activity was protected specifically by the FCA.

In 2023, the Tenth Circuit affirmed a jury verdict in favor of an employee claiming retaliation even though the employee did not present evidence to the jury showing that his employer was aware that he was acting based specifically on the FCA. *See United States ex rel. Barrick v. Parker-Migliorini Int'l, LLC*, 79 F.4th 1262, 1270 (10th Cir. 2023).

In that case, a relator filed a *qui tam* action alleging that the meat-exporting company he worked for was engaging in false labeling practices when exporting beef. *Id.* at 1268. On three occasions, the relator complained to the company's CFO, who "confirmed that [practices] were illegal." *Id.* Shortly after filing suit, the relator became a confidential informant for the FBI. *Id.* When the FBI raided the company, the relator was fired and he added an FCA retaliation claim.

After the jury verdict, the company argued that it was not aware of the relator's protected conduct because the relator "was required to 'convey a connection to the FCA.'" *Id.* at 1270. But the Tenth Circuit rejected this contention, explaining that the relator did not need "to say magic words, such as 'FCA violation' or 'fraudulent report to the government to avoid payment,' to put [the company] on notice." *Id.* Such a magic-words requirement would be "contrary to the text of the FCA which protects 'other efforts' to stop violations." *Id.* All that was required was that the company knew that relator accused it of "(1) engaging in fraudulent activity to avoid paying the government an obligation or (2) claiming unlawful payments from the government." *Id.* at 1271.

iv. The Tenth Circuit also held that "but for" causation does not mean "sole" cause for the first step of the retaliation framework.

In *Barrick*, the district court's jury instruction regarding causation stated that to satisfy the third element of the first step of the retaliation framework (i.e., the employer retaliated against the employee "because of" this conduct) , the plaintiff must prove that "but for" his engagement in protected activity, the defendant would not have retaliated against him. 79 F.4th at 1276. The Tenth Circuit clarified that this does not mean the plaintiff is required to prove that the that protected activity was the "sole" cause. *Id*.

v. The Sixth Circuit held that the failure to disclose circumstances underlying a retaliation claim excluded insurance coverage for settlement of the claim.

The Sixth Circuit held that a warranty exclusion barred coverage for an FCA retaliation claim arising from circumstances that were not disclosed in an insured's application for coverage. *See SHH Holdings, LLC v. Allied World Specialty Ins. Co*., 65 F.4th 830, 834 (6th Cir. 2023).

In that case, three relators filed a sealed *qui tam* suit in 2016, alleging a skilled nursing facility owner and operator provided medically unnecessary services to patients to bill for the highest possible Medicare reimbursement and then retaliated against the relators by terminating them for reporting the alleged FCA violations. *Id*. In 2017, DOJ solicited information from the defendant as part of its FCA investigation about the company's claims submissions and about recently terminated employees, including the three relators. *Id*.

In 2019, the defendant purchased an insurance policy and represented that it was not aware of any inquiries, investigations, claims, or lawsuits filed against it, or of any act, error, or omission that could give rise to a covered claim, suit, or action. *See id*. at 834–35. The policy excluded from coverage any claim arising from an inquiry, investigation, administrative charge, claim, or lawsuit that the company should have but failed to disclose. *Id*. at 835.

When the relators' complaint was unsealed, the defendant learned of the retaliation claim and submitted a claim for coverage under its insurance policy. *Id*. The insurance carrier denied the claim, and the defendant sued the carrier for breach of contract. *Id*. While that lawsuit was pending, the defendant settled the relators' retaliation claim for $2.2 million. *Id*. The district court ruled in the defendant's favor in the coverage litigation and awarded them damages and fees to cover the settlement. *Id*. at 836. But the Sixth Circuit reversed, finding that the defendant knew it had taken adverse employment action against the relators and that DOJ had requested recent termination information, meaning the defendant's failure to disclose that information when applying for an insurance policy excluded the subsequently unsealed retaliation claim from coverage. *Id*. at 840.

G. The Anti-Kickback Statute

i. The Sixth Circuit narrowly construed the definition of "remuneration" such that it requires an actual transfer of value.

The AKS does not define the term "remuneration." But the U.S. Department of Health & Human Services Office of Inspector General ("OIG") broadly defines "remuneration" in its advisory opinions as "the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind."[29] Relatedly, OIG guidance describes the AKS as a "criminal prohibition against payments (in any form, whether the payments are direct or indirect) made purposefully to induce or reward the referral." 70 Fed. Reg. 4,858, 4,863–64 (Jan. 31, 2005).

In *United States ex rel. Martin v. Hathaway*, the Sixth Circuit held that the term "remuneration" is limited to payments and other transfers of value, not any act that may be valuable to another. 63 F.4th 1043, 1048 (6th Cir. 2023). The alleged remuneration at issue was "a hospital's decision not to hire an ophthalmologist in return for a general commitment of continued surgery referrals from another ophthalmologist for patients from the local community." *Id*. at 1046. This transaction did not involve the transfer of

[29] Advisory opinion available at https://oig.hhs.gov/documents/advisory-opinions/1040/AO-22-14.pdf.

money, services, or goods, and thus the Sixth Circuit held that there was no remuneration.

The Sixth Circuit reasoned that a broader definition of "remuneration" would cover more than intended under the law. *See id*. at 1048–50. To make its point, the Sixth Circuit gave the follow example:

> Consider the hospital that opens a new research center, purchases top of the line surgery equipment, or makes donations to charities in the hopes of attracting new doctors. Or consider the general practitioner who refuses to send patients for kidney dialysis treatment at a local health care facility until it obtains more state-of-the-art equipment. Are these all forms of remuneration? Unlikely at each turn.

Id. at 1050.

Note that the Sixth Circuit's restriction of "remuneration" to transfers of value does not mean that *de minimis* transfers are excluded. *See, e.g.*, *United States ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc*., No. 13-cv-03003, 2024 WL 489708, at *12 (D. Minn. Feb. 8, 2024) (holding a single dinner at a restaurant consisting of a salad and a soda was an item of value and thus could constitute a kickback).

ii. The District of Massachusetts held that donations to a charitable foundation providing copay assistance was indirect remuneration to prescribing physicians.

In *United States v. Regeneron Pharmaceuticals, Inc.*, the government alleged that a pharmaceutical manufacturer induced physicians to prescribe one of its drugs by donating millions of dollars to a patient-assistance foundation that subsidized patients' co-pays for that drug. 2023 WL 6296393, at *1–*2 (D. Mass. Sept. 27, 2023). The manufacturer moved for summary judgment, arguing, among other things, that its donations did not qualify as "remuneration" under the AKS because it had no control over which patients the foundation assisted.

But the U.S. District Court for the District of Massachusetts disagreed, holding that the mere "promise of copay assistance" through the charitable foundation "indirectly provided remuneration to the physicians prescribing" the manufacturer's drug since the "copay assistance

eliminates the financial risk to physicians if they prescribed a drug for which patients cannot pay." *Id*. at *5.

In other words, the insertion of the charitable foundation in the chain between the manufacturer and the prescribing physicians did not insulate the manufacturer from AKS liability since the AKS prohibits even the indirect receipt of prohibited remuneration.

iii. The Eastern District of Virginia rejected a nonprofit organization's contention that the AKS prohibited only "corrupt" or independently unlawful payments.

In *Pharmaceutical Coalition for Patient Access v. United States*, the plaintiff, a nonprofit organization formed and funded by manufacturers of oncology drugs, filed suit to challenge a negative advisory opinion issued by OIG regarding the plaintiff's proposal to set up a patience assistance program that would subsidize eligible patients' copays for the manufacturers' oncology drugs, with Medicare Part D covering the rest of the drugs' costs. No. 3:22-cv-00714, 2024 WL 187707, at *3 (E.D. Va. Jan. 17, 2024).

OIG had concluded the proposed arrangement was likely to violate the AKS, since it included indirect remuneration (i.e., copay subsidies) from the manufacturers and the nonprofit organization to Part D beneficiaries (to induce the beneficiaries to purchase the manufacturers' drugs) as well as direct remuneration from the manufacturers to the nonprofit organization. *Id*. at *4.

The plaintiff argued OIG's opinion was inconsistent with the AKS, arguing that the word "induce" in the statute implies corrupt intent that must be read into the term "remuneration." In other words, the plaintiff argued that the AKS prohibits only corrupt payments, such as kickbacks and bribes, and not cost-sharing subsidies. *See id*. at *5–*12.

But the U.S. District Court for the Eastern District of Virginia rejected the plaintiff's arguments, holding "[t]he AKS does not specifically require that the things to be induced be independently unlawful—as is the case with criminal solicitation," and the AKS's text and legislative history supported the "plain, intentionally broad meaning of 'any remuneration.'" *Id*. at *8, *12.

H. Recovery, Damages, and Fees

i. The Seventh Circuit held that a settlement payment to resolve an FCA investigation was coverable by insurance as a compensatory, not restitutionary, payment.

A pharmaceutical manufacturer successfully sued its insurance carrier for coverage of an FCA settlement up to the $10 million policy limit. *See Astellas US Holding, Inc. v. Fed. Ins. Co.,* 66 F.4th 1055 (7th Cir. 2023). The government was investigating the company for potentially violating the FCA and AKS by making contributions to patient assistance plans that would subsidize patients' copays for one of the manufacturer's cancer drugs. *Id*. at 1058. But before the government brought any legal action, the parties agreed to settle for $100 million. *Id*. at 1060. The settlement agreement designated $50 million as "restitution to the United States" for tax deductibility reasons. *Id*.

When the manufacturer filed an insurance claim for coverage of the settlement, the insurer denied coverage on the basis that the settlement payment was wholly restitutionary and therefore uninsurable under Illinois law as a matter of public policy (as opposed to a compensatory payment, which would be insurable). *See id*. The manufacturer brought a declaratory judgment action against the insurer, and the district court granted the manufacturer's motion for summary judgment. *Id*.

The Seventh Circuit affirmed. Under Seventh Circuit precedent, a settlement payment is restitutionary if the payment disgorges

"something that belongs of right not to [the defendant] but to the plaintiff," or "seeks to deprive the defendant of the net benefit of the unlawful act" (such as profit from an FCA scheme). *Id*. at 1064 (citations omitted).

In this case, the Seventh Circuit held that the settlement payment was not restitutionary (and thus covered by insurance) for several reasons. First, the policy at issue defined covered losses to include settlement payments, and a policy exclusion that would have denied coverage was only applicable in the case of a final adjudication. Second, the FCA's language, legislative history, and relevant case law all indicate the FCA only allows for civil penalties and compensatory damages, not for restitution. Third, the restitution label only applied to half of the settlement, and even then only for tax purposes.

In short, *Astellas* illustrates that insurance coverage for payments to settle alleged FCA violations may depend on several factors, including the language of the insurance policy and applicable case law.

ii. Damages for AKS-tainted false claims are the entire amount paid, while damages for false claims in the sale of goods are the difference in value between what the government bargained for and what it got.

Two cases highlight the distinction between the measure of damages in AKS-tainted false claims and false claims involving contracts for goods or services.

The U.S. District Court for the District of Massachusetts held that the measure of damages in an FCA premised on AKS violations is "the entirety of the government's expenditures for claims resulting from the illegal kickbacks." *United States v. Teva Pharm. USA, Inc*., No. 1:20-cv-11548-NMG, 2023 WL 4565105, at *5 (D. Mass. July 14, 2023). The court explained that the rationale for this is that the government would not have paid any part of a claim tainted by an AKS violation had it known about the violation. *Id*.

In contrast, damages in FCA cases involving contracts for goods are generally equal to the difference in value between the goods that the government bargained for and the goods it received. *See Hendrix ex rel. United States v. J-M Manufacturing Company, Inc.*, 76 F.4th 1164, 1174 (9th Cir. 2023) (citing *United States v. Sci. Applications Int'l Corp*., 626 F.3d 1257, 1279 (D.C. Cir. 2010)).

In *Hendrix*, the defendant contracted to supply PVC pipe meeting certain industry standards. *Id*. at 1167. The industry standards required manufacturers to conduct additional testing if they materially changed their production processes. *Id*. at 1168. When the defendant materially changed its production process, it failed to conduct additional testing but continued to certify that its pipe complied with industry standards. *Id*.

In the liability phase of a bifurcated trial, the jury found that the defendant violated the FCA—that is, the defendant "did not uniformly comply with industry standards and could have delivered some noncompliant pipe." *Id*. at 1170. As a result, the plaintiffs argued that damages should equal the total amount paid for the pipe, relying on cases from the Fifth Circuit and Sixth Circuit holding that the proper measure of damages for defective or misrepresented goods was the entire contract price. *See id.* at 1173–74 (distinguishing *United States v. Aerodex, Inc.*, 469 F.2d 1003 (5th Cir. 1972) and *United States ex rel. Compton v. Midwest Specialties, Inc.*, 142 F.3d 296 (6th Cir. 1998)).

But in the cases cited by the plaintiffs, the government had received no tangible benefit because the goods were either plainly unusable, not used, or returned. *Id*. at 1174. In *Hendrix*, in contrast, the court found that "the pipe clearly had value because plaintiffs have received years, if not decades, of use from it," notwithstanding

the alleged risk of premature pipe failure posed by the noncompliance at issue. *See id*. at 1175. Accordingly, for a court to award any damages to the plaintiffs, they were required to provide evidence regarding the value or longevity of the pipe that they received so the factfinder could determine how it differed from what the plaintiff had contracted for. *See id*. at 1171, 1175–76.

I. Statute of Limitations

i. The Fifth Circuit held that the statute of limitations barred claims brought by the government when it intervened with new allegations eight years after the relator filed its original complaint.

The FCA's statute of limitations proscribes claims brought (1) more than six years after the violation is committed, or (2) more than three years "after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed." 31 U.S.C. § 3731(b).

Also, any government pleading relates back "to the filing date of the complaint of the person who originally brought the action, to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint of that person." *Id.* § 3731(c). "[T]o relate back, a new claim must be 'tied to a common core of operative facts.'" *United States ex rel. Vavra v. Kellogg Brown & Root, Inc*., 848 F.3d 366, 382 (5th Cir. 2017) (quoting *Mayle v. Felix*, 545 U.S. 644, 664 (2005)).

In 2023, the Fifth Circuit held that a damages award must be partially remitted in a case where the government had filed 18 motions to extend the seal period over eight years before intervening because the claims asserted in the intervenor complaint did not relate back to the relator's original complaint, and tolling under 31 U.S.C. § 3731(b)(2) did not apply. *See United States ex rel. Aldridge v. Corp. Mgmt., Inc.*, 78 F.4th 727, 741–45 (5th Cir. 2023).

The defendants included a corporate management company, company owner, corporate executives, and critical access hospital. The relator originally alleged that these defendants defrauded Medicare through fraudulent cost reporting, inflating supply costs, manipulating the swing bed status of hospitals controlled by a management company-defendant, and improperly waiving co-payments and deductibles. *Id*. at 743. The government intervened and alleged that the defendants defrauded Medicare by overbilling for the company owner's and his wife's compensation despite little or no reimbursable work. *Id*. A jury rendered a $10.9 million verdict against the defendants.

On appeal, the Fifth Circuit held that the government's intervening claims did not relate back to the relator's claims because "[r]ather than 'clarifying' or 'adding detail' to the relator's initial allegations, the government's intervening complaint set forth new ones." *Id*. Also, the Fifth Circuit held that tolling did not save the government's claims from the statute of limitations because the government did not act diligently by moving to extend the seal period 18 times. *Id*. at 745. Additionally, the government had submitted a memorandum to the district court in support of extending the seal period, which indicated that its expert recommended intervention five years after the relator's complaint. *Id*. at 744. But government did not actually intervene for another three years.

The Fifth Circuit therefore barred all claims that accrued more than six years before the government filed its first intervenor complaint and reduced the damages award to under $4.6 million, meaning "[t]he consequence of the Government's dilatory conduct [wa]s the reduction by over half of the judgment entered against Appellants." *Id.* at 745, 747.

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